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

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-MWF(SSx)

**UNITED'S OPPOSITION TO
PLAINTIFFS' MOTION FOR
PARTIAL SUMMARY
JUDGMENT**

*[Statement of Genuine Disputes;
Declaration of David J. Schindler; and
Declaration of Abid R. Qureshi filed
concurrently herewith]*

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

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1 I. INTRODUCTION

2 The government's motion for partial summary judgment is flawed for many
 3 reasons. It is procedurally improper because it does not seek judgment—partial or
 4 otherwise—and instead seeks a kind of “issue resolution” that Rule 56 prohibits. It
 5 is premature because it asks this Court to resolve a question now, based on limited
 6 evidence, that depends heavily on ambiguous pronouncements (requiring further
 7 extrinsic evidence) and disputed facts (requiring further discovery). It proposes a
 8 rule that is unsupported by the regulations, contractual provisions, and sub-
 9 regulatory guidance on which it relies, and it requests relief that would be contrary
 10 to a controlling federal statute. Its real purpose is to prevent further discovery of
 11 facts that already have begun to show the Achilles' Heel of the government's
 12 case. And ultimately it is pointless because that same discovery clearly will be
 13 relevant to many other issues in this case no matter how the Court rules here. Each
 14 of these reasons independently warrants denying the motion.

15 The motion is doomed at the very outset because, although styled as a
 16 motion for partial summary judgment, it instead asks this Court to resolve a “legal
 17 issue” that will not resolve any claim, or even any element of any claim, in this
 18 case. Pls.' Mem. of P. & A. in Supp. of Pls.' Mot. for Partial Summ. J. at 1, ECF
 19 No. 234-1 (“Mem.”). The motion thus seeks “an impermissible advisory opinion,”
 20 *Hanks v. Briad Rest. Grp., L.L.C.*, No. 2:14-cv-00786-GMN-PAL, 2015 WL
 21 770422, at *7 (D. Nev. Feb. 24, 2015), and is “entirely inappropriate under any
 22 provision of Rule 56.” *Powers v. Emcon Assocs.*, No. 14-cv-03006-KMT, 2017
 23 WL 4102752, at *2 (D. Colo. Sept. 14, 2017).

24 Like the government's Motion to Strike Affirmative Defenses, this motion
 25 also is a colossal waste of time. The government's stated purpose for moving now
 26 is to avoid discovery into “actuarial equivalence.” Having just begun—finally—to
 27 start producing discovery, the government has come to appreciate that documents
 28 and testimony from within the Centers for Medicare and Medicaid Services

(“CMS”) about that precise issue will undermine any suggestion that the conduct it has targeted in this case was improper. Already, the limited evidence United has obtained shows that CMS’s internal experts agree with United that (1) the key to ensuring appropriate payments in the Medicare Advantage (or “MA”) program is to draw accurate comparisons between MA beneficiaries and traditional Medicare beneficiaries, and (2) determining whether a plan has been overpaid therefore requires measuring actuarial risk in the two programs in the same way, or at least accounting for any differences in the measurement method. And so rather than bearing the risk that its case will unravel slowly through discovery, the government has filed an extraordinary motion asking this Court to lay this central issue to rest at the outset, on the theory that the government will then be able to withhold all of that damaging—the government says (at 2) “burdensome”—evidence.

Even if avoiding discovery were a legitimate basis for filing a premature motion like this one in a case of this magnitude, the government’s requested declaration here would not actually produce that result. The same discovery into the government’s rate of unsupported codes, the impact of those codes on the calculation of United’s payments, and numerous other related issues all still would be necessary even if the Court granted this motion, because that evidence clearly is relevant to the elements of scienter and materiality, and to show that United did not receive any overpayments and was not unjustly enriched.

Nor would a decision in the government’s favor streamline other aspects of the case. Even if the Court agreed with the government’s contention (at 1) that MA plans are required to delete every code they know is unsupported, that would not meaningfully advance the government’s case, which rests primarily on the notion that plans are required to delete unsupported codes they *could possibly have discovered* were unsupported by auditing separate submissions by providers. Those are very different things. Blind chart review by an MA plan based on the inexact science of coding does not give the plan “knowledge” under the False

1 Claims Act (“FCA”) that other specific codes separately submitted by providers
2 who saw the actual patients are unsupported. Indeed, Jeffrey Grant, a senior CMS
3 official, testified in this case that—even from CMS’s perspective—a plan need
4 only delete a code if it has “specific” knowledge the code is unsupported, and that
5 there is nothing “improper” or “fraudulent” in a plan reviewing medical records to
6 look for unreported diagnoses without also looking to see whether previously
7 submitted codes were unsupported.

8 The government knows all of this. It knows there is a difference between
9 the question whether an MA plan must delete codes it knows are unsupported and
10 the question whether an MA plan must try to reconcile the results of its own chart
11 review with the codes separately submitted by doctors. It knows CMS proposed
12 and then withdrew a rule that would have required the latter for the first time,
13 prospectively, in 2014. It knows that United had conversations with senior CMS
14 officials confirming United’s understanding that the rules did not require the latter.
15 It knows that United confirmed that understanding in bids and contracts CMS
16 accepted for payment. And it knows that the only witness to testify for the
17 government to date on this issue *agrees with United’s position*. No wonder the
18 government seeks to avoid discovery on the issue at the heart of this case. But that
19 discovery will take place regardless of how the Court rules here.

20 The motion also is premature. Many legal ambiguities and factual disputes
21 preclude entry of summary judgment, especially at this early stage of the litigation.
22 The regulations, contracts, and sub-regulatory guidance on which the government
23 relies do not remotely impose the rule it requests. At most, the provisions are
24 ambiguous, which means that in interpreting them the Court should look to
25 extrinsic evidence about their meaning—evidence the government’s motion is
26 designed to keep from the Court.

27 The proposed rule the Government requests also is contrary to statute. As
28 United has argued in its Administrative Procedure Act (“APA”) challenge before

Judge Collyer, the Medicare Act mandates that CMS “shall . . . ensure actuarial equivalence” when performing risk adjustment, 42 U.S.C. § 1395w-23(a)(1)(C)(i), and that CMS “us[e] the same methodology” when calculating the risk that patients present in both the MA and traditional Medicare programs, *id.* § 1395w-23(b)(4). Requiring MA plans to delete every diagnosis code they determine was unsupported or “should have known” was unsupported, without adjusting for the presence of such codes in CMS’s own traditional Medicare data, would violate both of those requirements.

The government’s attempts to excuse that violation are not persuasive. The government asserts that the Medicare Act’s commands are “discretionary,” but CMS has conceded that they are obligatory. The government also suggests that it would “not [be] a defense to liability in this FCA action” to show that its proposed rule is inconsistent with the Medicare Act. But that is directly contrary to what it said to Judge Collyer, when it urged her to stay the APA case so that the “actuarial equivalence” issue could be resolved as a defense in this case, with (it said then) the “benefit [of] a full factual record.” Ex. 54, APA U.S. Mot. for Stay, at 7.¹ On this issue the government’s representations to Judge Collyer were correct: CMS expressly agreed in its contracts with MA plans both that it would comply with the actuarial equivalence mandate when setting payments, and that in the event of any conflict between the contract and the statute, the latter would prevail.

The government’s proposed answer to much of this is the Ninth Circuit’s decision in *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1176 (9th Cir. 2016). But that case—in which all of the government’s claims eventually were dismissed—did not even raise, let alone resolve, the meaning of the Medicare Act’s mandate to “ensure actuarial equivalence” or the

¹ In this brief, citations to “Ex.” materials refer to exhibits to the Declaration of David J. Schindler filed herewith.

implications of that mandate for MA plans' risk adjustment data submissions. The Ninth Circuit made clear that it was not addressing a reverse false claim theory, that it was addressing only the narrow question of when a plan's affirmative risk adjustment attestations might be rendered false, and that "[u]nder Swoben's theory ... the false claims are the allegedly false § 422.504(l) certifications, *not the erroneously submitted diagnosis codes.*" *Id.* at 1183 (emphasis added). The Court specifically noted that it was not deciding whether the allegedly false certification caused "the government to pay out money or forfeit moneys due," which would be central to any case alleging overpayments. *Id.* at 1173 & n.7. And here, the government's false certification claims have been dismissed, and the only remaining False Claims Act claim is precisely the same one the Ninth Circuit made clear it was not deciding. Thus, as Judge Collyer put it when presented with a similar argument, "*Swoben* is not the droid the [government] is looking for." Ex. 57, APA MTD Order, at 12.

Accordingly, the Court should deny the government's motion and allow the case to continue in its normal course.

II. BACKGROUND

A. Medicare Advantage and the Risk Adjustment Process

This case concerns the MA program Congress created as an alternative to traditional Medicare. *See* 42 U.S.C § 1395w-21 *et seq.*² In traditional Medicare, CMS reimburses providers directly for the services they render to eligible individuals. For this reason, traditional Medicare beneficiaries are often referred to as fee-for-service ("FFS") beneficiaries. Under the MA program, by contrast, private insurers like United create insurance plans ("MA plans") in which Medicare-eligible individuals may choose to enroll. MA plans cover at least the

² Some of the government's allegations also concern the Medicare Part D program. United's arguments here apply equally to that program.

1 same benefits as traditional Medicare, and pay providers for their services. In
 2 return, CMS makes fixed per-member per-month payments to MA plans—
 3 effectively insurance premiums. *See generally id.* § 1395w-23. Those payments
 4 are not made to cover care that patients already have received, but rather to
 5 compensate plans for the risk they take on in agreeing to pay for *future* costs the
 6 patients may incur while under the MA plans’ coverage.

7 It costs more to insure sicker beneficiaries or beneficiaries who are projected
 8 to be sicker in the near future, of course, than to insure healthier beneficiaries. The
 9 MA program addresses that through an annual risk adjustment process. Each year,
 10 an MA plan agrees with CMS on the payment it will receive for providing benefits
 11 to a Medicare “enrollee with a national average risk profile.” *Id.* § 1395w-
 12 24(a)(6)(A); *see also* 42 C.F.R. § 422.254(b)(1). CMS then adjusts that payment
 13 amount to reflect the level of risk posed by the MA plan’s actual beneficiaries. If
 14 the MA plan’s beneficiaries are riskier than the average CMS beneficiary, the
 15 plan’s payment amount will go up; if they are less risky, it will go down.

16 CMS uses an actuarial model—the “CMS-HCC,” or “Hierarchical Condition
 17 Category,” model—to calculate those risk-based adjustments. *See* Compl. ¶ 63.
 18 The model relies on diagnosis codes that CMS has found to be predictors of future
 19 healthcare costs. *See* Ex. 58, 2014 Advance Notice, at AR4814-20 (listing the
 20 included codes). To assess the predicted added costs associated with these
 21 diagnosis codes, CMS analyzes the claims data of traditional FFS beneficiaries.
 22 CMS identifies FFS beneficiaries with the diagnosis codes in a base year,
 23 determines those beneficiaries’ actual healthcare costs the following year, and then
 24 uses regression analysis to estimate how much the various diagnoses, as well as
 25 demographic factors (such as age and sex), contribute to costs. Ex. 53, 2004
 26 Advance Notice, at AR3895-96 & n.1. CMS then converts these estimates into a
 27 numerical risk “coefficient” for each diagnosis code or demographic status. The
 28 model is designed so that a beneficiary with average healthcare costs has a risk

1 score of 1.0, meaning that if you added up all of the risk coefficients associated
2 with her diagnosis codes and demographic status, the total would be 1.0.

3 Having established the value of the various risk coefficients based on the
4 FFS data, CMS then applies those same coefficients in the same way to MA
5 beneficiaries. *Id.* at AR3903. An MA plan submits “risk adjustment data” that
6 includes the diagnosis codes its beneficiaries received in a given year. CMS adds
7 up the corresponding risk coefficients to arrive at a total risk score for each
8 beneficiary. CMS then uses the risk scores to adjust the plan’s payments. An MA
9 beneficiary with a risk score of 2.00, for instance, would trigger an MA payment
10 that is twice the standard payment. As CMS has acknowledged, the Medicare Act
11 mandates that these adjustments ensure equivalence “between the average
12 payments that CMS would expect to make on behalf of a given beneficiary under
13 traditional, fee-for-service Medicare, and the payments made to Medicare
14 Advantage insurers for covering an individual with those same characteristics.”
15 Ex. 38, APA CMS Opening Br., at 8.

16 **B. The Impact Of Diagnosis Coding Discrepancies On the Payment**
17 **Rates Calculated by CMS**

18 In both traditional Medicare and MA, providers sometimes submit diagnosis
19 codes that do not correspond perfectly with patients’ medical charts. *See, e.g.,* Ex.
20 15, Presentation from Division of Payment Validation, at CMS0005886 (CMS
21 presentation acknowledging that “In FFS Medicare, some portion of diagnoses on
22 FFS claims are not documented in medical records.”). When CMS calibrates its
23 risk adjustment model, however, it does not attempt to correct for those
24 discrepancies by auditing the FFS claims data to confirm that the diagnosis codes
25 are properly supported by charts. Instead, it assumes that every diagnosis code in
26 its FFS claims data represents an individual with the condition in question.

27 By design, therefore, the existence of beneficiaries whose provider assigned
28 them a particular diagnosis code but who do not actually have the associated

1 condition is built into the payment model. In other words, CMS's model assumes
 2 that some of the diagnosis codes in the data will be unsupported. And because
 3 beneficiaries who do not actually have a given condition obviously are unlikely to
 4 incur healthcare costs associated with that condition, their inclusion reduces the
 5 overall average, incremental risk coefficient the model calculates for that particular
 6 diagnosis code. *See, e.g.,* Ex. 7, Grant Dep. 231:11–15.

7 CMS's own Division of Payment Validation used an example to explain this
 8 concept to senior CMS leaders in a presentation. The Division hypothesized a
 9 scenario in which, when calibrating the CMS-HCC model, CMS identifies four
 10 FFS beneficiaries with the diagnosis code for diabetes and determines that their
 11 aggregate incremental healthcare costs the following year were \$12,000. Ex. 15 at
 12 CMS0005888. In that scenario, CMS would conclude that the average per-patient
 13 cost associated with diabetes is \$3,000, and would set the diabetes risk coefficient
 14 accordingly. *Id.* But, the presentation explained, suppose further that one of these
 15 diagnosis codes was a false positive; the beneficiary did not in fact have diabetes.
 16 That means that the \$12,000 was in reality attributable to just three beneficiaries,
 17 such that the true per-patient cost of diabetes was actually \$4,000 ($\$12,000 \div 3$
 18 beneficiaries). *Id.* at CMS0005887-5888. By averaging the cost over the four
 19 beneficiaries with the diagnosis code, rather than just the three beneficiaries who
 20 actually have diabetes, CMS's model produces a lower risk coefficient than it
 21 would have done if the diagnosis codes in the FFS data had been perfectly
 22 accurate. As the CMS presentation put it, "Inclusion of undocumented diagnoses
 23 [in the FFS data] tends to reduce risk adjustment values." *Id.* at CMS0005887.

24 The existence of FFS beneficiaries who have no costs associated with their
 25 reported conditions will not necessarily make risk adjustment payments to MA
 26 plans inaccurate, however. Suppose an MA plan also has four beneficiaries with
 27 the diagnosis code for diabetes. Applying the risk coefficient derived from the
 28 FFS data, CMS would pay the plan an incremental total of \$12,000 ($\$3,000 \times 4$)

for the diabetes diagnoses. If all four beneficiaries actually have diabetes, the \$12,000 would undercompensate the plan for its presumptive incremental costs, which would be \$16,000 (\$4,000 per beneficiary who actually has diabetes). If only two have diabetes, the payment will *overcompensate* the plan for its presumptive incremental costs (\$8,000). But if the proportion of beneficiaries among the MA plan's population who do not have the condition is the same as in the FFS population, such that three of the beneficiaries actually have diabetes, then the total payment of \$12,000 equals the plan's expected costs (\$4,000 × 3). For this reason, in determining whether a plan has received an overpayment, the *relative* accuracy of diagnostic coding in FFS and MA claims is the key metric.

C. CMS Recognition Of The Need To Assess MA Plans' Diagnosis Codes In Light Of The Codes Submitted In Traditional Medicare

Both Congress and CMS have acknowledged the importance of considering the relative accuracy of MA and FFS diagnostic coding when assessing whether MA plans have been paid appropriately. Two different aspects of the MA risk adjustment process make this clear: (1) Congress's enactment and CMS's implementation of a statutory "Coding Intensity Adjustment," and (2) CMS's recognition of the need for an "FFS adjuster" as part of its audit procedures.

1. The Coding Intensity Adjustment

MA plans have an incentive "to find and report as many diagnoses as can be supported by the medical record," which is referred to as coding with high "intensity." Ex. 5, Richard Kronick & W. Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Research Review, No. 2, 2014, at E3-E4. MA plans therefore arrange for "chart reviews" to look for diagnoses documented in their beneficiaries' charts that a provider failed to code. By contrast, reimbursement under traditional Medicare generally is not tied to diagnoses, so the incentive for comprehensive coding is weaker. *See id.* at E3. This can lead to different coding patterns that can affect risk adjustment payments.

1 To see why, suppose that an MA plan's beneficiaries are identical to a
 2 sample of FFS beneficiaries used to calibrate the risk adjustment model. Because
 3 the two sets of beneficiaries have the same medical conditions, they have the same
 4 expected future costs and should have the same risk scores. If, however, some
 5 documented diagnoses were not coded for the FFS beneficiaries but were coded for
 6 the MA beneficiaries, the MA beneficiaries will wind up with higher risk scores.
 7 That is, even though the MA beneficiaries' diagnosis codes are perfectly accurate
 8 in the absolute sense (*i.e.*, are supported by the medical charts), because they are
 9 more complete than those of their FFS counterparts, the MA plan will artificially
 10 appear to have taken on more risk, and might therefore be overpaid.

11 For this reason, Medicare experts have recognized that "for the purposes of
 12 creating an equitable MA payment system, the relevant question is whether MA
 13 risk scores are systematically *different* than those risk scores would be in FFS, and
 14 not which set of scores is more *accurate*" in an absolute sense. *Id.* at E4 (emphasis
 15 added). Congress understands this, too, and in 2006 it instructed CMS to analyze
 16 any "*differences* in coding patterns between Medicare Advantage plans and
 17 providers under [traditional Medicare]." Ex. 22, Pub. L. No. 109-171,
 18 § 5301(b)(2), 120 Stat. 4, 51 (2006) (emphasis added). Congress further said that,
 19 "to ensure payment accuracy," CMS should adjust MA beneficiaries' risk scores in
 20 light of those different coding patterns. *Id.*

21 In 2010, therefore, CMS began reducing MA plans' risk scores by a set
 22 percentage each year in order to replicate the risk score-adjusted payments that it
 23 calculated plans would have received if they had not engaged in activities such as
 24 chart reviews. Ex. 1, 2010 Rate Announcement, at AR4334. In doing so, it
 25 rejected commenters' argument that a downward adjustment would be appropriate
 26 only if MA plans were submitting *unsupported* codes. CMS recognized that MA
 27 plans might simply "be coding more completely than FFS," Ex. 21, 2009 Advance
 28 Notice, at AR4231, and was careful to say that it had not concluded that MA plans

1 had engaged in any “improper coding,” *id.*; *see also* Ex. 1, 2010 Rate
 2 Announcement, at AR4335. But even if none of a plan’s codes were “incorrect,”
 3 the mere fact that the plan’s coding “differs from FFS” coding was enough to
 4 require adjustment. Ex. 1, 2010 Rate Announcement, at AR4341. CMS explained
 5 that, because the risk adjustment model is calibrated on FFS data,

6 MA plans must code the way Medicare Part A and B providers do in
 7 order for risk adjustments to be valid. This means that *MA*
 8 *organizations are coding “accurately” when they are coding in a*
 9 *manner similar to [FFS] coding used on the beneficiaries to whom*
 10 *MA plan enrollees are being compared. In this sense, “differences”*
in coding patterns, regardless of the source, would make the MA plan
coding “inaccurate” for purposes of implementing risk adjustment.

11 *Id.* at AR4335 (emphases added). CMS noted that several members of Congress
 12 had expressly recognized this relative notion of accuracy. Senator Grassley, for
 13 instance, had explained that the intensity adjustment provision was intended to
 14 address “coding that is inaccurate or incomplete for the purpose of establishing risk
 15 scores that are consistent across both fee-for-service and Medicare Advantage
 16 settings, *even if such coding is accurate or complete for other purposes.*” *Id.* at
 17 AR4336 (emphasis added) (quoting 152 Cong. Rec. 511 (2006)).

18 CMS has applied the Coding Intensity Adjustment in every year since 2010.
 19 42 U.S.C. § 1395w-23(a)(1)(C)(ii). It never has found that higher MA coding
 20 intensity reflects the inclusion of codes unsupported by medical records; to the
 21 contrary, it has said the data “fail[] to show a systematic correlation between
 22 coding pattern differences and errors in the reporting of documented coding.” Ex.
 23 1, 2010 Rate Announcement at AR4337. Nevertheless, each year CMS reduces by
 24 a certain percentage the risk adjustment payments that an MA plan would
 25 otherwise have received based on the diagnosis codes it had submitted, in order to
 26 account for the MA plans’ more complete coding. CMS has insisted that “we
 27 believe that our methodology results in an accurate measure of the coding
 28 differential between FFS and MA.” Ex. 25, 2013 Rate Announcement, at AR4712.

1 **2. *The RADV FFS Adjuster***

2 CMS also acknowledges the importance of comparing coding in MA and
3 traditional Medicare through regulations on the “risk adjustment data validation”
4 (RADV) audits it uses to determine whether MA plans have been overpaid.

5 When it initiates a RADV audit, CMS selects a sample of an MA plan’s
6 enrollees, collects their medical records, and then assesses whether those records
7 support the enrollees’ diagnosis codes. Ex. 26, Final RADV Methodology, at
8 AR5312-13. Beginning in 2008, it became clear that in doing so, it was important
9 to account for the presence of unsupported codes not only in the audited plan’s
10 data, but also in CMS’s own FFS data. In that year, CMS announced that it would
11 start using its RADV audit findings to make “contract-level payment adjustments,”
12 meaning that it would extrapolate the results from the audited sample to all of a
13 plan’s enrollees, producing a payment adjustment for the plan’s entire MA
14 contract. MA plans objected, however, on the ground that the FFS data used to
15 calibrate the risk adjustment model contained coding discrepancies of its own, such
16 that MA payment amounts already accounted for the existence of some
17 unsupported codes (because they were lower than they would have been if CMS
18 had used only cost data from FFS beneficiaries who actually had the conditions in
19 question). See Ex. 18, 2010 RADV Rule, at AR2826. As the American Academy
20 of Actuaries later explained, CMS had developed risk coefficients “with FFS data
21 that . . . were not validated or audited for accuracy,” and it would therefore be
22 inappropriate to “apply those factors only to MA data that are validated.” Ex. 33,
23 Am. Academy of Actuaries Pub. Comments, at AR5235-36. Doing so, it said,
24 could result in “systematic underpayment.” *Id.* at AR5236.

25 In 2012, CMS acknowledged that the commenters were right. It agreed that
26 in determining any contract-level payment adjustments, it would apply a “FFS
27 adjuster.” Ex. 26, Final RADV Methodology, at AR5314. “The FFS adjuster,”
28 CMS explained, would “account[] for the fact that the documentation standard

1 used in RADV audits to determine [an MA] contract’s payment error (medical
 2 records) is different from the documentation standard used to develop the Part C
 3 risk-adjustment model (FFS claims).” *Id.* at AR5314-15. If the effect of the
 4 unsupported codes in CMS’s data was greater than or equal to the effect of the
 5 unsupported codes in the plan’s data, the audit would conclude with a finding that
 6 there has been no overpayment such that “the final recovery amount is equal to
 7 zero.” *Id.* at AR5314. CMS explained that the “amount of the adjuster” would “be
 8 calculated by CMS based on a RADV-like review of records submitted to support
 9 FFS claims data.” *Id.* at AR5315.

10 **D. Administrative Challenges To The Government’s Current** 11 **Overpayment Theory**

12 In 2014, in connection with CMS’s proposal of regulations about the
 13 “Reporting and returning of overpayments,” multiple MA plans urged CMS to
 14 make explicit in its overpayment regulation the point that it had already recognized
 15 in its audit regulation: That “an overpayment cannot exist for an MA
 16 organization’s particular contract unless CMS’s payments to the [plan] as a whole
 17 are inaccurate in light of an appropriate Fee-for-Service Adjuster that is applied to
 18 the entire contract.” Ex. 34, Pub. Comments of Humana, at AR907.

19 CMS refused. In its final rule (known as the “Overpayment Rule”), CMS
 20 instead adopted an understanding more like the one that the Department of Justice
 21 was developing in its then-sealed investigation of this case, under which “a risk
 22 adjustment diagnosis that has been submitted for payment but is found to be
 23 invalid because it does not have supporting medical record documentation *would*
 24 *result* in an overpayment,” regardless of the unsupported codes in the agency’s
 25 own FFS data. Ex. 36, Overpayment Rule, at AR1313 (emphasis added). CMS
 26 made no attempt to reconcile that view with its prior recognition of the need for a
 27 FFS adjuster when identifying overpayments through RADV audits. Instead, it
 28 argued that MA plans’ contracts with CMS required them to “certify (based on best

knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS.” *Id.* It also asserted that the agency had a “long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.” Ex. 36, Overpayment Rule, at AR1313-14.

United brought an APA suit challenging the Overpayment Rule in the U.S. District Court for the District of Columbia. United has argued there that unless CMS implements a mechanism to account for unsupported diagnosis codes in CMS’s own FFS data, requiring MA plans to delete unsupported codes in their provider-submitted data would violate CMS’s statutory obligation under 42 U.S.C. § 1395w-23(a)(1)(C)(i) to “ensure actuarial equivalence” between the MA and traditional Medicare programs. *See* Ex. 37, APA United Opening Br., at 8. In addition, United has argued that requiring deletions by MA plans without comparable adjustments in the FFS data would violate CMS’s statutory obligation to “us[e] the same methodology” when calculating risk scores of patients in the traditional Medicare program that it “expect[s] to be applied in making payments” to MA plans. 42 U.S.C. § 1395w-23(b)(4).

In response, CMS has argued that the Overpayment Rule does not present a proper opportunity to litigate whether every unsupported code submitted by an MA plan results in an overpayment and must therefore be deleted. *See, e.g.,* Ex. 40, APA CMS Reply Br., at 5-9. Relying on the same contractual, regulatory, and sub-regulatory provisions the government has invoked here, CMS has argued there that MA plans long have been required to delete all unsupported codes they identified, and that the Overpayment Rule changed nothing. *Id.*³ United has

³ Although CMS continues to defend the Overpayment Rule in court, it is not clear whether the agency in fact continues to have confidence that the position articulated there is consistent with the requirements of the Medicare Act. As United explains elsewhere in this brief, discovery in connection with this case has already resulted in evidence that shows senior agency officials’ recognition that

1 argued in turn that the contracts, manuals, and regulations are at best ambiguous,
 2 that they can and should be read in a manner consistent with CMS’s adoption of a
 3 FFS Adjuster, and that if they are *not* read that way—and instead read to require
 4 deletion of all unsupported codes without any adjustment for the FFS data—then
 5 those provisions would be just as unlawful as the Overpayment Rule itself. Ex. 39,
 6 APA United Resp. Br., at 28-39.

7 The parties completed summary judgment briefing in February (totaling over
 8 200 pages, including related motions and amicus filings), and Judge Collyer has
 9 scheduled argument for August 8, 2018.

10 **E. The Government’s Motion For Partial Summary Judgment Here**

11 Months after the close of the parties’ briefing in the APA case, the
 12 government filed its present motion for partial summary judgment in this Court.
 13 *See* ECF No. 234. In it, the government asks for “partial summary judgment in
 14 this case on the legal issue of whether defendants were required to delete diagnosis
 15 codes they knew (as that term is used in the False Claims Act) were unsupported
 16 by their beneficiaries’ medical records.” Mem. 1.

17 **III. ARGUMENT**

18 **A. The Government’s Motion Is Procedurally Improper**

19 **1. The Government’s Motion Seeks An Improper Advisory Opinion**

20 The first problem with the government’s motion is that it does not actually
 21 seek a partial summary judgment. As Wright & Miller explain, Rule 56 “adopts
 22 the terminology ‘Partial Summary Judgment’ for cases in which summary
 23 judgment is issued solely on liability.” 10B Charles Alan Wright et al., *Federal*
 24 *Practice & Procedure* § 2736 (4th ed. 2017) (hereinafter “Wright & Miller”). But
 25 the government does not seek a judgment as to liability (or anything else). Instead,
 26
 27 requiring MA plans to delete substantial numbers of unsupported diagnosis codes
 28 would result in those plans being underpaid unless adjustments were made for the
 presence of unsupported codes in CMS’s own data. *See, e.g., infra* at 44-45.

1 it asks this Court to resolve a bare “legal issue,” Mem. 1, which even the
 2 government does not contend will result in judgment on any claim or any element
 3 of any claim. Such a motion is a request for “an impermissible advisory opinion.”
 4 *Hanks*, 2015 WL 770422, at *7.

5 Rule 56(a) states that “[a] party may move for summary judgment,
 6 identifying each claim or defense—or the part of each claim or defense—on which
 7 summary judgment is sought.” Fed. R. Civ. P. 56(a). Under that rule, a party may
 8 seek judgment on individual claims (or its entire case) “as a matter of law” if
 9 “there is no genuine dispute as to any material fact.” *Id.* Or a party may seek
 10 judgment as to some but not all of the claims in the case, such as in a case where
 11 some claims are barred by the statute of limitations and others are not. *See, e.g.,*
 12 *Ely v. Sci. Applications Int’l Corp.*, 716 F. Supp. 2d 403, 409 (D. Md. 2010)
 13 (granting partial summary judgment because some of plaintiff’s claims were time
 14 barred). Or a party may seek judgment on liability, while reserving for trial the
 15 question of damages (or vice versa). *See, e.g., Wright & Miller, supra*, § 2736.

16 The government does not seek any of those things. Instead, it asks this
 17 Court to resolve a “legal issue” that might—depending on what facts the
 18 government later proves—be relevant to one element of its claims, but that would
 19 not itself produce a judgment for the government on any claim or even any element
 20 in the case. Such a motion, which asks a court “to resolve only one issue relevant
 21 to a plaintiff’s claims,” as opposed to “proffering a claim . . . upon which judgment
 22 could be granted,” is “entirely inappropriate under any provision of Rule 56.”
 23 *Powers*, 2017 WL 4102752, at *1.

24 Far from promoting the “just, speedy, and inexpensive” resolution of
 25 litigation, entertaining such motions would “encourage[] wasteful motion work” in
 26 which parties would ask the court to resolve independent legal issues one-by-one,
 27 disconnected from any ultimate judgment. *Cardenas v. KanCo Hay, L.L.C.*, No.
 28 14-1067-SAC, 2016 WL 3881345, at *7 (D. Kan. July 18, 2016). Courts therefore

1 routinely reject such requests “to piecemeal and separately decide” non-dispositive
 2 issues. *Moses H. Cone Mem’l Hosp. Operating Corp. v. Conifer Physician Servs.*,
 3 No. 1:13CV651, 2017 WL 1378144, at *5 (M.D.N.C. Apr. 11, 2017).⁴

4 The government cites just one case for its contrary assertion that “[p]artial
 5 summary judgment is appropriate to resolve purely legal questions.” Mem. 14
 6 (citing *In Re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277,
 7 288 (D. Mass. 2006)). But there, the court did not just resolve a legal issue in the
 8 abstract. Instead, the defendants argued that if they were right on the disputed
 9 legal questions, then they were entitled to judgment on all of their claims. See
 10 F. Supp. 2d at 288 (D. Mass. 2006). The court agreed with the defendants on some
 11 of the legal questions but not others, and entered final judgment against the
 12 plaintiffs’ claims for one year but not others. *Id.* The government does not even
 13 suggest that it is entitled to such a judgment here.⁵

14
 15 ⁴ See also, e.g., *Hamer v. City of Trinidad*, No. 16-cv-02545-NYW, 2017 WL
 16 5969815, at *5 (D. Colo. Dec. 1, 2017) (rejecting a plaintiff’s partial summary
 17 judgment claim because “[w]hile it would be dispositive had Defendant moved for
 18 summary judgment on the basis that Mr. Hamer is *not* a qualified individual, an
 19 affirmative finding in favor of Mr. Hamer that he *is* a qualified individual . . . is not
 20 dispositive as to any entire claim before the court”); *Cardenas*, 2016 WL 3881345,
 21 at *7 (“‘Judgment’ cannot be entered upon a finding of foreseeability or the other
 ‘elements’ of the claims upon which plaintiff moves for partial summary judgment.
 Nor can the court enter judgment for plaintiff merely on a finding that KanCo
 owed a duty of care.”); *Hanks*, 2015 WL 770422, at *7; *Home Design Servs. v.*
Schroeder Constr., No. 09-cv-01437-WJM-GJR, 2012 WL 527202, at *1-2 (D.
 Colo. Feb. 16, 2012) (rejecting a plaintiff’s motion “for summary judgment on
 only the first element of its [copyright] claim”).

22 ⁵ Elsewhere, the government describes *Parra v. Wright*, No. 11-CV-6270 CJS,
 23 2013 WL 6669235, at *7-8 (W.D.N.Y. Dec. 18, 2013) as “granting pre-discovery
 24 summary judgment . . . where ‘the legal principles are clear.’” Mem. 14. That
 25 case does not support its request for partial summary judgment on a “legal issue,”
 26 either. There, the defendants sought summary judgment on all of the plaintiffs’
 27 claims. The court denied the defendants’ argument in part based on the principle
 28 that “[o]nly in the rarest of cases may summary judgment be granted against a
 plaintiff who has not been afforded the opportunity to conduct discovery.” *Parra*,
 2013 WL 669235, at *7 (citation omitted). But on one set of claims, as to which it
 was plain that the plaintiff had not exhausted his administrative remedies and thus
 could not prevail as a matter of law, the court granted the defendants summary
 judgment. *Id.* Doing so resulted in a complete judgment on those claims, not just a
 legal opinion about an issue that might or might not later prove relevant.

1 The government’s reliance (at 14) on Wright & Miller fares no better. The
 2 part of the treatise to which it points does not deal with partial summary judgment
 3 motions at all, but rather with instances in which “the only issues to be decided *in*
 4 *the case* are issues of law” because, for example, “the parties agree on the facts.”
 5 10A Wright & Miller § 2725 (4th ed. 2017) (emphasis added). In such
 6 circumstances, deciding the legal issues will provide final resolution of all claims,
 7 and is thus appropriate. *Id.* But this is not such a case.

8 **2. The Government is Seeking to Preempt Judge Collyer**

9 The government’s motion is all the more inappropriate because it is so
 10 plainly intended to hedge the government’s bets against a decision in the APA case
 11 on similar issues. CMS, United, and America’s Health Insurance Plans (a trade
 12 association participating in the case as an *amicus*) have filed more than 200 pages
 13 of briefing in connection with the cross-motions for summary judgment in that
 14 case, based on a 12,000-page administrative record. The briefing addressed not
 15 only the statutory requirements of “actuarial equivalence” and “same
 16 methodology,” but also the government’s contention that the Overpayment Rule
 17 was merely a continuation of the very same regulations, contractual provisions, and
 18 sub-regulatory guidance that it draws on in its motion here. *See supra* at 14-15
 19 (discussing briefing). And a decision there is imminent, with argument scheduled
 20 for August 8, 2018. As a result, denying the government’s motion as procedurally
 21 inappropriate, and reserving resolution of the underlying merits issue for the close
 22 of discovery, will enable this Court to consider not only a full factual record but
 23 also a decision addressing similar issues in the APA case.⁶

24
 25 ⁶ If Judge Collyer rules that CMS cannot require MA plans to delete all
 26 unsupported diagnosis codes without making an adjustment for the presence of
 27 such codes in CMS’s own FFS data, United likely would move for summary
 28 judgment in this case, too, on that basis. Even if Judge Collyer resolve the merits
 of that issue against United, however, there will be numerous other defenses that
 the parties will need to brief at the close of discovery.

1 **3. *Granting the Government’s Motion Would Do Nothing To***
 2 ***Streamline This Case***

3 In addition to being procedurally improper, the government’s motion—like
 4 its simultaneously filed Motion to Strike—also is a waste of judicial and party
 5 resources. The only specific reason the government claims that granting this
 6 motion now will promote efficiency is that it would avoid discovery into facts
 7 relating to “actuarial equivalence.” Mem. 2, 15. But for many reasons, discovery
 8 into the unsupported codes in the government’s own data, the impact those codes
 9 had on the calculation of United’s payments, and related issues would all still be
 10 necessary irrespective of the outcome of this motion.

11 For one thing, as with its Motion to Strike, the government’s brief
 12 completely ignores the remaining two common law claims. One of those claims is
 13 for Unjust Enrichment. At their simplest, United’s “actuarial equivalence” and
 14 “same methodology” arguments are that because CMS’s payment model utilizes
 15 unaudited claims data that contain numerous unsupported codes, the resulting
 16 payment amounts that CMS sets *already account* for the existence of unsupported
 17 codes. Requiring plans to repay funds associated with unsupported codes, without
 18 first determining whether the plan’s rate of unsupported codes exceeds the rate
 19 already implicit in the payment model, would thus confer an unfair windfall on the
 20 government: the government would first have the benefit of lower payment rates
 21 that reflect the inclusion of unsupported codes in the model, and then would lower
 22 its payments a second time on the back end due to the presence within MA plan
 23 data of the same unsupported codes that the model already factored in. Evidence
 24 showing that the government’s recovery here would produce that inequitable effect
 25 would support United’s defense that it has not been unjustly enriched, and thus
 26 granting this motion would do nothing to avoid discovery on these subjects.

27 In addition, evidence that CMS itself recognized that plans would be
 28 underpaid if they were required to delete all unsupported codes also would be

relevant to whether the government had proven an “overpayment,” as it must in order to demonstrate the “obligation to pay or transmit money or property to the Government” that its remaining False Claims Act count requires. 31 U.S.C. §3729(a)(1)(G); *id.* § 3729(b)(3) (defining “obligation” to include “an established duty, whether or not fixed, arising from . . . retention of any overpayment”). And as United has argued in its opposition to the Motion to Strike, that evidence also would be relevant to scienter, because it would support United’s arguments that its interpretations were reasonable. *See* Opp’n to Mot. to Strike at 17-18. Such evidence would likewise weigh on questions like materiality, and should the case ever come to it, damages.

In short, granting this motion now would not actually change *anything* about the scope of discovery in the case. All it would do is ensure that this critical question is decided without the benefit of a full understanding of the facts.

B. The Applicable Statutes, Contracts, And Regulatory Backdrop All Foreclose The Government’s Legal Argument On The Merits

As just described, the government’s motion is improper, premature, and pointless, and should be denied as procedurally deficient. But on the merits, too, the government is wrong several times over.

First, the government’s view is contrary to statute. Congress has mandated that CMS pay MA plans in a manner that ensures they are paid for risk measured in the same way that risk is measured in the traditional Medicare program. CMS has committed to comply with that requirement in its contracts with MA plans (an aspect of the contracts that the government completely ignores). And CMS has acknowledged that when auditing plans to determine whether they have been overpaid, it cannot just look to the rate of unsupported codes in the MA plans’ data but must compare that rate to the comparable figure in CMS’s own data.

Second, the government’s proposed rule—which would require MA plans to delete unsupported codes without the necessary adjustment for CMS’s own data—

1 is not borne out by the regulatory, sub-regulatory, and contractual provisions on
 2 which the government relies. At the very least, those materials do not
 3 *unambiguously* support its position. The government thus would need to grapple
 4 with extrinsic evidence showing, among other things, that its own officials
 5 interpreted the pertinent provisions in the same way as United—evidence that
 6 would support reading any ambiguity in the contracts in favor of United and
 7 against the government. Just as the government’s prosecution theory about the
 8 materiality of United’s attestations turned out not to align with CMS’s own view
 9 about the significance of those attestations, discovery will show that many CMS
 10 officials (consistent with the agency’s own past position) do not agree with the
 11 government’s current prosecution theory that MA plans are required to delete
 12 every unsupported code they find. The limited amount of evidence United has
 13 obtained through FOIA and the government’s slow productions to date validates
 14 that suspicion. But it appears that the government is sitting on a mountain of
 15 additional evidence that likewise would be helpful to United’s arguments. This
 16 Court should not facilitate the government’s attempt to have this important
 17 question resolved before that evidence comes to light.

18 ***1. MA Plans Cannot Be Required To Use A Stricter Standard***
 19 ***For Measuring Risk Than CMS Uses In Traditional Medicare***

20 Congress established the framework for determining payments to Medicare
 21 Advantage plans in Section 1853 of the Medicare Act, codified at 42 U.S.C.
 22 § 1395w-23. Two specific requirements found in that section are relevant here.

23 *First*, Section 1395w-23(b)(4) provides that when CMS calculates the risk
 24 scores of its traditional Medicare beneficiaries—which then affects the amounts
 25 that MA plans are paid for equivalent beneficiaries—CMS must “us[e] the same
 26 methodology as is expected to be applied in making payments” to MA plans. 42
 27 U.S.C. § 1395w-23(b)(4). *Second*, Section 1395w-23(a)(1)(C)(i) mandates that
 28 when CMS risk adjusts an MA plan’s payment amount, it “shall” do so in a

manner that will “ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). CMS has acknowledged that this means it is required to achieve equivalence “between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional, fee-for-service Medicare, and the payments made to Medicare Advantage insurers for covering an individual with those same characteristics.” Ex. 38, APA CMS Opening Br., at 8. Thus, CMS must both 1.) measure actuarial risk in the two programs in the same way, and 2.) ensure that it is paying equivalent amounts in the two programs for patients who present equivalent levels of risk under that common measurement approach.

Those statutory requirements are relevant to the “legal issue” about which the government asks this Court to opine. CMS does not delete or otherwise account for the unsupported diagnosis codes in its FFS data when it is calculating risk scores for its traditional Medicare enrollees or calibrating the CMS-HCC model. *See id.* at 37. As a result, requiring MA plans to delete unsupported codes for purposes of calculating the risk scores of their enrollees, without accounting for the presence of such codes in CMS’s traditional Medicare data, would violate the “same methodology” provision. 42 U.S.C. § 1395w-23(b)(4). The government does not even *try* to argue otherwise here.

The government’s proposed rule likewise would violate the Medicare Act’s “actuarial equivalence” mandate, because it would result in identical groups of people being assigned different risks scores (and thus different anticipated costs or MA payment amounts) based solely on whether they are enrolled in MA or traditional Medicare. 42 U.S.C. § 1395w-23(a)(1)(C)(i). To see how, imagine two perfectly identical groups of 1,000 patients—one in traditional Medicare, one in MA. Both groups have the same 1,000 different demographic statuses, the same true health conditions, and the same collection and distribution of diagnosis codes—say, 5,000 diagnosis codes, including precisely the same 500 unsupported diagnosis codes. CMS might calculate, based on its traditional Medicare

1 expenditure data, that it had cost \$10 million to insure those patients in a given
2 year in the traditional Medicare program. It would then regress that \$10 million in
3 expected costs across the 1,000 different demographic statuses and 5,000 different
4 diagnosis codes from traditional Medicare. For present purposes, it is irrelevant
5 what precise value it assigns to each of the 5,000 diagnosis codes and 1,000
6 demographic statuses in particular; what matters is that taken together, the
7 incremental costs for all 6,000 would add up to exactly \$10 million. If CMS then
8 requires the MA plan to delete the 500 unsupported codes without any offsetting
9 adjustment, the result is that the plan will be underpaid, because it will not receive
10 whatever portion of the \$10 million in actual traditional Medicare costs CMS had
11 allocated to those 500 codes.

12 The same principle can also be seen by looking at individual beneficiaries
13 who are otherwise identical but for the fact that one is enrolled in an MA plan and
14 the other in traditional Medicare. In the APA case, for example, CMS offered a
15 hypothetical FFS beneficiary with \$10,000 in costs and three risk adjustment
16 factors: (1) her demographic group; (2) an unsupported diabetes diagnosis code;
17 and (3) a chart-supported multiple sclerosis diagnosis code. *See* Ex. 38, APA CMS
18 Opening Br., at 16-18. In that scenario, the CMS-HCC model would distribute the
19 \$10,000 in costs across the beneficiary's three different risk factors. Thus, while
20 the unsupported diabetes code might not in fact reflect that the beneficiary actually
21 has diabetes, the costs assigned to that code would nevertheless reflect real risks
22 presented by the patient because—as CMS acknowledged there—the model would
23 “assign to diabetes some portion of the cost actually due to demographics, and
24 some portion of the cost actually due to multiple sclerosis.” *Id.* Only by adding up
25 all three factors, therefore, would you arrive at the \$10,000 in costs for this patient.
26 So if CMS required an MA plan to delete the unsupported diabetes code of an
27 identical MA beneficiary (someone with the same real-world health conditions,
28 same demographics, and same mix of supported and unsupported codes), its

1 payment for that MA plan beneficiary would be less than \$10,000, even though the
2 expected cost for an identical beneficiary in traditional Medicare is \$10,000.

3 The government cannot dispute that the legal rule it asks this Court to adopt
4 in its motion would produce that result. Nor can it reconcile that result with its
5 acknowledgment that actuarial equivalence means “paying MAOs a sum
6 commensurate with the expected costs of providing traditional Medicare benefits
7 to a given beneficiary.” Mem. 23. Instead, it offers (at 24) that it would be
8 “absurd” to pay United based on unsupported codes, because that would amount to
9 “payments for conditions it knows are not substantiated by its beneficiaries’
10 medical records.” But that is simply a distortion. In the example of the 1,000
11 patients above, for example, the MA plan is not being paid for conditions its
12 patients do not have if it receives the full \$10 million payment. To the contrary,
13 the plan in that circumstance is being paid appropriately for the conditions its
14 beneficiaries do have. The fact that CMS’s model assigns some of those actuarial
15 costs to the 500 unsupported diagnosis codes does not make the costs any less real
16 (or payments based on those costs any less valid).

17 CMS’s adoption of a FFS adjuster for its RADV audits was based on
18 acceptance of this very point. CMS recognized that if the level of unsupported
19 codes in an MA plan’s data is the same as or less than the level of unsupported
20 codes in CMS’s FFS data, then the plan is *not* being paid for a level of risk higher
21 than its beneficiaries actually present, and has not received an overpayment. *See*
22 *supra* at 12-13. Only by evaluating unsupported codes across both sets of data can
23 an auditor determine whether an overpayment had been made.

24 Unable to reconcile its proposed rule with the “actuarial equivalence”
25 requirement, the government contends (at 22-23) that the requirement is merely
26 “discretionary.” Not so. The statute provides that “the Secretary *shall* adjust the
27 payment amount . . . so as to *ensure* actuarial equivalence.” 42 U.S.C. § 1395w-
28 23(a)(1)(C)(i) (emphases added). While Congress gave CMS some flexibility in

1 *how* to ensure actuarial equivalence, it did not give CMS flexibility about *whether*
 2 to ensure actuarial equivalence. By law, the government cannot impose a risk
 3 adjustment methodology that systematically fails to ensure actuarial equivalence
 4 between the MA and traditional Medicare programs. Indeed, CMS has conceded
 5 the point in the APA litigation. *See* Ex. 38, APA CMS Opening Br., at 28
 6 (conceding that the actuarial equivalence mandate is a “statutory requirement”).
 7 The government’s present suggestion that its statutory obligations are simply
 8 optional cannot be taken seriously.⁷

9 The government also argues (at 3-4, 20-21) that even if it would in some
 10 circumstances be necessary to account for unsupported codes in CMS’s own data,
 11 CMS need not do so here because United has engaged in chart reviews that lack a
 12 direct parallel in traditional Medicare. It suggests (at 4) that “United’s position
 13 [is] that the [actuarial equivalence] principle works in only one direction, and
 14 permits United to submit additional codes [identified in chart reviews] but does not
 15 permit the government to require the deletion of unsupported diagnoses.” But the
 16 government has it completely backwards. It is the *government* that is trying to
 17 employ the actuarial equivalence principle when it is beneficial to it, and then
 18 ignore it when it is not. As explained above, *see supra* at 9-11, through the Coding
 19 Intensity Adjustment CMS reduces MA plans’ payments for *supported* codes by an
 20 amount that is calculated to offset the greater “intensity” of coding by MA plans.
 21 CMS has determined that the Coding Intensity Adjustment fully accounts for that
 22 differential intensity of coding. *See* 2013 Rate Announcement, AR4712. And it is
 23 a substantial adjustment. In 2017, for example, CMS will reduce its payment to
 24

25 ⁷ In a footnote (at 23 n.14), the government claims that “[s]uch language has also
 26 been held to be procedural only and not a basis for creating substantive rights,”
 27 pointing to cases involving statutes that called for the government to provide its
 28 “best estimate.” But a call for the government to provide its “best estimate” is
 worlds away from the requirement here that CMS, when making payments to MA
 plans, “shall . . . ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i).

1 United by approximately \$2.9 billion precisely to account for the fact that United
 2 adds codes through chart reviews that CMS does not perform in traditional
 3 Medicare. *See* Ex. 24, Decl. of Mary Murley, ¶ 9. But having subtracted billions
 4 of dollars annually from its payments to United in order to maintain actuarial
 5 equivalence in the face of activities that tend to *increase* United’s risk scores as
 6 compared to those in traditional Medicare, the government then refuses to
 7 acknowledge that the same principle applies in reverse: If CMS were to require
 8 MA plans to engage in activities (such as identifying and deleting codes that are
 9 not supported by charts) that CMS itself does not engage in, the effect of which is
 10 to *decrease* plans’ risk scores, then it would likewise need to impose an offsetting
 11 adjustment to ensure that risk adjustment comparisons remain valid. The
 12 government’s willingness to use a comparative standard when that is to its
 13 advantage, then disavow it when it is not, is (to borrow the government’s terms)
 14 “transparently self-serving and logically untenable.” Mem. 4.

15 **2. *The Requirement That Risk Be Measured In An Equivalent***
 16 ***Way In Both MA and Traditional Medicare Forecloses The***
 17 ***Government’s Requested Rule***

18 The congressional mandates in Sections 1395w-23(a)(1)(C)(i) and 1395w-
 19 23(b)(4) foreclose the government’s argument in its present motion. That is true
 20 for two reasons. The first—which the government never acknowledges—is that
 21 the contract CMS signs with MA plans specifically obligates CMS to pay plans in
 22 compliance with those statutory requirements. *See* Decl. of Cheri Rice (“Rice
 23 Decl.”), Ex. 1 at 10.⁸ Article IV of the contract, which addresses “CMS Payment
 24 to MA Organization”—the core subject of this lawsuit—provides that “CMS
 25 agrees to pay the MA Organization under this contract in accordance with the

26
 27 ⁸ Citations herein to the Decl. of Cheri Rice refer to the Declaration of Cheri Rice
 28 in Support of United States and Relator Poehling’s Joint Mot. for Partial Summ. J.
 (ECF No. 234-2).

1 provisions of section 1853 of the [Medicare] Act and 42 CFR Part 422 Subpart G.”
 2 *Id.* And Section 1853 of the Medicare Act, as discussed, is the portion of the Act
 3 that includes the “actuarial equivalence” and “same methodology” provisions.

4 The second reason is that CMS cannot enforce contracts that violate federal
 5 law. United explains below (as it has explained at length in the APA case) that the
 6 regulatory and contractual provisions the government invokes do not state,
 7 unambiguously or otherwise, that a plan is overpaid every time it receives a
 8 payment associated with an unsupported code. *See infra* at 29-42. Nor do they
 9 state that an MA plan is required to delete every such code. But if those provisions
 10 *were* interpreted in that manner, they would be “invalid or void” as inconsistent
 11 with the Medicare Act. *Am. Airlines, Inc. v. Austin*, 75 F.3d 1535, 1538 (Fed. Cir.
 12 1996) (“Generally, a provision in a government contract that violates or conflicts
 13 with a federal statute is invalid or void.”). Indeed, the MA contract itself
 14 recognizes that if “any provision of this contract conflicts with the provisions of
 15 any statute or regulation applicable to an MA Organization, the provisions of the
 16 statute or regulation shall have full force and effect.” Rice Decl., Ex. 1 at 19.

17 Remarkably, the government claims (at 16) that even if the legal obligation
 18 that it is advocating for violates the Medicare Act, that is “not a defense to liability
 19 in this FCA action.” In doing so, it seeks to make the Medicare Act’s requirements
 20 irrelevant in this case. In prior filings, however, the government has recognized
 21 that those same requirements are *central* here. The government sought to delay a
 22 decision in the APA case by urging Judge Collyer to enter a stay until this Court
 23 had resolved the “actuarial equivalence” issue, arguing that this Court would
 24 “benefit from a full factual record.” Ex. 54, APA U.S. Mot. for Stay, at 7.
 25 Necessarily implicit in that argument was that if United were correct about its
 26 “actuarial equivalence” and related legal arguments, then they would constitute
 27 proper and valid defenses to enforcement—otherwise, this Court would have no
 28

1 occasion to resolve them.⁹ Having previously argued that the actuarial equivalence
 2 issue could (and should) be resolved here, the government cannot now claim that
 3 the issue is not even relevant.

4 The government's present argument is also wrong on the merits. To prevail
 5 on its reverse false claim suit, the government must show (among other things) that
 6 United had, and knew it had, a legal "obligation to pay or transmit money or
 7 property to the Government," and that United "improperly avoid[ed]" that
 8 obligation. 31 U.S.C. § 3729(a)(1)(G). An invalid contractual or regulatory
 9 provision cannot give rise to a legal "obligation to pay," and refusing to comply
 10 with an unlawful requirement is certainly not "improper." *See American Airlines*,
 11 75 F.3d at 1538. If the "actuarial equivalence" mandate means that the
 12 government cannot demand United return all payments made on the basis of
 13 unsupported diagnosis codes until it first accounts for the unsupported codes in its
 14 own data, then the government certainly cannot demand that United return those
 15 amounts *trebled* by bringing a False Claims Act suit. To hold otherwise would
 16 create perverse incentives for agencies to convert ordinary regulatory disputes into
 17 False Claims Act cases in order to avoid the limits of their organic statutes.

18 The "self-help" cases the government points to (at 17-18) are not to the
 19 contrary. Each of those cases rested on affirmatively false claims that were
 20 independently fraudulent, not on obligations unlawfully imposed by an invalid
 21 contract or regulation. *See, e.g., City & Cty. of San Francisco v. Tutor-Saliba*

23 ⁹ Judge Collyer declined the government's requested stay on the ground that
 24 evaluation of the Overpayment Rule "would be limited to the administrative record
 25 behind the 2014 Overpayment Rule." Ex. 56, APA Stay Order, at 4. But neither
 26 Judge Collyer nor United has disputed that actuarial equivalence was a central
 27 issue in this case. United did argue that the actuarial equivalence issue might never
 28 be reached here because this case might be resolved in United's favor on other
 grounds, such as "the government's inability to prove the materiality of any
 allegedly false claim." Ex. 55, APA United Stay Opp'n, at 10. But United also
 has maintained that it cannot be held liable under the False Claims Act on the basis
 of an obligation that the government could not lawfully impose.

1 *Corp.*, No. C 02-5286 CW, 2005 WL 645389, at *7 (N.D. Cal. Mar. 17, 2005)
 2 (“Plaintiffs’ claims . . . are not based upon the illegal contract, but upon the
 3 misrepresentations made by the Tutor Defendants in attempting to obtain and then
 4 to comply with the contracts.”). Here, however, the government abandoned its
 5 affirmative FCA counts after it was unable even to *allege* that the supposedly false
 6 statements on which they rested were material. And it offers no authority
 7 whatsoever for the proposition that it could seek treble damages under the reverse
 8 false claims provision on the basis of legally invalid obligations. That is all the
 9 more true when the legally invalid obligations violate CMS’s commitments to
 10 United under Article IV of the contract itself.¹⁰

11 **C. Even Setting The Medicare Act’s “Actuarial Equivalence” and**
 12 **“Same Methodology” Requirements Aside, The Government Has**
 13 **Not Identified Any Statutory, Regulatory, Or Contractual**
 14 **Provision Supporting Its Proposed Rule**

15 To prevail on its motion, the government must identify a statutory,
 16 regulatory, or contractual provision that requires MA plans to delete every
 17 unsupported code they find, regardless of how many such unsupported codes exist
 18 in the FFS data. Because it asks the Court to resolve that issue in a summary
 19 judgment-type posture early in discovery, moreover, the government must further
 20 show that the provision is *unambiguous* on this point, and that no evidence the
 21 government might turn over in the future could have any bearing on its
 22 interpretation.

23 The government fails to make that showing.

24 ¹⁰ The government’s analogy (at 3) to a physician who bills for procedures she did
 25 not perform because she believes the government’s payment amounts are too low
 26 is wholly inapposite. The physician in that example does not dispute the legal
 27 validity of the prohibition on billing for procedures that were not performed, and is
 28 simply invoking a “two wrongs make a right” argument. Here, though, United is
 most assuredly challenging the legality of any obligation to delete unsupported
 provider-submitted codes without accounting for CMS’s own errors and their
 impact on United’s payment amounts.

1 ***1. No Statute Or Regulation Supports The Government's Proposed***
 2 ***Rule***

3 In its motion for “partial summary judgment,” the government does not
 4 contend that there is any statutory provision that requires MA plans to delete every
 5 unsupported code they identify.¹¹ The government does, however, point to
 6 regulatory provisions that it claims create such a requirement. None of them does.

7 *First*, the government invokes (at 9) regulatory provisions requiring
 8 compliance with “laws and regulations designed to prevent or ameliorate fraud,
 9 waste, and abuse,” and implementation of a compliance program for that purpose.
 10 Unless specific “laws and regulations” obligated United to delete all unsupported
 11 codes, though, there was no relevant obligation for United to carry out through its
 12 compliance program. And while no one disputes that United was required to
 13 “conduct appropriate corrective actions (for example, repayment of overpayments
 14 . . .),” 42 C.F.R. § 503(b)(4)(vi)(G)(2), that does not in any way answer the
 15 question underlying this motion: Does every unsupported code result in an
 16 overpayment? Without a provision speaking to *that*, reliance on regulations about
 17 general compliance programs is entirely circular. And the only regulatory
 18 document in which CMS addressed that issue was the RADV methodology, in
 19 which it concluded there is no overpayment to recover unless the plan’s rate of
 20 unsupported codes exceeds CMS’s. *See supra* at 12-13.

21 *Second*, the government points (at 10-11) to the requirement in 42 C.F.R.
 22 § 422.310(e) that MA organizations “submit a sample of medical records for the
 23 validation of risk adjustment data.” But that requirement concerns a plan’s
 24 obligation to cooperate with the *government’s* validation of risk adjustment data,
 25 _____

26 ¹¹ That omission contrasts starkly with the government’s Motion to Strike, which
 27 appears to suggest that such a requirement can be found in Section 1395w-
 28 23(a)(1)(C)—the “actuarial equivalence” provision. *See* Memo In Support of Mot.
 to Strike at 8, ECF No. 235-1. As United has explained at length above, that
 section *forecloses* the government’s case—it certainly does not support it.

1 not an MA plan's responsibility to delete data on its own. And more importantly,
 2 when the government carries out those validation responsibilities to determine if
 3 the plan has received an overpayment, it does not recover funds associated with all
 4 diagnosis codes that lack chart support. To the contrary, as just discussed, it has
 5 recognized the need to apply a FFS Adjuster that compares the rate of unsupported
 6 codes in the MA plan's data with the rate in CMS's traditional Medicare data, and
 7 determines that a plan has been overpaid on its contract only if its rate of
 8 unsupported codes exceeds CMS's. That regulation thus provides no support
 9 whatsoever for the ruling the government seeks here.

10 *Third*, the government points (at 10) to regulations requiring MA plans to
 11 attest "based on best knowledge, information and belief" that the risk adjustment
 12 data they have submitted were "accurate, complete, and truthful." *See* 42 C.F.R.
 13 § 422.504(l). These are the same attestations for which the government could not
 14 get CMS approval to allege materiality, resulting in the dismissal of its entire case
 15 in *Swoben* and its affirmative False Claims Act counts here. They say nothing
 16 about whether a plan is overpaid whenever it submits an unsupported diagnosis
 17 code, such that it would be required to delete that code in order to return an
 18 overpayment. And in any event, as United has argued at length in the APA case,
 19 *see* Ex. 39, APA United Resp., at 30-34, the attestations' terms when used in the
 20 context of the MA program require a comparative standard rather than an absolute
 21 one. *See, e.g.,* Accurate, *American Heritage Dictionary of the English Language*
 22 (4th ed. 2000) ("Deviating only slightly or within acceptable limits from a
 23 standard.").¹² CMS has itself previously acknowledged that in the context of risk
 24 adjustment "MA organizations are coding 'accurately' when they are coding in a
 25 manner similar to fee-for-service coding used on the beneficiaries to whom MA

27 ¹² *See also* Truth, *American Heritage Dictionary of the English Language* (4th ed.
 28 2000) ("Fidelity to an original or standard.").

1 plan enrollees are being compared.” Ex. 1, 2010 Rate Announcement, at AR4335.

2 Indeed, under an absolute interpretation, no plan could *ever* submit the
3 attestation. That is because the attestation does not speak just to specific
4 knowledge about individual codes but about the plan’s “belief” about whether the
5 data *as a whole* are “accurate” and “truthful.” CMS itself has said that the
6 presence of at least some unsupported codes is “inevitable.” Ex. 41, 2001
7 Medicare Managed Care Manual § 110.2, at AR5349. The only way that CMS can
8 expect the plans to actually sign the attestation, therefore, is if the attestation is
9 understood to communicate a belief that the plan’s data “are cod[ed] in a manner
10 similar to fee-for-service coding,” Ex. 1, 2010 Rate Announcement, at AR4335, or
11 that any differences in the coding patterns have been accounted for. At the very
12 least, that prospect renders the attestations ambiguous.

13 **2. No Sub-Regulatory Provision Supports The Government’s Proposed** 14 **Rule**

15 Lacking any statutory or regulatory provision that speaks directly to the
16 requirement it asks this Court to impose, the government relies heavily on sub-
17 regulatory materials, including most prominently the Medicare Managed Care
18 Manual (hereinafter “Manual”). Such sub-regulatory guidance makes up the bulk
19 of the materials in the section of the government’s Amended Complaint purporting
20 to set forth “Obligations to Delete Invalid Diagnoses.” Compl. ¶¶ 103-114.

21 The threshold problem with the government’s reliance on that sub-regulatory
22 guidance is that it does not create binding legal obligations enforceable through a
23 False Claims Act suit. As the Secretary of Health and Human Services explained
24 in a recent brief, such “manuals are non-binding, interpretive guidelines.” Final
25 Brief for Secretary Burwell, Defendant-Appellee at 43 n.10, *Regents of the Univ.*
26 *of Cal., Inc. v. Burwell*, No. 16-5098 (D.C. Cir. Nov. 10, 2016). For that reason,
27 “agency manuals lack the force of law.” *Moore v. Apfel*, 216 F.3d 864, 869 n.2
28 (9th Cir. 2000); *see also Phoenix Baptist Hosp. & Med. Cntr. v. Heckler*, 767 F.2d

1304, 1307 (9th Cir. 1985) (“The [Provider Reimbursement Review] Manual is a guide for intermediaries in applying the Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation.”); 31 U.S.C. §3729(b)(3) (omitting sub-regulatory guidance from the types of authority that can give rise to a legal “obligation to pay or transmit money or property to the Government” for purposes of the False Claims Act). And the Department of Justice itself recently acknowledged that it would be improper to “use its enforcement authority to effectively convert agency guidance documents into binding rules” or to “use noncompliance with guidance documents as a basis for proving violations of applicable law” in False Claims Act Cases. Mem. for Heads of Civil Litigating Components & U.S. Att’ys from Assoc. Att’y Gen., Rachel Brand, *Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases* at 2 (Jan. 25, 2018), <http://src.bna.com/vY4>.

The government knows this is a problem. Because it cannot enforce the Manual and other sub-regulatory guidance directly, it tries to do so indirectly, claiming (at 9) that United agreed by contract to comply with whatever policies CMS might adopt about how plans’ payment amounts would be calculated. But as United explains in the ensuing sections, that argument raises four distinct issues that the government’s motion does not even address, let alone show can be unambiguously resolved in its favor at this early stage of the case.

a. The MA Contracts Do Not Unambiguously Require MA Plans To Comply With Informal CMS Guidance Relating To Risk Adjustment Payment Policies

The first issue is that the contracts do not require—and certainly do not unambiguously require—MA plans to comply with CMS “policies” in informal guidance about the risk adjustment payment system. The government’s contrary argument depends on a provision in Article II of the contracts with United, titled “Coordinated Care Plan,” in which United “agrees to operate one or more coordinated care plans as defined in 42 CFR 422.4(a)(1)(iii) . . . as described in its

1 final Plan Benefit Package (PBP) bid submission (benefit and price bid) proposal
 2 as approved by CMS . . . , and in compliance with . . . applicable Federal statutes,
 3 regulations, and policies (e.g., policies as described in the Call Letter, Medicare
 4 Managed Care Manual, etc.).” Rice Decl., Ex. 1 at 6. The government argues
 5 that this provision requires United to follow CMS’s informal policies not only in
 6 its “operat[ion]” of the Coordinated Care Plan, *id.*, but in all other aspects of its
 7 participation in the Medicare program as well.

8 Article II of the contract, however, does not relate to the MA payment
 9 system at all. Its function is to clarify that the MA organization will provide a
 10 “Coordinated Care Plan” as opposed to one of the other two types of MA plans.¹³
 11 The “Plan Benefit Package” referenced in Article II, in conjunction with the
 12 requirements set out in the Manual, establishes what medical services the plan will
 13 provide through that Coordinated Care Plan, the conditions under which those
 14 services must be available, the providers through whom the plan will provide them,
 15 and so forth. *See* Ex. 11, 2017 Manual, chapter 1 § 20.2 (listing obligations of
 16 operating a Coordinated Care Plan, but making no mention of risk adjustment data
 17 submission). Article II’s provisions do not extend, however, to the manner in
 18 which CMS will *pay* the MA plan.¹⁴ Instead, it is Article IV of the contract that
 19 sets out the terms governing submission of risk adjustment data and the manner in
 20 which MA plans are paid. As discussed above, Article IV provides that CMS will
 21 pay MA plans in accordance with Section 1853 of the Medicare Act and applicable
 22

23 ¹³ The other two types of MA plan are an “MA MSA plan” and an “MA private
 24 fee-for-service plan.” *See* 42 C.F.R. § 422.4 (describing the different types of MA
 plans and the requirements applicable to each).

25 ¹⁴ The government claims (at 9 n.7) that “[t]he Attestation of Benefit Plan, which
 26 is part of the contract, also requires compliance with the Medicare Managed Care
 Manual.” But like Article II of the MA contract, the Attestation of Benefit Plan
 27 makes clear that the MA plan is agreeing to comply with the Manual in its
 provision of *benefits*, not the terms on which it will be paid. *See* Rice Decl., Ex. 1
 28 at 33 (“*[T]hese benefits will be offered* in accordance with . . . the Medicare
 Managed Care Manual . . .”).

1 regulations. *See supra* at 26-27. Article IV also includes provisions on attestation
 2 and validation of risk adjustment data that are required by regulation (which, for
 3 the reasons just discussed, *see supra* at 30-32, do not support the government’s
 4 proposed rule). But in conspicuous contrast to Article II, Article IV contains no
 5 provision in which plans agree to be bound by CMS “policies” in sub-regulatory
 6 guidance. Likewise, in other contract provisions pertaining specifically to risk
 7 adjustment data that would affect CMS’s payment obligations, the MA
 8 organization agrees to comply with statutes and regulations but does not agree to
 9 comply with sub-regulatory policies like the Manual. *See, e.g.*, Section B.1(a)(vii)
 10 of the MA Contract (allowing termination of the contract if CMS determines that
 11 the MA organization “fails to provide CMS with valid risk adjustment data as
 12 required under §422.310 and 423.329(b)(3)”; Section B.7 of Art. VI of the MA
 13 Contract (“The MA Organization agrees to comply with the requirements in
 14 §422.310 for submitting risk adjustment data to CMS.”)

15 It is hardly surprising that the contract would allow CMS to direct the
 16 manner in which services are provided through sub-regulatory guidance, while
 17 reserving changes in payment-related issues to statutes and notice-and-comment
 18 rulemakings. Like any contractor, MA plans agree to accept direction from their
 19 client (here, CMS) about how to provide the specific services they have contracted
 20 to provide. Section C of Article II of the contract permits CMS to issue policy
 21 changes mid-year, so long as they do not “significant[ly]” increase the plan’s “cost
 22 or burden,” and with that protection in place MA plans can generally agree to
 23 comply with CMS guidance about issues like whether a new intervention needs to
 24 be covered in a given year. That is what Article II accomplishes.

25 Payment decisions, however, are entirely different. No contractor would
 26 agree to make the amount it is paid subject to the whims of its client’s “policies.”
 27 Yet that appears to be the government’s reading of the contract. On its view, when
 28 MA plans sign contracts with CMS, they agree to allow their core payment rights

1 to be modified through a take-it-or-leave-it process of informal staff-level policy
 2 pronouncements that are judicially unreviewable. That understanding would also
 3 mean that CMS could adopt mid-year changes that significantly reduce MA plans’
 4 risk adjustment payments, such as requiring that MA plans delete any diagnosis
 5 code that had not been verified by at least three physicians, and make those
 6 changes binding on MA plans simply by adding them unilaterally to the Manual.

7 That is not the risk MA plans agree to take. Article IV of the contracts
 8 carefully ensures that MA plans’ risk adjustment payments will be governed by
 9 statutes and regulations that CMS cannot unilaterally change. The government
 10 cannot undo those limitations by pointing to a reference to CMS “policies” in a
 11 portion of the contract that does not even address the payment system. Just as
 12 Congress “does not alter the fundamental details of a regulatory scheme in vague
 13 terms or ancillary provisions,” *Whitman v. Am. Trucking Ass’n, Inc.*, 531 U.S.
 14 457, 468 (2001), neither would MA plans “hide elephants in mouseholes,” *id.*, by
 15 using a clause about the services they will provide to beneficiaries to give CMS
 16 complete control over the terms on which it will pay MA plans. At a bare
 17 minimum, the contract is ambiguous on this point—foreclosing a ruling for the
 18 government until it has completed its discovery obligations.

19 *b. Reading Article II Of The MA Contract To Govern Payment*
 20 *Terms Would Create Additional Problems For The Government*

21 If Article II of the MA contracts did govern MA plans’ payment-related
 22 rights and responsibilities, then that would just create a different problem for the
 23 government. In the same sentence that references CMS policies, Article II also
 24 incorporates the “final Plan Benefit Package (PBP) bid submission . . . as approved
 25 by CMS.” Rice Decl., Ex. 1 at 6. Starting at least as early as 2011, United’s final
 26 Plan Benefit Package each year explicitly stated that United was *not* validating
 27 provider-submitted codes through review of medical records. “[C]onsistent with
 28 our prior year activities,” United explained, “[a]s part of the preparation of the

1 bids, we did not attempt to validate any actual or projected risk scores through a
 2 review of applicable medical records or of the systems used to submit RAF data to
 3 CMS.” Ex. 50, MA Supporting Documentation for CY2012 Bid, at 5; *see also* Ex.
 4 49, MA Supporting Documentation for CY2012 Bid, at 8 (stating in 2015 bid
 5 submission that United had “cease[d] one of its prior processes that identified and
 6 deleted certain diagnosis codes through the medical record review process”).

7 If Article II incorporates provisions about payment issues, not just program-
 8 of-care issues, then those bid limitations were incorporated into the contract’s
 9 payment scheme as well. They were express actuarial assumptions supporting
 10 United’s bid that CMS required United to specify and on which United relied in
 11 setting its bid amounts, and CMS reviewed and approved United’s bid submission
 12 prior to execution of the final contract, as required by law. *See* 42 C.F.R.
 13 § 422.256(b). Under settled principles of government contract law (as well as the
 14 language of Article II), those conditions became a binding part of the parties’
 15 agreement. *See, e.g., United Med. Supply Co. v. United States*, 63 Fed. Cl. 430,
 16 439 (2005) (noting that the government is charged with knowledge of what was
 17 contained in contractor’s offer, and thus could not avoid the inclusion of certain
 18 proposal language as part of contract); *GAI Consultants, Inc.*, ENGBCA No. 6030,
 19 95-2 B.C.A. (CCH) ¶ 27620 (Apr. 4, 1995) (contractor’s proposal specifying
 20 outdoor work would be performed during warmer months binding on government).

21 The government may respond that United’s bid provisions conflict with the
 22 guidance documents on which its case relies. But even if those guidance
 23 documents unambiguously required what DOJ alleges (and they do not, *see infra*),
 24 then that would simply create a conflict between two provisions incorporated into
 25 Article II of the contract that would need to be resolved by resort to extrinsic
 26 evidence (and thus cannot be resolved at this early stage). *See, e.g., United States*
 27 *ex rel. Lindenthal v. Gen. Dynamics Corp.*, 61 F.3d 1402, 1411 (9th Cir. 1995)
 28 (where language in a government contract “is unclear and suggests several

1 speculative interpretations, . . . extrinsic evidence is admissible to show what the
 2 parties intended” (citation omitted)); *Int’l Bhd. of Elec. Workers, AFL-CIO Local*
 3 *47 v. S. Cal. Edison Co.*, 880 F.2d 104, 107 (9th Cir. 1989) (holding that when
 4 contract terms conflict, “[t]he court should look to parol evidence to determine
 5 what the parties intended the conflicting provisions to mean”).

6 *c. At Most, The Government’s Interpretation Creates An Internal*
 7 *Contractual Conflict Precluding A Decision At This Stage*

8 Apart from the fact that United’s bids specified that United would not be
 9 validating its diagnosis codes in a way that CMS itself does not, reading Article II
 10 of the contract to cover payment issues would also create a conflict in another way.
 11 As discussed, Article IV of the contract specifically required CMS to comply with
 12 Section 1853 of the Medicare Act, including the requirements that it “ensure
 13 actuarial equivalence” and use the “same methodology” in both programs. If
 14 Article II is interpreted to incorporate Manual provisions that would conflict with
 15 that requirement (by demanding that MA plans delete all identified unsupported
 16 codes, without regard to the presence of such codes in CMS’s own traditional
 17 Medicare data), then that would create an additional intra-contractual conflict.

18 The proper way to reconcile that conflict would be by resort to the “standard
 19 rule of contract interpretation . . . that when provisions are inconsistent, specific
 20 terms control over general ones.” *United States ex rel. Welch v. My Left Foot*
 21 *Children’s Therapy, LLC*, 871 F.3d 791, 797 (9th Cir. 2017) (citation and internal
 22 quotation marks omitted). Here, Article IV speaks specifically to payment
 23 questions, and therefore any conflict between Article IV’s unquestionable
 24 incorporation of the “actuarial equivalence” and “same methodology”
 25 requirements and Article II’s supposed incorporation of informal CMS guidance
 26 would be resolved by giving effect to Article IV. But at the very least, that intra-
 27 contractual conflict would preclude a decision in the government’s favor at this
 28 stage, because United has a right to collect additional extrinsic evidence that could

1 shed light on how the parties intended any conflict between the provisions to be
 2 resolved. *See Int'l Bhd. of Elec. Workers, AFL-CIO Local 47*, 880 F.2d at 107.

3 *d. The Sub-Regulatory Provisions The Government Invokes Do*
 4 *Not Unambiguously Support The Rule It Proposes*

5 Finally, even if Article II of the MA contract did make CMS's sub-
 6 regulatory policies related to risk adjustment payment calculations legally binding,
 7 and even if Article IV provided no countervailing and superseding rule, that *still*
 8 would not support the rule that the government proposes because those sub-
 9 regulatory materials do not unambiguously adopt the government's proposed rule.

10 The government first cites (at 10-11) provisions in the Manual and the
 11 International Classification of Diseases (ICD) Guidelines stating that diagnoses
 12 should be supported in the medical record. Those provisions govern the standard
 13 that providers and other coders use for identifying diagnosis codes in claims forms
 14 based on reviewing medical charts. But they do not address, explicitly or
 15 implicitly, the question the government asks this Court to decide, which is what to
 16 do once one determines that an unsupported code already has been submitted, and
 17 whether plans are responsible for complying with a standard of accuracy stricter
 18 than the one applicable in FFS. After all, the same documentation requirements
 19 are equally applicable in the traditional Medicare program. *See, e.g.*, 42 C.F.R.
 20 § 424.32(a)(2) ("A [FFS] claim for physician services . . . must include appropriate
 21 diagnostic coding for those services using ICD-9-CM."). And yet CMS does not
 22 audit and then delete unsupported codes submitted by providers there. *See* Ex. 38,
 23 APA CMS Opening Br., at 37. Given that fact, the government cannot contend
 24 that the documentation standards themselves require deletion of such previously
 25 submitted codes in the MA program, either. Nor do these provisions address in
 26 any way whether a plan has been overpaid if the rate of unsupported codes in its
 27 data corresponds to the rate of unsupported codes already built into the payment
 28 amounts calculated by CMS. And they certainly do not do so unambiguously.

1 The government also relies on a provision that was added to the Manual in
 2 the middle of the 2013 payment year. That provision states that “[i]f upon
 3 *conducting* an internal review of *submitted* diagnosis codes, the plan sponsor
 4 determines that any ICD-9-CM diagnosis codes that have been submitted do not
 5 meet risk adjustment submission requirements, the plan sponsor is responsible for
 6 deleting the submitted ICD-9-CM diagnosis codes as soon as possible.” 2013
 7 Manual, Pub. 100-16, chapter 7 § 40 (Rice Decl. Ex. 5) (emphases added). This
 8 provision does not unambiguously support the rule the government asks this Court
 9 to adopt, either. In particular, the provision states merely that *if* a plan chooses to
 10 review “previously submitted codes,” it should delete codes it “determines” are
 11 unsupported. But the gravamen of the government’s complaint is instead that
 12 United *should have* reviewed the accuracy of previously submitted codes when it
 13 conducted chart reviews to look for codes that had *not* been previously submitted.
 14 The 2013 provision does not address this scenario at all, much less unambiguously.
 15 Moreover, its statement about deleting codes applies only when a plan
 16 “determines” that a code does not satisfy requirements. “Determine” means “[t]o
 17 establish or ascertain definitely”—*i.e.*, to obtain actual knowledge. Determine,
 18 *American Heritage Dictionary of the English Language* (4th ed. 2000). It thus
 19 provides no support for the broader rule the government seeks, under which
 20 something less than actual knowledge would trigger the deletion requirement. *See*
 21 Mem. 1 (requesting ruling that deletion was required if a plan “knew (*as that term*
 22 *is used in the False Claims Act*)” that a code was unsupported (emphasis added)).

23 What little evidence the government has produced to date supports this
 24 reading, and demonstrates that the provision is at most ambiguous. In one of the
 25 two depositions that United has taken, a CMS official who oversaw creation of the
 26 risk adjustment program—Jeffrey Grant—explained that even in his view, an MA
 27 plan’s submission of an unsupported code would be improper only if it was making
 28 the “very specific submission of a very specific data element . . . that [it] know[s]

1 is wrong.” Ex. 7, Grant Dep. 321:21-23. He further stated that performing one-
 2 way reviews that add diagnosis codes supported in the charts, without looking at
 3 whether previously submitted codes lack such support, would not create the
 4 requisite knowledge. *Id.* at 322:18-323:15.¹⁵ And he confirmed that it is not
 5 “improper” or “fraudulent” for a plan to perform chart reviews that make no
 6 systematic effort “to look at [previously submitted] claims data and see if every
 7 claim was one-for-one backed by a diagnosis.” *Id.* 309:17-310:16.

8 That is, moreover, exactly the message senior CMS officials—including the
 9 Administrator and Deputy Administrator—communicated to United during a series
 10 of calls, correspondence, and in-person meetings in 2014. For example, Larry
 11 Renfro, CEO of Optum (a United affiliate), testified that then-Deputy
 12 Administrator of CMS Jonathan Blum told him in a call in 2014 that unless and
 13 until CMS adopted a regulation requiring MA plans to perform two-way chart
 14 reviews, there was no obligation for plans to do so. Ex. 44, Renfro Dep. 134:1 –
 15 137:6. CMS Administrator Marilyn Tavenner told Renfro the same thing in a
 16 subsequent conversation. *Id.* 150:21 – 151:10; 160:9 – 163:17. And shortly after
 17 that, during a meeting other United executives had with then-Director of the
 18 Medicare Plan Payment Group Cheri Rice and four other top CMS officials,
 19 United was again told that unless the new regulation was adopted, MA plans had
 20 no affirmative obligation to design their chart reviews to measure overall, absolute
 21 accuracy. *See* Ex. 47, Apr. 29, 2014 CMS Meeting Notes, at MARA2157039-40;
 22 *United’s Statement of Genuine Disputes of Material Fact In Opp’n to Pls.’ Mot.*
 23

24 ¹⁵ The government will no doubt argue that even if CMS believed that a deletion
 25 requirement was only triggered by actual knowledge, the False Claims Act’s
 26 broader definition of “knowingly” would apply here. Because the government is
 27 proceeding under a reverse false claim theory, however, it must *first* identify an
 28 “obligation to pay or transmit money or property to the Government,” before the
 scienter standard ever comes into play. 31 U.S.C. §3729(a)(1)(G). Grant’s
 testimony is strong evidence that CMS did not understand an “obligation” to exist
 in the first place without actual knowledge.

1 *Partial Summ. J.* ¶¶ 126-29. In short, CMS officials themselves took a position
2 directly at odds with the rule the government now asks this Court to adopt.

3 **3. *The EDI Agreements Do Not Support the Government’s Proposed***
4 ***Rule***

5 Finally, the government invokes (at 12-13) the Electronic Data Interchange
6 agreements. They do not unambiguously impose the rule it seeks, either.

7 First and most obviously, the EDI agreements contain no provision requiring
8 adherence to CMS “policies.” Without such language, the EDI agreements cannot
9 convert the Manual provisions on which the government’s present theory rests into
10 binding legal “obligations,” and thus cannot support a reverse false claims theory.

11 The government instead points to the EDI agreement’s provision requiring
12 signatories to “correct encounter data discrepancies.” Rice Decl., Ex. 2 at 43.¹⁶
13 This provision on “data discrepancies,” however, is not directed to whether
14 individual diagnosis codes are supported by medical records. Instead, the
15 Electronic Data Interchange agreement is concerned with the sorts of data glitches
16 that can result from electronic submission of data—which is, after all, the subject
17 of the agreement. That is clear from the very next line of the EDI agreement, in
18 which the signatory agrees “[t]hat it will notify CMS or its contractor within 2
19 business days if any transmitted data are received in an unintelligible or garbled
20 form.” *Id.* CMS’s countervailing commitments in the agreement likewise relate to
21 data transmission. The government cannot take that requirement pertaining to
22 electronic submission issues and transform it into a *substantive* requirement that
23 MA plans meet a standard of chart support in their data (perfection) that CMS
24 itself makes no effort to achieve. It certainly cannot, as it must to prevail at this
25 stage, claim that the provision is unambiguous.

26
27 ¹⁶ The government inaccurately quotes the agreement as stating that MA plans
28 will “correct *risk adjustment* data discrepancies.” Mem. 13 (emphasis added).

D. At The Very Least, The Government Is Not Entitled To A Decision Embracing Its Rule At This Stage Of The Case

The foregoing sections have explained that the “actuarial equivalence” and “same methodology” requirements foreclose the government’s proposed rule, and that even if such a rule were not statutorily invalid, none of the materials the government relies on actually imposed that rule. This Court, however, need not resolve all (or any) of that at this stage. That is because, at the very least, the government’s proposed rule is not *unambiguously* required by any of the regulatory or contractual provisions to which it points. In such a circumstance, “extrinsic evidence may be utilized to interpret the parties’ intent in light of earlier negotiations, later conduct, related agreements, and industry-wide custom.” *United States v. Westlands Water Dist.*, 134 F. Supp. 2d 1111, 1136 (E.D. Cal. 2001) (citation and internal quotation marks omitted)). Indeed, even if the language of the contracts otherwise appeared “on its face” to support the government’s position, the Ninth Circuit has held that it would still be appropriate to “consider evidence of course of dealing, trade usage, or course of performance” to determine whether that meaning is in fact ambiguous. *Mohave Valley Irrigation & Drainage Dist. v. Norton*, 244 F.3d 1164, 1166 (9th Cir. 2001).

That forecloses a decision in the government’s favor on this motion for two separate reasons. The first is that the extrinsic evidence United has been able to obtain to date, taking all reasonable inferences in United’s favor, creates at a minimum a genuine issue of material fact precluding a ruling for the government. And the second is that United has a right, under Rule 56(d), to complete its discovery on these issues—almost certainly revealing even *more* extrinsic evidence supporting its position—before the Court resolves them against it.

1. The Extrinsic Evidence Available To Date Creates A Genuine Issue Of Material Fact Precluding The Government’s Requested Relief

United has already identified ample evidence beyond the four corners of the

1 contracts and regulations that supports its position. Some of that evidence appears
 2 above. But there is much more. In notes from an internal CMS presentation about
 3 the need for a FFS adjuster, for example, CMS's Division on Payment Validation
 4 noted that because "the factors that we developed using FFS data" are "implicit in
 5 all of the adjustments we make to plans['] payments to account for the relative risk
 6 of their populations," "we should be using the same standard for both" MA and
 7 FFS diagnosis code validation in order "[f]or our payments to be as accurate as
 8 possible." Ex. 16, Agenda, at CMS0006200. It offered that adoption of an FFS
 9 adjuster "from a technical point of view is the right thing to do," and also
 10 suggested that it would "put[] us in the best position to withstand litigation
 11 challenges." *Id.* at CMS0006201.

12 In a similar vein, Grant testified during his deposition that when experts talk
 13 about "accuracy" or "inaccuracy" in the context of risk adjustment payments, "they
 14 are not referring to the accuracy or inaccuracy of any specific code on any specific
 15 claim or any specific RAP submission. They're talking about comparable types of
 16 data." Ex. 7, Grant Dep. 174:21-175:8. "[T]he definition of accuracy here," he
 17 testified, is that MA plans "would be paid consistently with how the model is
 18 calibrated." *Id.* at 182:6-8. Accordingly, Grant testified that if a plan were to
 19 audit as little as 25 percent of its members' charts and delete the unsupported codes
 20 it found, without CMS deleting such codes in the FFS data, the MA plan would be
 21 underpaid.¹⁷ *See id.* at 274:22-277:25. And because United performed chart
 22 reviews that covered more than 25 percent of United's beneficiaries, *see* Ex. 52,
 23 Decl. of Jon Bird ¶ 6, Grant's testimony indicates that adopting the government's

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 25 ¹⁷ In acknowledging that plans would be underpaid in that circumstance, Grant
 26 assumed that the Coding Intensity Adjustment fully offsets the effect of MA plan
 27 activities that increase the intensity of coding in the MA program. *See* Ex. 7, Grant
 28 Dep. 274:22-275:7. Grant testified that he did not know whether that assumption
 was accurate. *Id.* at 275:10-24. CMS, however, has determined that it is. *See* Ex.
 25, 2013 Rate Announcement, at AR4712 ("[W]e believe that our methodology
 results in an accurate measure of the coding differential between FFS and MA.").

1 proposed rule would result in a substantial underpayment to United here.

2 Grant also testified that CMS had provided oral instructions to MA plans
3 stating that “if they submitted data like fee for service they would be paid
4 equivalent to the calibration.” Ex. 7, Grant Dep. 208:15-17. Such oral instructions
5 would constitute, or at least inform, the “policies” that the government argues are
6 binding on MA plans, *see supra* at 33-34, and substantially undermine the
7 government’s claim that MA plans’ data should be evaluated without making
8 comparisons to data in the traditional Medicare program. United cites many more
9 pieces of evidence in its Statement of Additional Material Facts. *See* Statement of
10 Genuine Disputes of Material Fact in Opp’n to Pls.’ Mot. for Partial Summ. J.

11 In deciding the government’s motion, this Court must take that “evidence[,]
12 and all reasonable inferences drawn therefrom[,] in the light most favorable” to
13 United. *Furnace v. Sullivan*, 705 F.3d 1021, 1026 (9th Cir. 2013). Doing so
14 wholly precludes a decision in favor of the government’s proposed rule. Even if it
15 is *possible* that notwithstanding this evidence, the parties to the MA contract
16 actually intended to embrace the rule the government advances now, it is certainly
17 reasonable to conclude based on this evidence that they did not. That by itself is a
18 sufficient reason to deny the government’s motion.

19 **2. *In The Alternative, United Is Entitled Under Rule 56(d) To Collect***
20 ***Additional Discovery Related To This Issue***

21 The materials already discussed are just the tip of the evidentiary iceberg—
22 the small portion that United has been able to gather in the face of the
23 government’s persistent resistance to discovery. As the accompanying Rule 56(d)
24 affidavit demonstrates, future depositions with CMS officials and productions of
25 government documents are likely to provide additional evidence that will further
26 support United’s arguments. *See* Decl. of Abid R. Qureshi Pursuant to Fed. R.
27 Civ. P. 56(D). Evidence about the rate of unsupported codes in CMS’s own data
28 and the effect that such codes have on CMS’s payments to MA plans, for example,

1 would help demonstrate the extent to which United would be underpaid under the
 2 deletion rule the government proposes, and that United certainly did not retain an
 3 overpayment. Evidence about RADV audits of other health plans will shed
 4 additional light on CMS's course of performance in applying these provisions,
 5 demonstrating that CMS has understood itself to be obligated to apply a FFS
 6 adjuster to account for the unsupported codes in its own data rather than
 7 demanding that audited plans delete every unsupported code. Testimony from the
 8 CMS officials who reviewed MA plans' bids and attestations will help show that
 9 the trade usage of terms like "accurate," in the context of MA risk adjustment, was
 10 focused on a comparative rather than an absolute standard. And the accompanying
 11 Rule 56(d) Affidavit identifies numerous other examples, including extrinsic
 12 evidence relevant to the meaning of the at-most ambiguous MA contract.

13 This prospect is not lost on the government. To the contrary, its explicit
 14 purpose in offering its motion now is to try to avoid having to turn over such
 15 evidence before this Court resolves the legal issue. *See* Mem. 15. Especially
 16 following the Grant deposition, it knows full well that such evidence will
 17 fundamentally undermine its position. But the Court should not let the
 18 government's strategic desire for haste hurry it into an unforced error. Given the
 19 magnitude of damages the government is pursuing in this case, it certainly is not
 20 too much to ask—and Rule 56(d) demands—that the government first produce the
 21 documents and other evidence that United can use to defend itself. There will be
 22 time enough to resolve these issues later, when they are fully crystalized.

23 **B. *Swoben* Did Not Resolve The Issue That The Government Is**
 24 **Asking This Court To Decide**

25 In the face of all this, the government offers a final argument (at 18-20):
 26 that the Ninth Circuit resolved all of these issues in its *Swoben* decision, such that
 27 this Court has no choice *but* to adopt its rule. As Judge Collyer put it when
 28 presented with a similar argument, however, "*Swoben* is not the droid the

[government] is looking for.” Ex. 57, APA MTD Order, at 12.

First, the Ninth Circuit’s decision in *Swoben* involved only an affirmative False Claims Act theory, not a claim under the reverse false claims provision that the government invokes here. *See Swoben*, 848 F.3d at 1172 n.6 (declining to address “the ‘reverse false claims’ provision”). Indeed, the Ninth Circuit was very clear that the only theory before it was a “false certification theory,” and that it was not presented with an “archetypal” case where a contractor overcharges under a contract because the claim for payment is false. 848 F.3d at 1173. It emphasized that “[u]nder *Swoben*’s theory . . . the false claims are the allegedly false § 422.504(l) certifications, *not the erroneously submitted diagnosis codes*.” *Id.* at 1183 (emphasis added). The parties therefore had not briefed, and the Court had no occasion to decide, whether and in what circumstances a plan that learned that it had *previously* submitted an unsupported code would be required to delete that code, which might in turn give rise to an “obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G). The Court specifically noted that it was not deciding whether the allegedly false certification caused “the government to pay out money or forfeit moneys due,” which would be central to any case alleging overpayments. 848 F.3d at 1173 & n.7. Nor did it address the implications of the fact that MA payment amounts already account for the presence of some unsupported codes (a point the parties also had not briefed). Its analysis was concerned only with whether under certain circumstances a “one-way review” might cause the attestation to be false—an issue that was relevant to the claims this Court dismissed on materiality grounds, but not to those that remain.

Second, *Swoben* was decided on the pleadings, and thus drew all reasonable inferences in favor of the plaintiff. *See, e.g., id.* at 1175-76. It emphasized, for example, that it did “not intend to suggest that the practice of concealing previously submitted diagnosis codes from coders conducting retrospective reviews is necessarily a suspect practice,” and that it was holding only that such a

1 practice might be impermissible in *some* circumstances such that dismissal on the
 2 pleadings was inappropriate. *Id.* In this motion, however, the burdens are
 3 reversed. If it is possible to infer from the existing record (or from the record that
 4 United’s Rule 56(d) affidavit suggests that discovery will reveal) that the rule
 5 which the government seeks did not exist, then the Court must deny the
 6 government’s motion. The Ninth Circuit certainly did not say that there was no set
 7 of facts that might be relevant to the issue—for example, evidence that CMS
 8 officials themselves do not believe that there is anything improper in doing one-
 9 way looks and that they do not result in a plan identifying an overpayment.

10 *Third*, the Ninth Circuit’s decision in *Swoben* did not even involve, let alone
 11 decide, the relevance or meaning of the Medicare Act’s “actuarial equivalence”
 12 mandate. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Instead, United and the other MA
 13 plans there argued that because of a separate regulation, 42 C.F.R. § 422.310(d),
 14 “they were not required to take *any* affirmative steps to find unsupported diagnosis
 15 codes.” *Swoben*, 848 F.3d at 1179 (emphasis added). Under United’s
 16 interpretation of that regulation, which the Ninth Circuit rejected, MA plans would
 17 have had no obligation to delete unsupported codes even if they knew their rate of
 18 unsupported codes far outstripped the rate of unsupported codes in CMS’s
 19 traditional Medicare data. The implications of the Medicare Act’s “actuarial
 20 equivalence” mandate, however, are materially different. For one thing, as a
 21 statutory provision, Section 1395w-23(a)(1)(C)(i) would displace any contrary
 22 regulatory understanding. And for another, United’s present position is
 23 significantly more limited than the theory it advanced in the Ninth Circuit based on
 24 Section 422.310(d). United does not argue here that MA plans never have *any*
 25 obligation to delete unsupported codes, but rather that their obligation to do so
 26 depends on a comparison with the rate of unsupported codes in CMS’s own data.
 27 As discussed above, that is the approach CMS itself endorsed with its FFS
 28 Adjuster for contract-wide audits of MA plans’ codes. *See supra* at 12-13. It is a

1 logical corollary to CMS's application of the Coding Intensity Adjustment. *See*
 2 *supra* at 9-11. And the government has offered no persuasive response to it, either
 3 in this case or in the APA case before Judge Collyer. There is simply no basis to
 4 conclude that the Ninth Circuit silently resolved that issue without ever considering
 5 the applicable statutory text and regulatory history.

6 *Fourth*, and finally, the Ninth Circuit in *Swoben* assumed (without deciding)
 7 the validity of the Overpayment Rule that United has challenged in its APA suit, as
 8 well as the validity of all the regulatory, sub-regulatory, and contractual provisions
 9 that United has argued would be unlawful if they were construed in the fashion that
 10 the government urges. *See Swoben*, 848 F.3d at 1169 n.4. Even if this Court were
 11 to hold that *Swoben* interpreted those provisions in the way the government says,
 12 and even if this Court were to conclude that the Ninth Circuit's interpretation was a
 13 binding holding rather than dicta offered by way of background, there is no
 14 conceivable way to read the Ninth Circuit's decision to hold that those provisions
 15 can be applied in a way that would violate the Medicaid Act.

16 **II. CONCLUSION**

17 The motion should be denied for any number of reasons. It is procedurally
 18 improper, premature, legally incorrect, and would accomplish nothing even if
 19 granted. Above all, though, it is an unfair attempt to prevent United from
 20 defending itself in this proceeding. Having chosen to pursue this case, the
 21 government cannot deny United the right to discover the facts at the heart of it.
 22 Nor can the government complain about the burdens that will be imposed on it by
 23 allowing United a full opportunity to explore all the defenses discovery may
 24 develop. United has experienced those burdens for six years. Now it is the
 25 government's turn to live up to its discovery obligations. The Court should deny
 26 the motion and allow this case to continue in its normal course.

1 Dated: July 23, 2018

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

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING

Plaintiffs,

v.

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

Defendants.

CASE NO. 2:16-cv-08697-MWF (SSx)

**STATEMENT OF GENUINE
DISPUTES OF MATERIAL FACT
IN OPPOSITION TO PLAINTIFFS'
MOTION FOR PARTIAL
SUMMARY JUDGMENT**

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

UnitedHealth Group, Inc. (“United” or “UnitedHealth”) submits this Statement of Genuine Disputes and Additional Uncontroverted Facts under Local Rule 56-2 in response to the United States’ and relator Benjamin Poehling’s [Proposed] Statement of Uncontroverted Facts and Conclusions of Law.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
A. Medicare Parts A, B, and C	
1. Medicare is a federal health insurance program for the elderly and disabled, <i>see</i> 42 U.S.C. § 1395 <i>et seq.</i> , administered by the Centers for Medicare and Medicaid Services (“CMS”), an agency of the United States Department of Health and Human Services (“HHS”).	Undisputed.
2. Medicare Part A “covers medical services furnished by hospitals and other institutional care providers.” <i>Ne. Hosp. Corp. v. Sebelius</i> , 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5).	Undisputed.
3. Medicare Part B “is an optional supplemental insurance program that pays for items and services not covered by Part A, including outpatient physician services,” as well as “clinical laboratory tests, and durable medical equipment,” among other things. <i>Id.</i> at 2 (citing 42 U.S.C. §§ 1395j to 1395w-4).	Undisputed.
4. Medicare Part C, now known as Medicare Advantage, allows people to opt out of Parts A and B and instead enroll in health insurance plans offered by private insurers, the Medicare	Undisputed.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
Advantage Organizations (“MAOs”). <i>See</i> 42 U.S.C. §§ 1395w-21 to 1395w-29.	
5. MAOs “must provide enrollees the benefits and services (other than hospice care) that are available to people . . . under Medicare Parts A and B, <i>see</i> 42 U.S.C. § 1395w-22(a)(1), and may also offer supplemental benefits approved by the Secretary of [HHS], <i>see</i> 42 U.S.C. § 1395w-22(a)(3).” <i>Matthews v. Leavitt</i>, 452 F.3d 145, 146 n.1 (2d Cir. 2006).	Undisputed.
6. Pursuant to contracts with CMS, MAOs receive monthly payments from Medicare for each beneficiary enrolled in their Medicare Advantage (MA or Part C) plans and Prescription Drugs (PD or Part D) plans. <i>See, e.g.</i> Medicare Advantage Contract Between United Healthcare of California and CMS (“MA Contract”), 2011, Article IV, CMS Payment to MA Organization (Exhibit 1).¹	Undisputed.
7. Under Parts A and B, CMS pays providers directly for medical services rendered to beneficiaries under a “fee-for-service” regime. <i>Methodist Hosp. of Sacramento v. Shalala</i>, 38 F.3d 1225, 1227 (D.C. Cir. 1994).	Undisputed.

¹ “United” is used herein to refer to all of the United Defendants in this action. Exhibits 1-8 are attached to the Declaration of Cheri Rice. Exhibits 9-15 are attached to the United States’ and Relator Poehling’s Request for Judicial Notice.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
8. In contrast, under Part C, MAOs contract with providers to render services to the beneficiaries enrolled in their plans and pay those providers. For each beneficiary in a MA plan, CMS pays the MAO a monthly base amount (which CMS and the MAO agree to before the start of the payment year) which is adjusted for each beneficiary based on that beneficiary’s risk score. 42 U.S.C. § 1395w-23(a)(1)(A).	Undisputed.
9. The adjusted amount is based on the characteristics of each beneficiary, including “such risk factors as age, ... gender, ... and such other factors as the Secretary determines to be appropriate, including adjustment for health status.” <i>Id.</i> § 1395w-23(a)(1)(C)(i).	Undisputed.
10. Under this “risk adjustment” system, MAOs are paid the predicted cost of providing benefits to a given beneficiary (regardless of the services, if any, actually provided to the beneficiary).	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. Although it is undisputed that “risk adjustment” payments are not made to cover services already provided to the beneficiary, United disputes the remainder of the statement as incomplete. In determining the “predicted cost of providing benefits to a given beneficiary,” CMS’ objective is to obtain “[r]isk scores [that] are consistent across both fee-for-service and Medicare Advantage settings,” Declaration of David J. Schindler, July 23, 2018 (“Schindler Decl.”) Ex. 1,

1 PLAINTIFFS' 2 UNCONTROVERTED FACTS	UNITED'S RESPONSE
	2010 Rate Announcement, at AR4336, such that “[r]isk scores for beneficiaries with the same diagnoses and characteristics should be identical” in the MA and traditional Medicare programs, Schindler Decl. Ex. 2, GAO, <i>Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments</i>, at AR12043 (January 2013); <i>see also</i> Schindler Decl. Ex. 3, Gregory C. Pope et al., <i>Evaluation of the CMS-HCC Risk Adjustment Model: Final Report</i>, at AR011889, AR011892 (March 2011) (explaining that the CMS-HCC model is intended to “pay plans appropriately for their expected <i>relative</i> costs” and that “[t]he predicted costs from the risk adjustment models are . . . converted to relative risk factors so that payment adjustments can be made <i>relative</i> to the average Medicare beneficiary”) (emphasis added); <i>see also id.</i> at AR011892 (explaining that the cost predictions are designed to be accurate at the group level rather than for an individual beneficiary).
11. MAOs thus receive more for providing benefits to older and sicker people, and less for younger and healthier ones.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United does not dispute that the risk adjustment system was designed to pay MAOs more for caring for older and sicker people and less for younger and healthier people, as compared to the average FFS beneficiary in the same area. However,

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PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
	MAOs do not always receive more money for providing benefits to sicker people in practice because patients’ diagnoses are not always fully captured in the data reported to CMS. <i>See, e.g.,</i> Schindler Decl. Ex. 4, Medicare Payment Advisory Commission, Issues for Risk Adjustment in Medicare Advantage at 103-04, in <i>Report to Congress: Medicare and Health Care Delivery System</i> (Chapter 4), Washington, DC (June 2012) (finding inconstant coding of chronic conditions from year to year in both FFS and MA data); Schindler Decl. Ex. 5, Richard Kronick & W. Pete Welch, Measuring Coding Intensity in the Medicare Advantage Program, <i>Medicare & Medicaid Research Review</i>, 4(2), at E5 (2014) (“FFS coding is known to be both incomplete and variable. . . . [as] evidenced by lack of persistence in coding of chronic conditions”); Schindler Decl. Ex. 6, Deposition of Jeffrey Grant at 88:11–24 (March 20, 2018) (“March Grant Dep.”)) (Q: “Okay, and have you formed your own opinion?” A: “I have.” Q: “And what is that opinion? . . .” THE WITNESS [A]: “That there is a degree of error in doctors’ coding, that the codes on claims are not perfect.” Q: “In the sense that the codes on claims do not capture everything in the medical chart? . . .” THE WITNESS [A]: “That is one potential problem”). To the extent this statement suggests otherwise, it is disputed.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
12. Adjusting the monthly payments based on risk factors is the Secretary’s method of ensuring “actuarial equivalence” between the average payments that CMS would expect to make under fee-for-service Medicare, and the payments that CMS makes to MAOs for covering an individual with the same characteristics. <i>Id.</i>	Disputed. This statement is argumentative and a legal conclusion that requires no response. To the extent a response is required, however, United disputes as incomplete Plaintiffs’ characterization of the risk factor-based payment adjustments as the Secretary’s method of ensuring “actuarial equivalence.” Although 42 U.S.C. § 1395w-23(a)(1)(C)(i) imposes a requirement that the Secretary adjust the risk factor-based payments “so as to ensure actuarial equivalence,” United disputes that the risk adjustment factors (coefficients) calculated by the Secretary comply with the statutory mandate, or that the Secretary’s calculated risk adjustment factors would be legally compliant if plans had to delete unsupported codes when CMS does not audit its own data and has not implemented a mechanism to account for its own errors. <i>See Opp. to Mot. for Part. Sum. J.</i> at 3-4, 14, 21-26.
B. The Risk Adjustment Payment System	
13. When Congress established Part C, it directed the Secretary of HHS to implement “a risk adjustment methodology that accounts for variations in per capita costs based on	Undisputed.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
health status and other demographic factors.” <i>Id.</i> § 1395w-23(a)(3)(C)(i).²	
14. The Secretary has broad discretion under this provision to adopt a methodology and determine how to adjust payment levels based on the health status of Medicare beneficiaries.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. This statement is also argumentative and a legal conclusion that requires no response. United disputes as inaccurate Plaintiffs’ legal characterization regarding the Secretary’s alleged discretion with respect to her ability to deviate from the requirement of actuarial equivalence. <i>See</i> Opp. to Mot. for Part. Sum. J. at 3-4, 14, 21-22, 24-25.
15. Since 2004, the Secretary has used the Hierarchical Condition Category (HCC) model to determine these amounts under Part C.	Undisputed, except that this model was only fully applicable to payments beginning in 2007.
16. The Secretary has used a similar model (the RxHCC model) to risk adjust for health status under Part D. <i>See</i> 42 C.F.R. § 423.329(b)(1), (2).	Undisputed.
17. HCC is a complex regression model that collects and analyzes payment data in order to assign estimated costs to certain characteristics of Medicare beneficiaries such as age, gender, and health status.	Undisputed, provided that “payment data” refers to CMS’s unaudited FFS claims data.
18. The model includes a set of	Undisputed.

² Part C was established by the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 299 (Aug. 25, 1997).

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multipliers – that is, “coefficients” – used to determine “the marginal (additional) cost” of each medical “condition or demographic factor (<i>e.g.</i>, age/sex group, Medicaid status, disability status).” Medicare Managed Care Manual, Pub. 100-16, Chapter 7, § 70.1 (June 7, 2013) (Exhibit 5).	
19. The multipliers are determined based on data included in claims submitted to CMS by providers for payments for their services to beneficiaries under Parts A and B of the Medicare Program. <i>See</i> Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter, at 17 (Feb. 15, 2013) (Exhibit 6).	Undisputed.
20. For each Part C beneficiary, the multipliers are added to form a “risk score” and then computed against the negotiated base (fixed) monthly rate to determine how much CMS will pay an MAO for insuring that beneficiary.³	Disputed. The CMS-HCC risk adjustment model does not purport to predict the precise medical expenses for a given beneficiary in any given year. The model’s explanatory power (as measured by R-squared) of

³ For example, a 72-year-old woman living independently without a disability would have “demographic” characteristics (*i.e.*, age, sex, institutional and disability statuses) assigned a coefficient of 0.348 in 2014. Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, Table 1, at 67 (Exhibit 7). If the woman had no diagnosed conditions, an MAO would be paid 34.8% of its base rate. If the beneficiary had diabetes without complications, another 0.118 would be added to her score, which would become 0.466 (0.348 + 0.118). *Id.* Her expected healthcare costs would be 46.6% as much as the average beneficiary, and an MAO would thus be paid 46.6% of its base rate for covering her. A diagnosis of multiple sclerosis would add another 0.556 to her risk score, for a total of 1.022 (0.348 for demographics + 0.118 for diabetes without complications + 0.556 for

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	individual variation in beneficiaries’ expenditures was approximately 11 percent for the v12 model. Schindler Decl. Ex. 3, Evaluation of the CMS-HCC Risk Adjustment Model: Final Report, at AR011892-895; Schindler Decl. Ex. 7, Deposition of Jeffrey Grant at 320: 9–16 (May 16, 2018) (“May Grant Dep.”) (A: “You’re trying to predict large groups of people accurately. You’re not trying to predict one individual’s cost accurately. You’re trying to get a reasonable relative risk score for people that have health conditions, people that don’t have health conditions, people that have a mix of health conditions.”)
21. MAOs submit diagnosis codes to CMS so the agency can apply the multipliers for each beneficiary’s health status.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United disputes the suggestion that MAOs submit diagnosis codes only for the purpose of CMS’s applying “multipliers” for each beneficiary’s health status. MAOs submit diagnoses codes to CMS for a variety of reasons. Per 42 C.F.R. § 422.310(f)(1), CMS may use risk adjustment data, which includes

multiple sclerosis). *Id.* at 68. Her expected healthcare costs would now be 102.2% as much as the average beneficiary, and an MAO would receive 102.2% of its base rate for covering her. Thus, when an MAO submits a diagnosis code that maps to an HCC for a beneficiary, that code increases the amount paid to the MAO for coverage. *See* 2000 Rule, 65 Fed. Reg. at 40268 (explaining that the diagnosis data is a claim for payment); *see generally* Defendants’ Mem. in Support of Cross-Mot. for Summ. J. and in Opp’n to Plaintiff’s Mot. for Summ. J., *United Healthcare Ins. Co. v. Hargan*, CV 16-157-RMC, Dkt. 57-1, at 14-16 (D.D.C. filed Dec. 4, 2017) (“APA case”) (Exhibit 13).

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	diagnosis codes, for a range of purposes described in § 422.310(f)(1)(i)-(ix), including but not limited to “conduct[ing] quality review and improvement activities,” and “update[ing] risk adjustment models.” Only one of the nine purposes listed is “[t]o determine the risk adjustment factors used to adjustment payments. . . .” Additionally, the risk scores of beneficiaries who switch from Medicare FFS to MA in a given year are not determined from data submitted by the MA plan. <i>Cf.</i> Schindler Decl. Ex. 8, Brad Piper & Hillary Millican, Medicare Advantage Risk Score Primer: What You Need to Know About Diagnoses Supporting Risk Scores and Revenue Payment Timing at 2, <i>Milliman White Paper</i>, (Oct. 2017).
22. Since 2004, they have submitted the codes through CMS’s Risk Adjustment Processing System (“RAPS”).	Undisputed.
23. In the last several years, they submit the codes through RAPS and CMS’ Encounter Data System (“EDS”).	Undisputed.
24. Each RAPS submission includes only a few data fields: the beneficiary’s identification number, the date of the medical encounter, the type of healthcare provider, and the diagnosis code(s) reported by the provider for that encounter. <i>See, e.g.,</i> 2013	Disputed. United disputes this statement to the extent that it implies that providers are the only acceptable source of diagnosis codes reported on RAPS submissions. MAOs are permitted to submit diagnosis code(s) not reported by the provider. <i>See, e.g.,</i>

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Medicare Managed Care Manual, Pub. 100-16, chapter 7 at § 120.2.3 (Exhibit 5).	Schindler Decl. Ex. 9, CMS, 2012 <i>Regional Technical Assistance Participant Guide: Encounter Data</i>, §§ 2.4.3, 3.5.7, 3.5.7.1, 3.5.7.2 (Aug. 6-7, 2012); <i>see also</i> Schindler Decl. Ex. 7, May Grant Dep. at 163: 14–18 (Q: “Okay. The same question with respect to pulling charts for review. Is that an appropriate activity for MA plans to engage in?” MS. KRIEG: “Object to the question.” A: “Yes”). The remainder of the statement is undisputed.
25. RAPS also has a field called a “Delete Indicator” that allows MAOs to delete invalid diagnosis codes that were previously submitted and thereby retract the claim for payment for those invalid diagnoses. <i>Id.</i>	Undisputed.
26. A diagnosis that has been deleted in RAPS will not cause an increase in the risk score or risk adjusted payment that otherwise would have been based on the deleted diagnosis code.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United disputes this statement to the extent it implies that every diagnosis code submitted in RAPs affects payment. Not all diagnosis codes submitted in RAPs affect risk scores and thereby payments. The rest of the statement is undisputed.
27. When an MAO acquires information about invalid diagnoses after payment is made, it can still delete the invalid diagnosis codes through RAPS, and CMS will reconcile	Disputed. United disputes the suggestion that it is always possible for an MAO to delete diagnosis codes submitted through RAPs. Until 2014, there was no formal process in place

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its payments as part of a routine process. 42 C.F.R. § 422.310(g)(2)(ii).	for deleting diagnosis codes during the closed period. <i>See</i> Schindler Decl., Ex. 10, CMS, <i>Guidance for Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments to the Centers for Medicare & Medicaid Services (CMS)</i>, (Feb. 18, 2015) (announcing the process for reporting and returning overpayments beginning on January 1, 2015). United also disputes that CMS consistently reconciles or otherwise adjusts payments when plans do submit deletions.
28. EDS works much the same way with respect to the deletion of invalid diagnosis codes. <i>See</i> CMS 2012 Regional Technical Assistance Participant Guide, Encounter Data, at 3-32 to 3-33 (Exhibit 8).	Disputed. This statement is unclear as to what is meant by “much the same way” such that United cannot meaningfully assess the statement. For purposes of this motion the statement is disputed.
C. Part C and D Payment Data Integrity Requirements and Obligations	
29. MAOs have a financial incentive to submit as many risk-adjusting diagnoses as possible to generate as much payment as possible.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United does not dispute that MAOs are paid in part based on the risk-adjusting diagnoses they submit to CMS and that they therefore have a financial incentive to submit complete risk adjustment data reflecting all of the diagnoses supported by the medical record. However, United disputes that MAOs have a financial incentive to submit “as

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	many risk-adjusting codes as possible.”
30. Accordingly, to ensure that payments are based on valid diagnosis data and are not improperly inflated, payment integrity requirements and obligations are imposed on MAOs.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. The alleged “fact” is also argumentative and a legal conclusion that requires no response.
31. These requirements and obligations are contractual as well as regulatory, and apply to all United MAOs and to entities related to these MAOs, including, the non-MAO United Defendants in this action. <i>See</i> Section D(5) of Article V of the MA Contract (Exhibit 1) (if any MAO responsibility is delegated to another entity, “all contracts or written agreements must specify that the related entity, contractor or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions”); <i>see also</i> 42 C.F.R. §422.504(i)(3)(iii), (4)(v) (Part C) (requiring related entities and contractors to comply with the MAO’s contractual obligations to CMS and to comply with all applicable Medicare laws, regulations, and CMS instructions); 42 C.F.R. § 423.505(i)(3)(iii), (iv) (Part D) (same).	Disputed. The alleged “fact” is argumentative and a legal conclusion that requires no response. United also objects on the grounds that the term “These requirements” is vague.
32. One of the most fundamental payment integrity requirements is that diagnoses must be substantiated by the beneficiaries’ medical records to be valid and one of the most important	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. The alleged “fact” is also argumentative and a legal

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payment integrity obligations is that MAOs and their related entities and contractors delete unsubstantiated diagnoses when they have information, knowledge or a belief about them.	conclusion that requires no response.
33. In order to participate in the Part C and Part D programs, the Defendant MAOs were required to agree in writing to comply with Part C and D regulations and other terms and conditions. 42 C.F.R. §§ 422.503, 422.504 (Part C); 42 C.F.R. §§ 423.504, 423.505 (Part D).	Disputed. The alleged “fact” is argumentative and a legal conclusion that requires no response.
34. Each year, one or more executives of defendant UnitedHealthcare, Inc. or its affiliates or predecessors entered into these contracts with CMS on behalf of the Defendant MAOs. <i>See e.g.</i> Signature Attestation page at the end of Exhibit 1.	Disputed. United does not dispute that its executives signed Risk Adjustment Attestations. However, United objects on the grounds that the term “Each year” and “these contracts” is vague. Although unclear what Plaintiffs mean by “these contracts,” United also disputes that its “executives . . . entered into these contracts with CMS on behalf of the Defendant MAOs.”
35. During the payment years at issue in this case, the contracts obligated defendants to operate their Part C and D plans “in compliance with the requirements of [the] contract[s] and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.)” and to comply with “Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse,” including the False Claims Act. <i>See,</i>	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited contract. However, the interpretation of the contract is a legal conclusion that United disputes and that requires no response. This statement is also disputed as incomplete and misleading. The portion of the contracts only partially quoted by the government deals with MA plans’ agreements to operate a particular type of MA plan (a coordinated care plan, as opposed to

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<i>e.g.</i>, Section A of Article II and Section A(1) of Article IX of the Part C contract, which is part of Exhibit 1.⁴	one of two other categories of MA plans – private FFS plans or MSA plans, <i>see</i> Schindler Decl. Ex. 11, 2017 Manual Chapter 1, §§ 20.1, 20.2; 42 C.F.R. § 422.4(a)) and the provision of services to beneficiaries as part of that “Coordinated Care Plan.” Ex. 1 to Decl. of Cheri Rice, at 6. That “coordinated care plan” governs the medical services that the plan is required to provide to its members, the conditions under which those services must be available, the providers through whom the plan will provide them, and so forth, and various requirements that apply to coordinated care type MA plans in particular. <i>See</i> 42 C.F.R. 422.4(a)(1); Schindler Decl. Ex. 11, 2017 Manual Chapter 1, § 20.2. It does not extend, however, to the manner in which CMS will pay the plan. The terms governing that issue are instead set out in Article IV, governing “CMS Payment to MA Organization.” <i>See</i> Opp. to Mot. for Part. Sum. J. at 33-36.
36. The contracts also required defendants to implement an effective compliance program in accordance with the Part C and D compliance regulations. <i>See, e.g.</i>, Section F of Art. III of the MA Contract and Section J of Art. II of the Part D Addendum, also	Disputed. United does not dispute that pursuant to the referenced MA Contract, the MAO defendants agreed to implement a compliance program in accordance with Part C and D compliance regulations. However, the interpretation of the contract is a legal

⁴ The Attestation of Benefit Plan, which is part of the contract, also requires compliance with the Medicare Managed Care Manual and other documents issued by CMS. This Attestation is included as part of Exhibit 1.

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part of Exhibit 1.	conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30.
37. Since 2005, the Part C compliance regulation itself has obligated United to monitor for noncompliance with CMS requirements, identify compliance risks, and respond to and correct compliance problems, including taking “affirmative steps to address errors” in the data it submitted for payments. <i>United States ex rel. Swoben v. United Healthcare Ins. Co.</i>, 848 F.3d 1161, 1174 (9th Cir. 2016) (citing 42 C.F.R. § 422.503(b)(4)(vi), (vi)(F), (vi)(G) (2005)); <i>see also</i> 42 C.F.R., § 423.504(b)(4)(vi), (vi)(F), (vi)(G) (2007) (Part D compliance regulation setting forth same requirements).	Disputed. United does not dispute that the language that appears in quotation marks appears in the sources that are cited. However, the interpretation of these regulations and case law is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 46-49.
38. The compliance regulations state that the MAO “must conduct appropriate corrective actions (for example, repayment of overpayments . . .).” 42 C.F.R. § 422.503(b)(4)(vi)(G)(2); <i>see also</i> 42 C.F.R., § 423.504(b)(4)(vi)(G)(2) (Part D) (same).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited source. However, the interpretation of these regulations is a legal conclusion that United disputes and that requires no response. Further, this factual allegation is disputed as incomplete. 42 C.F.R. § 422.503(b)(4)(vi)(G)(2) states that an MAO “must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.” 42 C.F.R. § 422.503(b)(4)(vi)(G)(1) states,

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	“If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.” The analogous Part D regulations provide similarly. To the extent Plaintiffs’ statement suggests otherwise, the cited regulations do not impose an obligation on MAOs to delete unsupported codes. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30.
39. In 2013, the obligation to withdraw erroneous risk adjustment data was also reiterated in the Medicare Managed Care Manual, which, as noted above, was expressly incorporated into all of the contracts. <i>See, e.g.</i>, 2013 Medicare Managed Care Manual, Pub. 100-16, chapter 7 at § 40 (Exhibit 5) (stating: “If upon conducting an internal review of submitted diagnosis codes, the plan sponsor [or MAO] determines that any ICD-9-CM diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor [or MAO] is responsible for deleting the submitted ICD-9-CM diagnosis codes as soon as possible”).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited Medicare Managed Care Manual. However, the interpretation of the contract and Medicare Managed Care Manual is a legal conclusion that United disputes and that requires no response. Further, Plaintiffs mischaracterize the meaning of the cited provisions, which describe a responsibility to delete codes <i>if</i> a plan chooses to undertake an internal review of previously submitted codes <i>and</i> that review determines that submitted codes do not meet the risk adjustment submission requirements. <i>See</i> Opp. to Mot. for Part. Sum. J. at 40. To the extent Plaintiffs’ statement suggests otherwise, the cited Manuals do not impose an obligation on MAOs to delete unsupported codes. Finally, the Manual is a guidance

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	document that does not impose any legal obligations on plans and that United did not agree to comply with in its contract with CMS. <i>See</i> Opp. to Mot. for Part. Sum. J. at 32-33.
40. In addition, in accordance with 42 C.F.R. § 422.504(l) (Part C), the contracts obligated an officer of each United MAO to annually attest to the accuracy, completeness, and truthfulness of the diagnosis data submitted for risk adjustment payments based on best knowledge, information, and belief. <i>See</i> Section D.2 of Article IV of the MA Contract (Exhibit 1).⁵	Disputed. Plaintiffs mischaracterize the cited regulation and contracts. The contracts and applicable regulation provide that a chief executive officer, a chief financial officer, “or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer” can sign. 42 C.F.R. § 422.504(l); Pls.’ Mem. of P. & A. in Supp. of Pls.’ Mot. for Partial Summ. J., ECF No. 234-1 (“Mem.”) Ex. 1 at 11, ECF No. 234-3.
41. This regulatory and contractual obligation also applied to each related entity and contractor that generated (that is, submitted) risk adjustment data for the United MAOs, including defendant Optum (and its predecessor, Ingenix). <i>Id.</i>	Disputed. The alleged “fact” is a legal conclusion that that requires no response.
42. Importantly, this contractual and regulatory attestation requirement imposed affirmative duties on the MAOs and their related entities and contractors.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. The alleged “fact” is also argumentative and a legal conclusion that requires no response. United further objects on the grounds that the term “affirmative duties” is

⁵ The Part D regulations include a similar attestation requirement for diagnoses submitted for risk adjustment payments under the prescription drug program. Under the applicable Part D regulation, these attestations are referred to as certifications. 42 C.F.R. § 423.505(k).

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	vague and ambiguous.
43. As explained by the Ninth Circuit and “as CMS has long made clear,” to attest to the accuracy, completeness, and truthfulness of their risk adjustment data submitted to CMS, MAOs have always had a duty to take actions to ensure the accuracy, completeness, and truthfulness of the data and are responsible for “making good faith efforts” to certify the accuracy, completeness, and truthfulness of the data. <i>Swoben</i>, 848 F.3d at 1174 (citing 65 Fed. Reg. at 40,268); <i>see also</i> 2004 Manual (Exhibit 4), § 111.7 (discussing this requirement).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited source. However, the interpretation of case law and the underlying regulations and Managed Care Manual are legal conclusions that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 31-33, 46-49. Further, in each year since 2014, United has submitted its risk adjustment data attestations subject to certain clarifications, including the understanding that it was not obligated to perform two-ways looks. In 2014, United explained that it had suspended the “process through which [it] review[s] certain medical records to determine the accuracy of risk adjustment diagnoses and submit[s] appropriate deletes” while it considered whether to make changes. <i>See</i> Schindler Decl. Ex. 12, Email from Steve Nelson to Cheri Rice dated April 30, 2014, produced at MARA1296259. In 2015 and 2016, United clarified that it “previously had a process through which [it] reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes” but that it “ended this process and informed [CMS] of that decision.” Schindler Decl. Ex. 13, Email from Steve Nelson to Cheri Rice dated June 26, 2015, produced at MARA2152278; Schindler

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	Decl. Ex. 14, Email from Cheri Rice to Johanna Kreisel dated June 7, 2016, produced at USBP000498420. It further clarified that the decision remained operative and explicitly communicated that United “did not use [its] previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record.” <i>See</i> Schindler Decl. Ex. 13, Email from Steve Nelson to Cheri Rice dated June 26, 2015, produced at MARA2152278; Schindler Decl. Ex. 14, Email from Cheri Rice to Johanna Kreisel dated June 7, 2016, produced at USBP000498420. United also made similar qualifications in its bid assumptions that CMS reviewed and approved prior to the parties executing the contracts here at issue. <i>See, e.g.,</i> Schindler Decl. Ex. 49, MA Supporting Documentation for CY2015 Bid, UHC of California, Inc., Contract No. H0543-001-000, dated Aug. 5, 2014 (emphasis added) (providing: “We . . . adjusted projected risk scores to account for changes in our medical record review processes. Specifically, <i>based on multiple conversations with CMS and CMS’s treatment of medical record review in its recent rulemaking process, the health plan has decided to cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process</i>”); <i>see also</i> Opp. to Mot. for Part. Sum. J. at 36-38.
44. Thus, MAOs and their related	Disputed. The alleged “fact” is a legal

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entities and contractors cannot turn blind eyes to information about the invalidity of their diagnosis data or act with reckless disregard or deliberate ignorance of the falsity of the data and one of the affirmative duties or actions that MAOs and their related entities and contractors must undertake because of the attestation requirement is to correct or withdraw erroneous data. <i>Id.</i> at 1174.	conclusion that United disputes and that requires no response.
45. The Medicare Managed Care Manual has long specified that diagnosis data must be substantiated by the beneficiaries’ medical records – a requirement that has been in every version of the Manual since at least 2001. <i>See, e.g.</i>, 2001 Manual (Exhibit 3), §§ 110.3, 110.4 (requiring diagnosis data to “be substantiated by the hospital’s medical record”); 2004 Manual (Exhibit 4), §§ 111.1, 111.4, 111.8 and Exhibit 30 [to the Manual] (Aug. 13, 2004) (“a medical record must substantiate all diagnostic information provided to CMS”); 2013 Manual (Exhibit 5), § 40 (“All diagnosis codes submitted must be documented in the medical record”).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited sources. However, the rest of the statement, including the interpretation of the Medicare Managed Care Manuals, is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 32-36, 39.
46. The Manual, in accordance with federal regulation, also has long specified that diagnoses be coded according to <i>International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting</i> and the ICD Guidelines have long specified that the	Disputed. The effect and interpretation of the Manual and ICD Guidelines are legal conclusions that United disputes and that require no response. Further, United disputes the contention that “the ICD Guidelines have long specified that the medical record must substantiate the diagnosis coding.” In

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medical record must substantiate the diagnosis coding. <i>See, e.g.</i>, 2013 Manual § 40 (Exhibit 5); <i>see also</i> 45 C.F.R. §§ 162.103, 162.1000(a) and 162.1002(a)(1), (b)(1), (c)(2)(i) (by which the Secretary of HHS adopted certain “code sets as the standard medical data code sets[.]” including the ICD-9-CM (Ninth Edition) until it was superseded in October 2015 by the ICD-10-CM (Tenth Edition), and made their use mandatory for “covered entities,” which includes health plans and providers).	addition, the Manuals do not impose legal obligations and United did not contractually agree to comply with the Manuals in connection with submission of risk adjustment data or payment. <i>See</i> Opp. to Mot. for Part. Sum. J. at 32-41.
47. The Ninth Edition of the ICD Guidelines (effective during many of the years at issue here), “published by the United States Government” and “required for reporting diagnoses and diseases to all . . . [CMS] programs,” included the requirement of medical record documentation to substantiate diagnosis coding. Joint Appendix of Rulemaking Record Excerpts from APA case, ICD-9-CM Coding Guidelines, Preface at 1 (Exhibit 15); <i>see also id.</i> at 5 (explaining “[t]he importance of consistent, complete documentation in the medical record,” without which accurate diagnosis coding “is a difficult, if not impossible, task”).	Disputed. United does not dispute that the language that appears in quotation marks appears in the source that is cited. However, the effect and interpretation of the ICD Guidelines are legal conclusions that United disputes and that require no response. Further, United disputes Plaintiff’s contention that “[t]he Ninth Edition of the ICD Guidelines . . . included the requirement of medical record documentation to substantiate diagnosis coding.” <i>See</i> Opp. to Mot. for Part. Sum. J. at 39.
48. The Tenth Edition of the ICD Guidelines does the same. ICD-10-CM Official Guidelines for Coding and Reporting FY 2018, at 1 (Exhibit 16) (“importance of consistent, complete	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited source. However, the effect and interpretation of the ICD Guidelines are legal

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documentation in the medical record cannot be overemphasized”).	conclusions that United disputes and that require no response. Further, United disputes Plaintiff’s contention that the Tenth Edition of the ICD Guidelines included a requirement of medical record documentation to substantiate diagnosis coding. <i>See</i> Opp. to Mot. for Part. Sum. J.
49. Moreover, pursuant to their MA Contracts, the Defendant MAOs agreed “to comply with the requirements in § 422.310 for submitting risk adjustment data to CMS” and could be terminated if they “fail[ed] to provide CMS with valid risk adjustment data as required under § 422.310 and 423.329(b)(3).” <i>See</i> Section B.7 of Art. VI and Section B.1(a)(vii) of Article VIII of the MA Contract.⁶	Disputed. United does not dispute that the language that appears in quotation marks appears in the MA Contract. However, the interpretation of the contract is a legal conclusion that United disputes and that requires no response.
50. One of the requirements of § 422.310 (a Part C regulation) pertains to the “[v]alidation of risk adjustment data.”	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.310. However, the interpretation of the regulation is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30-31.
51. Section 422.310(e) also establishes the medical record as the source for determining the validity of risk adjustment data: “MA	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.310(e). However, the

⁶ The contracts are also subject to termination when “[t]here is credible evidence that the MA Organization committed or participated in false, fraudulent or abusive activities affecting the Medicare program, including the submission of false or fraudulent data.” *See, e.g.,* Section B.1(a)(iv) of Article VIII of the MA Contract (Exhibit 1).

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organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS.”	interpretation of the regulation is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30-31.
52. “There may be penalties for submission of false data.” 42 C.F.R. § 422.310(e).⁷	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.310(e). However, the interpretation of the regulation is a legal conclusion that United disputes and that requires no response. <i>See</i> 30-31.
53. Similarly, the regulation relating to CMS’ risk adjustment data validation (RADV) audits refers to the medical records as the source for validating diagnoses in order “to ensure risk adjusted payment integrity and accuracy.” 42 C.F.R. § 422.311(a).	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.311(a). However, the interpretation of the regulation is a legal conclusion that United disputes and that requires no response. This “fact” is also disputed as incomplete and potentially misleading. The provision Plaintiffs’ cite discusses data validation in the specific context of Risk Adjustment Data Validation (RADV) audits rather than a general obligation to validate risk adjustment data. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30-31. The entirety of the quoted subsection states: “In accordance with § 422.2 [Definitions] and § 422.310(e), the Secretary annually conducts RADV audits to ensure risk adjusted payment

⁷ Section 423.329(b)(3) addresses the collection of data for Part D risk adjustment based on health status. It references the requirements of section 422.310.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
	integrity and accuracy.” 42 C.F.R. § 422.311(a). To the extent Plaintiffs’ statement suggests otherwise, it is disputed.
54. And, because the medical record is the “source of truth” for the determining the validity of risk adjustment data, United’s MA Contracts, in accordance with 42 C.F.R. § 422.504(e)(2), provided the government with the right to audit, evaluate, and inspect “medical records,” “patient care documentation, and other records” in the possession or control of the United MAOs, related entities, and contractors that relate to the “determination of amounts payable under the contract[s].” <i>See, e.g.</i>, Section A.2(b), (d) of Article VI of the MA Contract (Exhibit 1).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited contract and regulation. The rest of the statement is argumentative and a legal conclusion that United disputes and requires no response. Additionally, Plaintiffs have mischaracterized the meaning of the quoted language; the cited contract does not give “the government” a right; rather it provides that “HHS, the Comptroller General, or their designees may audit, evaluate, or inspect. . . medical records. . . patient care documentation, and other records of the MA Organization, . . .and determination of amounts payable under the contract. . . .” Mem. Ex. 1 at 13, ECF No. 234-3; 42 C.F.R. § 422.504(e)(2) (providing similarly).
55. During the relevant time period, 2009-2017, the United Defendants were also bound by the terms and conditions of Electronic Data Interchange (“EDI”) Agreements.	Disputed. This statement is a legal conclusion that United disputes and requires no response.
56. The United MAOs and any related entity or contractor that submitted risk adjustment data on their behalf (here Optum and its predecessor, Ingenix) were required to execute these agreements in order to submit the data,	Disputed. This statement is a legal conclusion that United disputes and requires no response.

1 PLAINTIFFS' 2 UNCONTROVERTED FACTS	UNITED'S RESPONSE
3 including diagnoses, to CMS' RAPS 4 and EDS and to receive payments. <i>See,</i> 5 <i>e.g.,</i> Electronic Data Interchange 6 Agreement Between United and CMS 7 (Exhibit 2); <i>see also</i> 2004 Manual (Exhibit 4), § 111.6.1 (discussing this requirement).	
8 57. Pursuant to the EDI Agreements, 9 the defendant MAOs and Optum (and 10 its predecessor, Ingenix) agreed that 11 they were responsible for all risk 12 adjustment data submitted by 13 themselves, their employees, and 14 agents and that "[b]ased on best 15 knowledge, information, and belief, [they would] submit risk adjustment data that are accurate, complete, and truthful." <i>Id.</i> at Sections A.1 and 5.	Disputed. Plaintiffs have misquoted the language in the cited EDI Agreements. The EDI Agreements state that the MAO will be responsible "for all Medicare encounter data submitted to CMS by itself, its employees, or its agents," and that, "Based on best knowledge, information, and belief, [the MAO] will submit encounter data that are accurate, complete, and truthful." Mem. Ex. 2 at 43. Further, the interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> <i>Opp. to Mot. for Part. Sum. J.</i> at 42.
19 58. Moreover, they agreed to 20 "correct risk adjustment data 21 discrepancies." <i>Id.</i> at Section A.11.	Disputed. Plaintiffs have misquoted the language in cited EDI Agreements. The source refers to "research[ing] and correct[ing] encounter data discrepancies." Mem. Ex. 2 at 43. Further, the interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See Opp. to Mot. for Part.</i> <i>Sum. J.</i> at 42.
27 59. Of equal significance, pursuant 28 to the EDI Agreements, they also agreed that the government had the	Disputed. United does not dispute that the language that appears in quotation marks appears in the EDI Agreements.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
right to “audit and confirm” the data submitted by them and that they would provide the government with access to “medical records related to the eligible organization’s submissions” in order for the government to audit data and confirm that the submitted-diagnosis were supported by the medical records. <i>Id.</i> at Section A.4.	However, the interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 42.
60. Thus, the EDI Agreements also established the medical records as the “source of truth” for validating diagnosis data and Defendants’ entitlement to payments.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. Plaintiffs’ interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 42.
61. Any conclusion of law that is deemed a finding of fact is incorporated herein by this reference.	Disputed. To the extent any conclusion of law is deemed a finding of fact, United objects.

**ADDITIONAL MATERIAL FACTS AND EVIDENCE THAT PRECLUDES
PARTIAL SUMMARY JUDGMENT**

United presents the following additional material facts and evidence in opposition to the United States’ and Ben Poehling’s Motion for Partial Summary Judgment. As set forth in the Declaration of Abid R. Qureshi submitted pursuant to Federal Rule of Civil Procedure 56(d), filed concurrently, United expects to develop additional evidence on many of the factual matters that support the arguments in its Opposition through ongoing discovery in this litigation. *See* Declaration of Abid R. Qureshi, July 23, 2018.

**UNITED’S ADDITIONAL
MATERIAL FACTS AND
SUPPORTING EVIDENCE:**

A. Additional Material Facts Establishing the Impact of Diagnosis Coding Discrepancies on the Payment Rates Calculated by CMS

62. In determining the predicted cost of providing benefits to a given beneficiary, CMS’ objective is to obtain “[r]isk scores [that] are consistent across both fee-for-service and Medicare Advantage settings, Schindler Decl. Ex. 1, 2010 Rate Announcement, at AR4336, such that “[r]isk scores for beneficiaries with the same diagnoses and characteristics should be identical” in the MA and traditional Medicare programs, Schindler Decl. Ex. 2, GAO, *Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments*, at AR12043.

63. In both traditional Medicare and Medicare Advantage providers sometimes submit diagnosis codes that

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	do not correspond perfectly with	
5	patients’ medical charts. <i>See, e.g.,</i>	
6	Schindler Decl. Ex. 15, Presentation	
7	from Division of Payment Validation at	
8	CMS0005886 (internal CMS	
9	presentation acknowledging that “In	
10	FFS Medicare, some portion of	
11	diagnoses on FFS claims are not	
12	documented in medical records.”);	
13	Schindler Decl. Ex. 7, May Grant Dep.	
14	at 233:4-17 (“Q: So you are aware that	
15	there are errors [in FFS data], but you	
16	don’t know the amount or extent	
17	because you believe there’s no	
18	systematic study evaluating this	
19	issue? ... A: Again, ‘aware’ is a strong	
20	term. I would say it is my firm belief,	
21	having processed data for years, that	
22	any data set has errors in it. My	
23	experience with data would say that	
24	every data set you ever deal with that is	
25	a very large data set has some degree of	
26	error and the only question is what that	
27	degree of error is. And unless you	
28	study it, it is not knowable what that	
	degree of error is.”)	
	64. CMS has acknowledged that the	:
	FFS claims data it collects in the	
	traditional Medicare program contains	
	unsupported diagnosis codes. <i>See supra</i>	
	63.	
	65. Yet, when CMS calibrates the	
	CMS-HCC risk adjustment model, it	
	does not attempt to correct for those	
	discrepancies by auditing the FFS	
	claims data to confirm that the	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	diagnosis codes are properly supported	
5	by medical records. <i>See</i> Schindler	
6	Decl. Ex. 15, Presentation from	
7	Division of Payment Validation at	
8	CMS0005887; Schindler Decl. Ex. 16,	
9	FOIA Agenda at CMS0006200	
10	(“...we’ve got another documentation	
11	standard for risk adjustment, which	
12	reflects a certain level of codes that	
13	aren’t documented in a medical	
14	record”).	
15	66. Instead, when CMS uses its own	
16	data to calculate the average	
17	incremental relative cost of having a	
18	particular condition, it assumes that	
19	every diagnosis code in its claims data	
20	represents an individual who actually	
21	has the condition in question. <i>See</i>	
22	Schindler Decl. Ex. 17, Pope et al.,	
23	Risk Adjustment of Medicare	
24	Capitation Payments Using the CMS-	
25	HCC Model, at AR11867, <i>Health Care</i>	
26	<i>Financing Review</i> , 25(4) (Summer	
27	2004); Schindler Decl. Ex. 18, 2010	
28	RADV Rule, at AR2826.	
	67. The existence of these “zero	
	cost” conditions affects the overall	
	average, incremental risk coefficient	
	that the model calculates for that	
	particular condition. <i>See</i> Schindler	
	Decl. Ex. 7, May Grant Dep. at 229:3-	
	231:15 (Q: “Mr. Grant, is that sort of	
	what the purpose is of slide 2? You’re	
	referencing a healthy personal	
	mistakenly coded as sick and then	
	assigning the relative cost to that	

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UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
individual?” . . .“A. Yes. So this is again, with the God-like power to know everybody's cost, I know that these healthy people coded as sick cost the same as all the other healthy people and I magically already know they all cost \$500, an unknowable fact when running a risk adjustment calibration, but in this world I've created I know this. And so I have two people thrown into the sick category from a coding perspective, but from a cost perspective appropriately residing in the healthy category . . . And as you see from this - - and this is only -- by the way, it’s a one-directional look at this, I will point out too, just looking at the incorrect coding, not going the other direction. The incorrectly -- incorrectly coded as sick, not healthy, incorrectly coded as healthy. It's not a robust presentation that has both sides. It's a one sided -- . . . And then we just walk through it and say we haven't thrown any sick people into the healthy category erroneously, so healthy people still cost 500 bucks apiece. But by virtue [sic] adding two healthy people into the sick population, you lower the perceived average cost of the sick population.... Q: “So what is the principle that you’re illustrating with this example?” A: “That if there is a pattern of overreporting of diagnosis codes in fee for service, then that pattern would result in a underprediction of the disease-related factors in the	

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
model”)	
68. CMS’s own Division of Payment Validation used a simplified hypothetical to explain this concept internally to senior CMS leaders. In the slide presentation attached as Schindler Decl. Ex. 15, they hypothesized a scenario in which, when calibrating the CMS-HCC model, CMS identifies four FFS beneficiaries with the diagnosis code for diabetes and determines that the aggregate incremental healthcare costs for the four beneficiaries the following year were \$12,000. <i>Id.</i> at CMS0005888. In that scenario, CMS would conclude that the average per-patient cost associated with diabetes is \$3,000, and it would set the diabetes risk coefficient accordingly. <i>Id.</i> But, the presentation explained, suppose further that one of these diagnosis codes was a false positive; the beneficiary did not in fact have diabetes. That means that the \$12,000 was in reality attributable to just three beneficiaries, such that the true per-patient cost of diabetes was actually \$4,000 ($\\$12,000 \div 3$ beneficiaries). <i>Id.</i> at CMS0005888-89. By averaging the cost over the four beneficiaries with the diagnosis code, rather than just the three beneficiaries who actually have diabetes, CMS’s model produces a lower average incremental cost (and associated risk coefficient) than it would have done if the diagnosis codes in the FFS data had	

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
been perfectly accurate. As the CMS presentation put it, “Inclusion of undocumented diagnoses [in the FFS data] tends to reduce risk adjustment values.” <i>Id.</i> at CMS0005888.	
69. Jeffrey Grant, one of CMS’s risk adjustment experts, used a similar hypothetical when explaining to senior CMS officials that “Plans must submit like FFS to be paid full costs of sick population.” Schindler Decl. Ex. 19, PowerPoint Presentation at 3, produced by UnitedHealth at USBP000011428; <i>see also</i> Schindler Decl. Ex. 20, Email from Jeffrey Grant to Thomas E. Hutchison dated May 29, 2009, produced at USBP000011424, attaching Schindler Decl. Ex. 19.	
70. In addition to recognizing the impact of coding discrepancies on payment rates internally, CMS also orally instructed MA plans that “if they stuck to how the data comes in to FFS, they would be paid correctly.” Schindler Decl. Ex. 20 at USBP000011426 (“Plans were told that if they stuck to how the data comes in to FFS, they would be paid correctly.”); Schindler Decl. Ex. 7, May Grant Dep. at 207:20-208:17 (testifying that CMS provided oral instructions to MA plans stating that “if they submitted data like fee for service, they would be paid equivalent to the calibration.”)	
B. Additional Material Facts Establishing CMS Recognition Of The Need	

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
To Assess MA Plans’ Diagnosis Codes In Light Of The Codes Submitted In Traditional Medicare	
<i>1. The Coding Intensity Adjustment</i>	
71. Because MA risk adjustment is based on diagnosis codes, MA plans have an incentive “to find and report as many diagnoses as can be supported by the medical record”—to code with high “intensity.” Schindler Decl. Ex. 5, Kronick & Welch, <i>supra</i>, at E3-E4.	
72. By contrast, reimbursement under traditional FFS Medicare generally is not tied to diagnoses, so the incentive for comprehensive coding is weaker. <i>See id.</i> at E3.	
73. MA plans therefore arrange for “chart reviews” to look for diagnoses documented in their beneficiaries’ charts that a provider failed to code in claims data.	
74. CMS has long known that MA plans engage in chart review activities and, in effect, code more completely. <i>See, e.g.</i>, Schindler Decl. Ex. 21, 2009 Advance Notice at AR004229-31 (“CMS understands that MA plans have made efforts to identify enrollees’ conditions and may be coding more completely than FFS.”)	
75. Although CMS officials have recognized that this is “an appropriate activity for MA plans to engage in,” <i>see, e.g.</i>, Schindler Decl. Ex. 7, May	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	Grant Dep. at 163:14-18, CMS also	
5	recognized that the divergent financial	
6	incentives between MA and traditional	
7	Medicare can lead to different coding	
8	patterns that affect risk adjustment	
9	payments.	
10	76. Medicare experts have long recognized that “for the purposes of creating an equitable MA payment system, the relevant question is whether MA risk scores are systematically different than those risk scores would be in FFS, and not which set of scores is more accurate” in an absolute sense. Schindler Decl. Ex. 5, Kronick & Welch, at E4 (emphasis added); Schindler Decl. Ex. 7, May Grant Dep. at 174:21 – 175:8 (“[T]hey are using accuracy not to talk about whether any specific diagnosis code in fee-for-services or managed care is accurate. It is to compare – to have comparable diagnoses. So it is accuracy of risk adjustment, really, not accuracy of coding . . . when they say “inaccurate” they are not referring to the accuracy or inaccuracy of any specific code on any specific claim or any specific RAP submission. They're talking about comparable types of data.”); <i>id.</i> at 182:6-8 (“[T]he definition of accuracy here,” is that MA plans “would be paid consistently with how the model is calibrated.”)	
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28	77. Congress understands this, too, and in 2006 it instructed CMS to	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	analyze any “ <i>differences</i> in coding	
5	patterns between Medicare Advantage	
6	plans and providers under part A and B	
7	[i.e., traditional FFS Medicare].”	
8	Schindler Decl. Ex. 22, Pub. L. No.	
9	109-171, § 5301(b)(2), 120 Stat. 4, 51	
10	(2006) (emphasis added).	
11	78. Congress further said that, “to	
12	ensure payment accuracy,” CMS	
13	should adjust MA beneficiaries’ risk	
14	scores in light of those different coding	
15	patterns. <i>Id.</i>	
16	79. As recognized by the United	
17	States Government Accountability	
18	Office (“GAO”): “Risk scores for	
19	beneficiaries with the same diagnoses	
20	and characteristics should be identical,	
21	regardless of whether the beneficiaries	
22	are in an MA plan or Medicare FFS.”	
23	Schindler Decl. Ex. 2, GAO,	
24	<i>Substantial Excess Payments</i>	
25	<i>Underscore Need for CMS to Improve</i>	
26	<i>Accuracy of Risk Score Adjustments</i> , at	
27	AR012043; <i>see also</i> Schindler Decl.	
28	Ex. 6, March Grant Dep. at 117:7-18	
	(agreeing with this statement).	
	80. In other words, “the implicit	
	assumption in the design of the MA	
	payment system” is that if “Jane Doe	
	would have a risk score of 1.0 if she	
	were in FFS,” then “she would have	
	had the same risk score of 1.0 if she	
	were enrolled in MA.” Schindler Decl.	
	Ex. 5, Kronick & Welch, at E4; <i>See</i>	
	<i>also</i> Schindler Decl. Ex. 6, March	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	Grant Dep. at 122:2-23 (agreeing with this statement).	
5	81. Requiring MA plans to delete	
6	diagnosis codes that are unsupported	
7	even though CMS does not do the same	
8	for its FFS population would violate	
9	this fundamental risk adjustment	
10	requirement: it would result in an MA	
11	beneficiary having a lower risk score	
12	than an identical FFS beneficiary,	
13	resulting in a lower payment. <i>See,</i>	
14	<i>generally</i> , Schindler Decl. Ex. 19,	
15	USBP000011428 at 3 (“Plans must	
16	submit like FFS to be paid full costs of	
17	sick populations”); <i>see also</i> Schindler	
18	Decl. Ex. 7, May Grant Dep. at 274:22-	
19	277:16	
20	82. CMS began imposing a	
21	downward adjustment to MA plans’	
22	risk scores in 2010, calculated to	
23	replicate the risk score-adjusted	
24	payments that would have resulted had	
25	plans not engaged in different coding	
26	activities. Schindler Decl. Ex. 1, 2010	
27	Rate Announcement, at AR4334.	
28	83. CMS explained that, because the	
	risk adjustment model is calibrated on	
	FFS data,	
	MA plans must code the way	
	Medicare Part A and B providers do	
	in order for risk adjustments to be	
	valid. This means that MA	
	<i>organizations are coding</i>	
	<i>“accurately” when they are coding</i>	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	<i>in a manner similar to fee-for-</i>	
5	<i>service coding used on the</i>	
6	<i>beneficiaries to whom MA plan</i>	
7	<i>enrollees are being compared. In</i>	
8	<i>this sense, “differences” in coding</i>	
9	<i>patterns, regardless of the source,</i>	
10	<i>would make the MA plan coding</i>	
11	<i>“inaccurate” for purposes of</i>	
12	<i>implementing risk adjustment.</i>	
13	<i>Id. at AR4335 (emphases added).</i>	
14	84. CMS noted that several members	
15	of Congress had expressly recognized	
16	this relative notion of accuracy.	
17	Senator Grassley, for instance, had	
18	explained that the intensity adjustment	
19	provision was intended to address	
20	“coding that is inaccurate or	
21	incomplete for the purpose of	
22	establishing risk scores that are	
23	consistent across both fee-for-service	
24	and Medicare Advantage settings, even	
25	if such coding is accurate or complete	
26	for other purposes.” <i>Id. at AR4336.</i>	
27	85. CMS has applied the Coding	
28	Intensity Adjustment in every year	
	since 2010. 42 U.S.C. § 1395w-	
	23(a)(1)(C)(ii).	
	86. CMS has never found that higher	
	MA coding intensity reflects the	
	inclusion of codes unsupported by	
	medical records; to the contrary, it has	
	said the data “fail[] to show a	
	systematic correlation between coding	
	pattern differences and errors in the	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	reporting of documented coding.”	
5	Schindler Decl. Ex. 1, 2010 Rate	
6	Announcement, at AR4337.	
7	87. Nevertheless, CMS continues to	
8	recognize that “to ensure payment	
9	accuracy,” it must account for	
10	“differential coding patterns in MA and	
11	FFS.” Schindler Decl. Ex. 23, 2014	
12	Rate Announcement, at AR4865.	
13	88. Each year, CMS reduces by a	
14	certain percentage the risk adjustment	
15	payments that an MA plan would	
16	otherwise have received based on the	
17	diagnosis codes it had submitted, in	
18	order to account for the MA plans’	
19	more complete coding. In 2017, for	
20	example, United expects that CMS will	
21	reduce its payment to United by	
22	approximately \$2.9 billion through its	
23	application of the Coding Intensity	
24	Adjustment. See Schindler Decl. Ex.	
25	24, Declaration of Mary Murley ¶ 9	
26	(July 23, 2018).	
27	89. CMS has found that “our	
28	methodology results in an accurate	
	measure of the coding differential	
	between FFS and MA.” Schindler	
	Decl. Ex. 25, 2013 Rate	
	Announcement, at AR4712.	
	90. Jeffrey Grant, one of only two	
	CMS officials deposed in this case to	
	date, testified that assuming the coding	
	intensity adjustment fully offsets any	
	activities that the plan undertakes to	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	code more completely, an MA plan	
5	would be <i>underpaid</i> if it were to audit	
6	just 25 percent of its members’ charts	
7	(or even fewer) and delete any	
8	unsupported codes it found, while	
9	CMS continued its policy of not	
10	deleting such codes in the FFS data that	
11	it uses to calibrate its model. <i>See</i>	
12	Schindler Decl. Ex. 7, May Grant Dep.	
13	at 274:22-277:22 (Q: “Well, I want you	
14	now to assume, sir, in this hypothetical	
15	world that the coding intensity adjuster	
16	that we talked about earlier, I want you	
17	to assume that it fully offsets any	
18	activities that the plan undertakes to	
19	code more completely, chart reviews,	
20	home visits, whatever, but they’re	
21	completely offset by the coding	
22	intensity adjuster. If the plan were to	
23	submit only the codes of people who	
24	are truly sick, to use your presentation	
25	example [Exhibit 1017], then that plan	
26	would be underpaid.” A: “In a	
27	hypothetical word that you are	
28	creating . . . in that world, in theory,	
	yes . . .” Q: “Mr. Grant, I want you to	
	again assume that the coding intensity	
	adjuster fully offsets all the activities	
	that a plan might undertake to code	
	more fully. I also want you to assume	
	that a plan audits every one of its charts	
	and deletes every unsupported code.	
	The problem that you highlight in your	
	slide presentation, Exhibit 1017, would	
	still exist in that scenario?” A: “In my	
	opinion, if you could have that	
	scenario, yes.” Q: “The problem	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	would still exist?” A: “The problem	
5	would still exist if you have that	
6	scenario.” Q: “Okay. Now I’d like to	
7	change the assumption slightly. Once	
8	again, the coding intensity adjuster	
9	fully offsets all activities that the plan	
10	undertakes that code more fully, but	
11	now the plan audits 50 percent of a	
12	chart, of its charts, and deletes the	
13	unsupported codes in that set. Would	
14	the problem still exist?” A: “Okay, we	
15	have multiple assumptions right? So	
16	we have the assumption that	
17	overcoding is the bias in the data. We	
18	have the assumption of perfect	
19	adjustment for plan coding activities.	
20	To a degree, it exists. It exists to a	
21	smaller amount.” Q: “Same	
22	assumption regarding the coding	
23	intensity adjuster, but now the plan is	
24	auditing 25 percent of its charts and	
25	deleting the unsupported codes. Does	
26	the problem still exist? . . . ” A:	
27	“Again, assumption of overcoding,	
28	endemic in fee for service, and	
	assumption of plan – plan coding	
	activities being 100 percent offset in	
	theory it exists to the degree that	
	diagnosis codes are deleted.”)	
	91. United performed chart reviews	
	that covered significantly more than 25	
	percent of United’s beneficiaries in	
	2009-2017. Schindler Decl. Ex. 52,	
	Declaration of Jon Bird ¶ 6 (July 23,	
	2018).	

**UNITED'S ADDITIONAL
MATERIAL FACTS AND
SUPPORTING EVIDENCE:**

92. Jeffrey Grant also testified that in his view he did not believe it was “improper” or “fraud” for a plan to perform one-way reviews that add additional diagnosis codes supported in the charts, without looking at whether previously submitted coded lack such support. Schindler Decl. Ex. 7, May Grant Dep. at 307:11-310:16 (Q: “Mr. Grant, I believe you testified earlier there was at least one plan for which you recall HRP performed a chart review while you were there; is this correct?” A: “Well there’s . . . more than one plan that we performed chart reviews for, yes.” Q: “Yeah. For the purpose of adding codes, you recall at least one plan?” A: “Yes.” Q: “And do you recall the identity of the plan?” A: “I do.” Q: “Okay. What is the identity?” A: “It was Coventry.” Q: “And in connection with that project, were you the relationship manager with Coventry?” A: “I was the overall relationship manager for Coventry, like all clients . . .” Q: “Is it fair to say that you were involved in that engagement?” A: “Right. And I oversaw all of our client engagements. I was the senior vice president for client services. I had client services that did the day-to-day for any client, and then if it was a special project that involved special skills, we might have people that were further managing the relationship with respect to that skill set because it required specialized

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	skill.” Q: “Understood. The one	
5	instance in which you recalled in which	
6	there were review of charts to add	
7	codes, do you recall whether there were	
8	any efforts to reconcile those codes	
9	against previously submitted claims	
10	data?” A: “So from a coding	
11	perspective, we did totally blind	
12	coding, so the coders had no idea what	
13	was previously submitted. We did	
14	have the capacity not to duplicate	
15	submit [sic] diagnoses. We weren’t	
16	going one for one and trying to look at	
17	claims data and see if every claim was	
18	one-for-one backed by a diagnosis on	
19	that date.” Q: “As part of this effort,	
20	did HRP compare the codes identified	
21	in the blind coding effort against the	
22	claims data that was submitted by	
23	providers and delete codes that HRP’s	
24	coders did not identify?” . . . A: “I’m	
25	not sure. I believe we may have done –	
26	not systematically, not on a large-scale	
27	basis, but I believe there were cases	
28	where we did.” Q: “And at that time,	
	did you have a belief that not engaging	
	in such a systematic effort was	
	improper?” . . . A: “At that time, no.”	
	Q: “Okay. At that time, did you think it	
	was fraud?” A: “No, I did not	
	knowingly participate in [a] fraudulent	
	activity [laughter].” ⁸	

⁸ The prepared transcript of Mr. Grant’s deposition states: “No, I did not knowingly participate in the fraudulent activity.” United believes the transcript contains an error: Mr. Grant’s oral testimony on this issue did not contain the word “the” in describing “fraudulent activity.” Instead United understands Mr. Grant testified “I did not knowingly participate in a fraudulent

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
93. Mr. Grant explained that in his view, an MA plan’s submission of an unsupported code would be improper only if it was making the “very specific submission of a very specific data element . . . that [it] know[s] is wrong.”) <i>See id.</i> at 321:21-23.	
2. The RADV FFS Adjuster	
94. The purpose of Risk Adjustment Data Validation (“RADV”) audits is to recover “overpayments.” <i>See</i> Schindler Decl. Ex. 18, 2010 RADV Rule, at AR2819 (“Under the RADV audit process we plan to recover the overpayments identified during the RADV audit.”) (emphasis added).	
95. When CMS initiates a RADV audit for a plan, it selects a sample of the plan’s enrollees for the audited year, collects those enrollees’ medical	

activity.” On July 21, 2018, United requested that the court reporter review the video and revise the transcript to correct the error. The court reporter, however, declined to do so. United respectfully disagrees with the court reporter’s decision not to revise the transcript. Prior to this statement and based on his experience at Health Risk Partners (“HRP”)—a company Mr. Grant described as akin to “a risk adjustment support company” and where Mr. Grant worked from 2008-2010, Schindler Decl. Ex. 6, March Grant Dep. at 27:4-9—Mr. Grant testified that when HRP performed chart reviews for at least one MA plan whose relationship Grant managed, HRP did not engage in a systematic effort to compare the codes identified during chart review against the claims data submitted by providers and delete codes that HRP’s coders did not identify. Mr. Grant further testified that he did not find this improper, which United believes implies he did not think it was fraudulent. Mr. Grant was not discussing a specific fraudulent incident. United therefore believes that Mr. Grant’s oral testimony only makes sense given the context if he testified that he “did not knowingly participate in a fraudulent activity.” For the Court’s convenience and determination, United is submitting excerpts of Mr. Grant’s video-taped deposition testimony at Schindler Decl. Ex. 59.

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	records, and then assesses whether	
5	those records adequately support the	
6	enrollees’ diagnosis codes. Schindler	
7	Decl. Ex. 26, Final RADV	
8	Methodology, at AR5312-13.	
9	96. In 2008, CMS announced that it	
10	would eventually start using its RADV	
11	audit findings to make “plan-level	
12	payment adjustments,” meaning that it	
13	would extrapolate the results from the	
14	audited sample of the plan’s	
15	beneficiaries to all of a plan’s enrollees	
16	producing payment adjustment for the	
17	plan’s entire contract with CMS.	
18	Schindler Decl. Ex. 43, Announcement	
19	of CY 2009 Parts C and D Rates and	
20	Policies, at 22 (Apr. 7, 2008).	
21	97. MA plans objected, and by 2010,	
22	CMS acknowledged a possible	
23	problem with defining	
24	“overpayment[s]” to include all	
25	payments resulting from unsupported	
26	diagnosis codes submitted by MA	
27	plans—namely, that the FFS data used	
28	to calibrate the risk adjustment model	
	contained coding discrepancies of its	
	own, meaning that MA payment	
	amounts already accounted for the	
	existence of some unsupported codes.	
	<i>See</i> Schindler Decl. Ex. 18, 2010	
	RADV Rule, at AR2826.	
	98. As commenters pointed out,	
	CMS needed to assess the discrepancy	
	rate in the FFS data and compare it to	
	the discrepancy rate of a given MA	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	plan before it could determine whether	
5	the plan had been overpaid. <i>See, e.g.,</i>	
6	Schindler Decl. Ex. 27, Public	
7	Comments of Aetna on the Proposed	
8	2009 RADV Rule at AR2627;	
9	Schindler Decl. Ex. 28, Public	
10	Comments of AHIP on the Proposed	
11	2009 RADV Rule at AR2744-45.	
12	99. Jeffrey Grant made this same	
13	point to CMS officials in 2009, while	
14	working at Health Risk Partners. <i>See</i>	
15	Schindler Decl. Ex. 19,	
16	USBP000011428 at 3 (“Plans must	
17	submit like FFS to be paid full costs of	
18	sick populations).	
19	100. CMS acknowledged that there	
20	was “potential merit” in this concern	
21	and said it was “currently studying this	
22	issue.” Schindler Decl. Ex. 18, 2010	
23	RADV Rule, at AR2826.	
24	101. The issue received intensified	
25	scrutiny after CMS proposed a RADV	
26	sampling and adjustment-calculation	
27	methodology that did not account for	
28	unsupported FFS codes. Schindler	
	Decl. Ex. 29, Proposed RADV	
	Methodology, at AR5020-22.	
	102. Numerous commenters pointed	
	out that this omission was a serious	
	flaw. <i>See, e.g.,</i> Schindler Decl. Ex. 30,	
	Public Comments of Aetna on the	
	Proposed RADV Methodology, at	
	AR5053-57; Schindler Decl. Ex. 31,	
	Public Comments of Humana on the	

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
Proposed RADV Methodology, at AR5105-08; Schindler Decl. Ex. 32, Public Comments of United on the Proposed RADV Methodology, at AR5205-07.	
103. Among them was the American Academy of Actuaries, which stated that it was inappropriate to develop risk coefficients “with FFS data that . . . were not validated or audited for accuracy” but then “apply those factors only to MA data that are validated.” Schindler Decl. Ex. 33, Public Comments of the American Academy of Actuaries on the Proposed RADV Methodology, at AR5235-36. Doing so, it said, could result in “systematic underpayment.” <i>Id.</i> at AR5236.	
104. Multiple commenters also noted that this approach would violate the statutory requirement that risk adjustment ensure “actuarial equivalence.” <i>See, e.g.,</i> Schindler Decl. Ex. 30, Public Comments of Aetna at AR5053-54; Schindler Decl. Ex. 31, Public Comments of Humana, at AR5114 (Humana); see also 42 U.S.C. § 1395w-23(a)(1)(C)(i).	
105. CMS officials acknowledged that the commenters were right, stating in internal CMS documents: “The industry has argued that in the RADV audits we are holding them to a standard of perfection for diagnosis coding but that	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	physician claims in FFS Medicare often include diagnoses that aren’t supported in the medical record. And this wouldn’t matter except that we use FFS claims data to develop our risk adjusters for Medicare Advantage. So when we estimate the relative cost of any given condition, we use diagnosis and cost data from FFS Medicare. So implicit in all of the adjustments we make to plans payments to account for the relative risk of their populations, are the factors that we developed using FFS data. ... [f]or our payments to be as accurate as possible, we should be using the same standard for both... To answer this issue, we can incorporate a FFS adjuster that estimates how much higher the plans payment would be if the model had been built using perfect data. This factor would reduce the estimated RADV overpayments due from each plan. We think this approach makes sense and from a technical point of view is the right thing to do.”) Schindler Decl. Ex. 16, FOIA Agenda, at CMS0006200-01 (emphasis added).	
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27	106. When CMS published a revised RADV methodology in February 2012,	
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1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	it said that in determining any contract-	
5	level payment adjustments, it would	
6	apply a “FFS adjuster.” Schindler	
7	Decl. Ex. 26, Final RADV	
8	Methodology, at AR5314.	
9	107. CMS explained that “[t]he FFS	
10	adjuster” would “account[] for the fact	
11	that the documentation standard used in	
12	RADV audits to determine [an MA]	
13	contract’s payment error (medical	
14	records) is different from the	
15	documentation standard used to	
16	develop the Part C risk-adjustment	
17	model (FFS claims).” <i>Id.</i> at AR5314-	
18	15.	
19	108. If the effect of the unsupported	
20	codes in CMS’s data is greater than or	
21	equal to the effect of the unsupported	
22	codes in the plan’s data, the audit will	
23	conclude with a finding that there has	
24	been no overpayment such that “the	
25	final recovery amount is equal to zero.”	
26	<i>Id.</i> at AR5314.	
27	109. CMS stated that the “amount of	
28	the adjuster” would “be calculated by	
	CMS based on a RADV-like review of	
	records submitted to support FFS	
	claims data.” <i>Id.</i> at AR5315.	
	110. CMS has not yet published a	
	FFS adjuster or the FFS payment error	
	rate, despite publishing the relevant	
	methodology over six years ago. <i>See</i>	
	<i>Id.</i> at AR5314	
	C. Additional Material Facts Establishing the Link Between This Motion	

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
and United’s Pending Administrative Challenges To The Government’s Current Overpayment Theory	
111. In 2014, in connection with CMS’s proposal of regulations about the “Reporting and returning of overpayments,” multiple MA plans urged CMS to make explicit in its overpayment regulation the point that it had already recognized in its audit regulation: That “an overpayment cannot exist for an MA organization’s particular contract unless CMS’s payments to the [plan] as a whole are inaccurate in light of an appropriate Fee-for-Service Adjuster that is applied to the entire contract.” Schindler Decl. Ex. 34, Public Comments of Humana on the Overpayment Rule, at AR907.	
112. United explained to the agency that, “[u]nder the Proposed Rule, [MA plans] will be undercompensated for the relative risk of their membership if they delete diagnosis codes from claims that are unsupported in a medical record and CMS does not simultaneously account for the equivalent diagnoses in FFS data.” Schindler Decl. Ex. 35, Public Comments of United on the Overpayment Rule, at AR1041.	
113. CMS refused, announcing in its final rule (known as the “Overpayment Rule”) that any undocumented diagnosis code would result in an overpayment to an MA plan: “[A] risk adjustment diagnosis that has been	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	submitted for payment but is found to	
5	be invalid because it does not have	
6	supporting medical record	
7	documentation would result in an	
8	overpayment,” regardless of the errors	
9	in the agency’s own FFS data.	
10	Schindler Decl. Ex. 36, Overpayment	
11	Rule, at AR1313.	
12	114. The agency made no attempt to	
13	reconcile that view with its prior	
14	recognition of the need for a FFS	
15	adjuster when identifying	
16	overpayments through RADV audits.	
17	Instead, it argued that MA plans’	
18	contracts with CMS required them to	
19	“certify (based on best knowledge,	
20	information, and belief) the accuracy,	
21	completeness, and truthfulness of the	
22	risk adjustment data they submit to	
23	CMS.” <i>Id.</i> ; see 42 C.F.R. § 422.504(l).	
24	It also asserted that the agency had a	
25	“long-standing risk adjustment data	
26	requirement that a diagnosis submitted	
27	to CMS by an MA organization for	
28	payment purposes must be supported	
	by medical record documentation.”	
	Schindler Decl. Ex. 36, Overpayment	
	Rule, at AR1314-15.	
	115. United subsequently brought an	
	Administrative Procedure Act suit	
	challenging the Overpayment Rule in	
	the U.S. District Court for the District	
	of Columbia. United has argued there	
	that unless CMS implements a	
	mechanism to account for unsupported	
	diagnosis codes in CMS’s own FFS	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	data, requiring MA plans to delete	
5	unsupported codes in their provider-	
6	submitted data would violate CMS’s	
7	statutory obligation under 42 U.S.C.	
8	§ 1395w-23(a)(1)(C)(i) to “ensure	
9	actuarial equivalence” between the MA	
10	and traditional Medicare programs.	
11	<i>See</i> Schindler Decl. Ex. 37, APA	
12	United Opening Br. at 8 (ECF 47-1).	
13	116. In addition, United has argued	
14	that requiring deletions by MA plans	
15	without comparable adjustments in the	
16	FFS data would violate CMS’s	
17	statutory obligation to “us[e] the same	
18	methodology” when calculating risk	
19	scores of patients in the traditional	
20	Medicare program that it “expect[s] to	
21	be applied in making payments to MA	
22	plans. 42 U.S.C. § 1395w-23(b)(4).	
23	<i>See</i> Schindler Decl. Ex. 37, APA	
24	United Opening Br.	
25	117. In response, CMS has argued	
26	that the Overpayment Rule does not	
27	present a proper opportunity to	
28	challenge its present view that every	
	unsupported diagnosis code submitted	
	by an MA plan results in an	
	overpayment and must therefore be	
	deleted. Schindler Decl., Ex. 40, APA	
	CMS Reply Br., at 5-9 (ECF 64).	
	118. Relying on the same contractual,	
	regulatory, and sub-regulatory	
	provisions the government has invoked	
	here, CMS has argued there that MA	
	plans have long been required to delete	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	all unsupported codes they identified,	
5	and that the Overpayment Rule	
	therefore changed nothing. <i>Id.</i>	
6	119. United has argued in turn that	
7	the contracts, manuals, and regulations	
8	are at best ambiguous, that they can	
9	and should be read in a manner	
10	consistent with CMS’s adoption of a	
11	FFS Adjuster, and that if they are not	
12	read that way—and instead read to	
13	require deletion of all unsupported	
14	codes in MA data without any	
15	adjustment for the FFS data—then the	
16	provisions at issue would be unlawful	
	in light of the statutory provisions	
	discussed above. Schindler Decl. Ex.	
	39, APA United Resp. Br., at 28-39	
	(ECF 60).	
17	120. The parties completed summary	
18	judgment briefing in February (totaling	
19	over 200 pages), and Judge Collyer has	
20	scheduled argument for August 8,	
	2018.	
21	D. Additional Material Facts Demonstrating that CMS Communicated to United that Two-Way Looks Were Not Required	
22	121. Given the “volume and variety”	
23	of diagnosis codes, CMS has	
24	recognized that the presence of at least	
25	some unsupported codes is	
26	“inevitable.” Schindler Decl. Ex. 41,	
27	2001 Medicare Managed Care Manual	
	§ 110.2, at AR5349.	
28	122. In 2014, CMS considered and	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	then affirmatively decided not to	
5	finalize a proposed rule that would	
6	have prohibited MA organizations from	
7	performing reviews that only looked	
8	for additional diagnosis codes (known	
9	as “one-way” reviews). <i>See</i> Schindler	
10	Decl. Ex. 42, 79 Fed Reg 1918, 2000	
11	(January 10, 2014) (proposed medical	
12	record review rule); Schindler Decl.	
13	Ex. 36, 79 Fed Reg 29844, 29926 (May	
14	23, 2014) (finalized rule without	
15	medical record review component).	
16	123. During conversations between	
17	United and CMS over the course of the	
18	spring and early summer of 2014, CMS	
19	confirmed multiple times that “two-	
20	way” looks were not required. <i>See</i>	
21	Schindler Decl. Ex. 44, Deposition of	
22	Larry Renfro at 134:1 – 137:6 (May 6,	
23	2016) (“Renfro Dep.”) (describing a	
24	conversation between Larry Renfro, the	
25	CEO of Optum, and then-Deputy	
26	Administrator of CMS Jonathan	
27	Blum); Renfro Dep. at 150:21 – 151:10	
28	(describing a telephone conversation	
	between Mr. Renfro and Marilyn	
	Tavener, then-Administrator of CMS,	
	on April 8, 2014); Schindler Decl. Ex.	
	45, MARA2160500 (reflecting the	
	same April 8, 2014 conversation	
	between Ms. Tavener and Mr. Renfro	
	regarding the implications of the	
	proposed rule); Schindler Decl. Ex. 46,	
	MARA1998459 (coordinating by email	
	an in-person meeting between senior	
	officials at CMS and United regarding	
	United’s obligations in light of the	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	proposed medical record review rule);	
5	Schindler Decl. Ex. 47,	
6	MARA2157039 (T. Johnson notes	
7	from April 29, 2014 meeting between	
8	United and CMS officials).	
9	124. Specifically, in March 2014,	
10	Deputy Administrator of CMS	
11	Jonathan Blum told Larry Renfro, CEO	
12	of Optum (a United affiliate), that	
13	unless and until CMS adopted a	
14	regulation requiring MA plans to use	
15	their chart reviews to look both ways,	
16	there was no obligation for plans to do	
17	so. Schindler Decl. Ex. 44, Renfro	
18	Dep. at 134:1 – 137:6 (including	
19	testimony by Mr. Renfro that Mr. Blum	
20	“told me that at this point [the proposed	
21	rule]’s not in effect. As a result of not	
22	being in effect, we shouldn’t be doing	
23	it,” referring to United’s claims	
24	verification program).	
25	125. CMS Administrator Marilyn	
26	Tavener told Mr. Renfro the same	
27	thing in a subsequent telephone	
28	conversation. <i>See id.</i> at 150:21 –	
	151:10; 160:9 – 163:17 (including	
	testimony by Mr. Renfro paraphrasing	
	Ms. Tavener’s telling him that “If the	
	proposed rule goes into effect January	
	1, 2015, [United] should be doing	
	normal business, which means [United]	
	d[id] not have to be doing claims	
	verification”); <i>see also</i> Schindler Decl.	
	Ex. 45, MARA2160500 (reflecting the	
	same April 8, 2014 conversation	
	between Ms. Tavener and Mr. Renfro	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	regarding the implications of the proposed rule).	
5	126. On April 29, 2014, UnitedHealth	
6	sent four executives to meet with no	
7	fewer than five top officials from CMS:	
8	the new Deputy Administrator and	
9	Director of the Center for Medicare,	
10	Sean Cavanaugh; the Director of the	
11	Medicare Plan Payment Group, Cheri	
12	Rice; the Deputy Director of Medicare	
13	Parts C and D, Cynthia Tudor; the	
14	Special Assistant at CMS, Dan Farmer;	
15	and the Director of the Division of	
16	Capitated Plan Audits, Financial	
17	Services Group. Schindler Decl. Ex.	
18	47, MARA2157039 (T. Johnson notes	
19	from April 29, 2014 meeting between	
20	United and CMS officials).	
21	127. As Ms. Tavenner acknowledged	
22	during her deposition, Mr. Renfro set	
23	up this meeting between United and	
24	CMS to obtain clarification regarding	
25	United's obligations in light of the	
26	proposed rule. . See Deposition of	
27	Marilyn B. Tavenner at 126:15-127:10	
28	(February 28, 2018) ("Tavenner Dep.")	
	(Q: You testified a moment ago you	
	said "I understand your concern,"	
	okay? What was the concern that you	
	understood Mr. Renfro to be expressing	
	to you? A: It's basically what's written	
	here. He was getting ready to sign an	
	attestation. He was unclear about what	
	to do with the records that he had	
	reviewed, and it didn't really get into as	
	much detail as was in this email, but it	

1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	was enough where the proposed rule, the fact that he wanted to sign for validation, he needed an answer. I referred him to the staff. Q: And he needed an answer about whether it was appropriate for United to cease looking for diagnosis codes to delete, correct? MR. FREEBORNE: Objection to form. A: He was looking for an answer about what he was supposed to do with the records he had reviewed, because he wanted to sign the attestation, and he wanted to make sure he did it correctly.”); <i>see also</i> Schindler Decl. Ex. 46, MARA1998459 (coordinating by email an in-person meeting between senior officials at CMS and United to “confirm [United’s] understanding”).	
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16	128. During that meeting, CMS told United that unless and until a proposed rule governing the review of medical records became final, MA plans did not, and do not, have an affirmative obligation to confirm whether diagnosis codes submitted by physicians are supported in the medical records. <i>See</i> Schindler Decl. Ex. 47, MARA2157039 (T. Johnson notes from April 29, 2014 meeting between United and CMS officials, noting that “CMS representatives reiterated that, under CMS regulations, MA plans were not required to design their chart review programs for overall accuracy until the proposed rule is finalized” and that Cheri Rice of CMS stated that “until the proposed rule relating to	
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1	UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	medical records review was finalized,	
5	MA plans do not have a proactive	
6	responsibility to confirm whether	
7	diagnoses submitted by physicians are	
8	correct”).	
9	129. United MA Plans memorialized	
10	this understanding, including in	
11	subsequent bids and risk adjustment	
12	data attestations they provided to CMS	
13	under the contracts. <i>See, e.g.,</i>	
14	Schindler Decl. Ex. 12,	
15	MARA1296259 (April 30, 2014 email	
16	from S. Nelson to C. Rice (CMS)	
17	regarding 2012 DOS risk adjustment	
18	data attestation, noting that CMS	
19	confirmed “that MA plans are . . . not	
20	currently required to design their	
21	medical record reviews to determine	
22	the accuracy of risk adjustment	
23	diagnoses”); Schindler Decl. Ex. 13,	
24	MARA2152278 (June 26, 2015 email	
25	from S. Nelson to C. Rice regarding	
26	2013 DOS risk adjustment data	
27	attestation, noting “During our	
28	conversations last year before the	
	proposed rule was withdrawn, CMS	
	confirmed to us that the proposed	
	requirements would not apply until the	
	effective date of the rule, and that MA	
	plans were thus not required to design	
	their medical record reviews to	
	determine the accuracy of risk	
	adjustment diagnoses); Schindler Decl.	
	Ex. 20, USBP000498420 (June 7, 2016	
	email from S. Nelson to C. Rice	
	regarding 2014 risk adjustment data	
	attestation, providing similarly);	

1	UNITED’S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	Schindler Decl. Ex. 49, MA Supporting	
5	Documentation for CY2015 Bid, UHC	
6	of California, Inc., Contract No.	
7	H0543-001-000, at 8, dated Aug. 5,	
8	2014 (emphasis added) (providing:	
9	“We . . . adjusted projected risk scores	
10	to account for changes in our medical	
11	record review processes. Specifically,	
12	<i>based on multiple conversations with</i>	
13	<i>CMS and CMS’s treatment of medical</i>	
14	<i>record review in its recent rulemaking</i>	
15	<i>process, the health plan has decided to</i>	
16	<i>cease one of its prior processes that</i>	
17	<i>identified and deleted certain</i>	
18	<i>diagnoses codes through the medical</i>	
19	<i>record review process”).</i>	
20	E. Additional Material Facts Demonstrating That Under the Government’s	
21	Reading of the Contract, United’s Bid Limitations Stating that United Was	
22	Not Validating Codes Were Incorporated Into the Contract’s Payment	
23	Scheme As Well	
24	130. Article II of the MA contracts	
25	incorporates the “final Plan Benefit	
26	Package (PBP) bid submission (benefit	
27	and price bid proposal as approved by	
28	CMS. Rice Decl. Ex. 1, at 6.	
29	131. CMS requires MAOs to explain	
30	the assumptions underlying their bids,	
31	provide supporting documentation for	
32	their bids, and have an actuary certify	
33	that the assumptions are reasonable.	
34	<i>See, e.g., Schindler Decl. Ex. 51,</i>	
35	<i>Instructions for Completing the</i>	
36	<i>Medicare Advantage Bid Pricing Tools</i>	
37	<i>for Contracy Year 2014, at 95-110</i>	
38	<i>(Apr. 5, 2013).</i>	

UNITED’S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
132. Starting at least as early as 2011, United’s final Plan Benefit Package each year explicitly stated: “[C]onsistent with our prior year activities ... [a]s part of the preparation of the bids, we did not attempt to validate any actual or projected risk scores through a review of applicable medical records or of the systems used to submit RAF data to CMS.” Schindler Decl. Ex. 50, MA Supporting Documentation for CY2012 Bid, Pacificare of California, Inc., Contract No. H0543-007-000, at 5, dated June 5, 2011; <i>see also</i> Schindler Decl. Ex. 49, MA Supporting Documentation for CY2015 Bid, UHC of California, Inc., Contract No. H0543-001-000, at 8, dated Aug. 5, 2014 (stating in 2015 bid submission that “the health plan has decided to cease one of its prior processes that identified and deleted certain diagnosis codes through the medical record review process”).	
133. CMS reviewed and approved United’s bid submission prior to execution of the final contract. <i>See</i> 42 C.F.R. 422.256(b).	

1 Dated: July 23, 2018

LATHAM & WATKINS LLP
DAVID J. SCHINDLER
DANIEL MERON
KATHRYN H. RUEMMLER
ABID R. QURESHI

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5 By /s/ David J. Schindler
David J. Schindler
Attorneys for United Defendants
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Attorneys for United Defendants

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

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-MWF(SSx)

**DECLARATION OF ABID R.
QURESHI PURSUANT TO FED. R.
CIV. P. 56(D)**

*[Opposition to Motion for Partial
Summary Judgment; Statement of
Genuine Disputes; and Declaration of
David J. Schindler filed concurrently
herewith]*

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

1 **DECLARATION OF ABID R. QURESHI**

2 I, Abid R. Qureshi hereby declare as follows:

3 1. I am a partner at Latham & Watkins LLP, the law firm that represents
 4 UnitedHealth Group Incorporated and its affiliated entities named as Defendants in
 5 this action (collectively, “United”). I submit this Declaration pursuant to Federal
 6 Rule of Civil Procedure 56(d) to provide details on additional discovery required to
 7 further support United’s *Opposition to Plaintiffs’ Motion for Partial Summary*
 8 *Judgment* (the “Opposition”), filed concurrently herewith. I have personal
 9 knowledge, information, or belief of the facts stated herein and, if called as a witness,
 10 I could and would testify competently thereto.

11 **Through Discovery, United Expects to Develop Additional Evidence on**
 12 **Specific Factual Issues in its Opposition**

13 2. United disputes the government’s assertion that the *Plaintiffs’ Motion*
 14 *for Partial Summary Judgment* presents only legal matters, and not factual matters.

15 3. In discovery, United expects to develop additional evidence on many
 16 of the factual matters that supports the arguments in its Opposition.

17 4. For example, United expects to obtain documents from the government
 18 regarding numerous issues relevant to the Opposition, including, but not limited to:

- 19 a. The rate of unsupported codes in CMS’s own data and the impact
 20 the presence of such unsupported codes have on CMS’s payments
 21 to Medicare Advantage (“MA”) plans;
- 22 b. CMS’s course of performance in applying risk adjustment payment
 23 regulations and guidance in the context of Risk Adjustment Data
 24 Validation (“RADV”) audits of other health plans;
- 25 c. CMS’s understanding that it needs to apply a fee-for-service
 26 (“FFS”) adjuster to account for the presence of unsupported codes
 27 in its own FFS data before it can determine whether a given MA
 28 plan had been overpaid;

- d. The government's interpretation of the term "accurate" in the context of MA risk adjustment;
- e. The government's knowledge of whether or not MA plans were conducting "two-way" looks;
- f. The government's understanding that MA plans were not required to conduct two-way looks;
- g. The government's knowledge of MA plans' efforts to exercise reasonable diligence to report or return overpayments or to undertake due diligence to ensure the accuracy, completeness, and truthfulness of encounter data;
- h. The government's understanding of any requirements that medical record reviews be designed to determine the accuracy of provider-submitted diagnoses previously submitted by MA plans to CMS;
- i. Discussion and analysis of the overpayment standard, including the government's understanding of any requirements for plans to exercise reasonable diligence in reporting and returning overpayments;
- j. The government's understanding of any requirement or obligation that MA plans validate the accuracy of diagnosis codes submitted to CMS;
- k. Evidence that CMS officials reviewed United's attestations and did not think the qualifications United included in them were improper;
- l. Evidence that CMS officials understood the qualifications in United's attestations and therefore knew what they were approving by accepting them;
- m. Evidence that CMS officials accepted United's attestations with knowledge of the qualifications United included in them;

- n. Evidence that CMS officials reviewed United's bids and did not think the qualifications and assumptions United included in them were improper;
- o. Evidence that CMS officials understood the assumptions in United's bids and therefore knew what they were approving by accepting them;
- p. Evidence that CMS officials agreed to United's bids with the knowledge of the qualifications and assumptions United included in them;
- q. Evidence that the government understands the phrase "research data discrepancies" in the EDI agreements to be about glitches in the electronic transmission of data between an MA plan and CMS and not about auditing whether a provider code is supported by the medical record;
- r. The government's understanding that requiring MA plans to delete a substantial number of codes that were unsupported by the medical record would result in MA plans being underpaid;
- s. CMS's understanding that it has a statutory obligation under 42 U.S.C. § 1395w-23(a)(1)(C)(i) to "ensure actuarial equivalence" between MA and traditional Medicare programs and CMS's understanding of what it means to "ensure actuarial equivalence";
- t. CMS's acknowledgement and understanding that FFS and MA beneficiaries with identical characteristics should have identical risk scores and that requiring plans to delete unsupported codes without adjustment by CMS for the errors in its own FFS data violates the principle of actuarial equivalence;
- u. The government's interpretation and understanding of the phrase to "operate a coordinated care plan" in Article II of the MA contract

- 1 and that the provision does not address submission of risk
2 adjustment data or payment;
- 3 v. The government's knowledge of United's and other MA plans'
4 practices related to risk adjustment;
- 5 w. Additional evidence that, in 2009, United informed the U.S.
6 Department of Health and Human Services, Office of the Inspector
7 General ("OIG") that United was not performing two-way looks,
8 including documents and testimony related to the government's
9 internal discussion and analysis of this information;
- 10 x. The government's participation in discussions and meetings with
11 United in the spring and early summer of 2014 related to CMS's
12 proposed medical record review rule, *see* 79 Fed. Reg. 1918, 2000
13 (January 10, 2014) ("the Proposed Rule"), which would have
14 prohibited MA organizations from performing reviews that only
15 looked for additional diagnosis codes (known as "one-way"
16 reviews);
- 17 y. The government's knowledge and understanding of statements
18 CMS made to United in the spring and early summer of 2014 that
19 unless and until the Proposed Rule governing the review of medical
20 records became final, MA plans did not, and do not, have an
21 affirmative obligation to confirm whether diagnosis codes submitted
22 by physicians are supported in the medical records;
- 23 z. The government's understanding, knowledge, and approval of
24 United's practices, including conducting "one-way" reviews; and
- 25 aa. Evidence that the government believes that MA plans have to delete
26 codes that are unsupported only where the MA plan has actual
27 knowledge the codes are unsupported, not where the MA plan
28

1 potentially should have known the codes are unsupported or has
2 knowledge as that term is defined in the False Claims Act.

3 **Discovery in this Action is Ongoing**

4 5. Discovery in this matter commenced on or about July 17, 2017.

5 6. Plaintiffs have proposed fact discovery in this matter continue until
6 May 31, 2019. *See* Ex. A to the Amended Joint Rule 26(f) Report, Dkt. 224-1.

7 7. United served its first set of requests for production of documents to the
8 government on or about August 24, 2017.

9 8. United served its second set of requests for production of documents to
10 the government on or about January 19, 2018 and its third set of requests for
11 production of documents to the government on or about July 16, 2018.

12 9. United's first, second, and third requests for production seek documents
13 related to specific factual issues highlighted in United's Opposition and listed in
14 Paragraph 4 above.

15 **The Government Has Not Yet Responded**

16 **Fully to Outstanding Discovery Requests**

17 10. The government did not begin producing documents until February 22,
18 2018, almost six months after United served its first set of requests.

19 11. As of July 23, 2018, the government has produced fewer than 40,000
20 documents. In contrast, United has produced over 230,000 documents and
21 approximately 7 billion records on four two-terabyte hard drives to the government
22 in this litigation thus far. This is in addition to the approximately 600,000 documents
23 United produced to the government during the government's investigation of this
24 matter and the approximately 34,000 documents United produced to the government
25 in the now-dismissed *United States ex rel. Swoben v. Secure Horizons*, CV-09-5013-
26 JFW (JEM), which the government considered a related case, *see* United States' Not.
27 of Mot. & Mot. for Consolidated Actions, 271 at 2; Joint Representation Pursuant to
28 Fed. R. Civ. P. 26, Local Rule 26-1, and Court's Feb. 21, 2017 Order 287, at 8.

12. The government's own statistical data indicates that it is currently only producing approximately 53% of responsive documents, plus or minus a 5.24% margin of error, meaning the government may be producing as little as 48% of the responsive universe of documents. Attached hereto as Exhibit 1 is a true and correct copy of the government's correspondence dated April 6, 2018 regarding its statistical data.

13. United understands the government is continuing to produce documents in response to United's first and second set of requests.

14. The government has not yet begun its production of documents in response to United's third set of requests, and its responses to these requests are not due until mid-August 2018.

15. Subject to making progress with the government at an upcoming discovery conference, United intends to move to compel the government to improve its review efforts and produce additional documents responsive to the first, second, and third set of requests.

The Government is Refusing to Produce Certain Documents

16. Despite numerous and ongoing efforts to resolve discovery disputes between the parties, the government refuses to produce particular categories of documents that are relevant to issues in United's Opposition.

17. For example, the government is refusing to search the electronic files of particular key individuals from the OIG in connection with responding to at least eleven specific document requests issued by United. *See* United States' May 22, 2018 Ltr. to United at 4.

18. Among other things, these requests seek documents in OIG's possession related to overpayment standards, guidance, and rules, including but not limited to whether MA plans were required to look both ways and the government's knowledge as to whether MA plans were looking both ways.

1 19. Attached hereto as Exhibits 2, 3, and 4 are true and correct copies of
 2 United's and the government's April 27, 2018, May 15, 2018, and May 22, 2018
 3 correspondence reflecting the government's refusal to include OIG as custodians for
 4 certain requests.

5 20. The government also is refusing to produce documents from other
 6 investigations of Medicare Advantage plans, claiming that such documents are "not
 7 proportional to the needs of this case . . . and thus are well outside the bounds of
 8 permissible discovery." *See* United States' Apr. 6, 2018 Ltr. to United at 3.

9 21. Attached hereto as Exhibits 1, 3, and 4 are true and correct copies of
 10 United's and the government's April 6, 2018, May 15, 2018, and May 22, 2018
 11 correspondence reflecting the government's refusal to produce documents related to
 12 investigations of other MA plans.

13 22. On May 1, 2018, pursuant to Local Rule 37-1, the parties had a
 14 telephonic conference to try to resolve the areas of disagreement regarding the
 15 government's refusal to produce documents from the electronic files of key
 16 individuals from OIG and documents related to other investigations. However, the
 17 parties were unable to come to a resolution.

18 23. On July 12, 2018, Magistrate Judge Segal held an informal discovery
 19 conference on these and other discovery issues. *See* Tr. of Telephonic Conference
 20 Regarding Discovery, *United States ex rel. Poehling v. UnitedHealth Group, Inc.*,
 21 No. 2:16-cv-08697-MWF-SS (July 12, 2018). Based on the informal discovery
 22 conference, United expects formal briefing will be required to reach a resolution on
 23 the appropriate scope of discovery of these issues.

24 **The Government's Assertion of Deliberative Process Privilege**
 25 **Deprives United of Documents Relevant to its Opposition**

26 24. Based on the government's description of documents in its privilege
 27 logs, the government is withholding several categories of documents on grounds of
 28 deliberative process privilege.

25. In particular, according to the four privilege logs provided by the government, it is withholding over 7,500 documents based solely on the grounds of deliberative process privilege.

26. The government's descriptions of these withheld documents suggest they are highly relevant to the facts and arguments highlighted in the Opposition, including, but not limited to, "RADV audit methodology," "calculation of RA error rate," "calculation of RA factors/model," "calculation of coding intensity adjuster," "FFS adjuster," "RA supporting documentation requirements," and "medical coding in support of RA payments."

27. Attached hereto as Exhibits 5 and 6 are true and correct copies of United's and the government's correspondence dated June 15, 2018 and June 29, 2018, respectively, regarding deliberative process privilege.

28. As explained to Magistrate Judge Segal during the informal conference held on July 12, 2018, United intends to challenge the government's assertions of the deliberative process privilege. Tr. of Telephonic Conference Regarding Discovery at 65–66, *United States v. United Health Group, Inc.*, No. 2:16-cv-08697-MWF-SS (July 12, 2018).

**Because of the Government's Delays and Refusals in Document Production,
United Has Taken Only Two Depositions**

29. As of July 20, 2018, United has taken only two depositions of government witnesses.

30. As discovery progresses, United expects to take additional depositions of current and former government personnel regarding issues raised in United's Opposition.

31. During one of these depositions, Mr. Jeffrey Grant, a current CMS official who helped create the risk adjustment payment system, provided testimony that supports United's Opposition. Attached as Exhibits 6 and 7 to the Declaration of David J. Schindler in Support of United's Opposition to Plaintiffs' Motion for

1 Partial Summary Judgment is a true and correct copy of excerpts of Mr. Grant's
2 video-taped deposition transcript.

3 32. For example, Mr. Grant testified on several factual issues highlighted
4 in the Opposition:

5 a. Q: "Sir, let's go back to your email. In the same section, you write:
6 'Plans were told that if they stuck to how the data comes into FFS,
7 they would be paid correctly.' Did I read that correctly?"

8 A: "Yes."

9 Q: "And was that a true statement when you wrote it?"

10 . . .

11 A: "The concept that it is conveying, again, I do not want to say that
12 – like, I'm summarizing conversations with plans here, not giving
13 direct quotes. That's all I want to say. So as the general concept
14 reflected by the entire paragraph in an email, I am trying to – not a
15 policy document or something else. I am in a brief email trying to
16 summarize issues that I believe exist with an extrapolation. And one
17 of them is the assurances that if they submitted data like fee for
18 service, they would be paid equivalent to the calibration and they
19 didn't need to worry about finding out data to supplement fee-for-
20 service data." Transcript of Deposition of Jeffrey Grant 207:20–
21 208:17 (May 16, 2018).

22 b. When people talk about "accuracy" in the context of risk
23 adjustment, "[t]hey are using accuracy not to talk about whether any
24 specific diagnosis code in fee-for-services or managed care is
25 accurate," but rather "to have comparable diagnoses. . . . [W]hen
26 they say 'inaccurate' they are not referring to the accuracy or
27 inaccuracy of any specific code on any specific claim or any specific
28

1 RAP submission. They're talking about comparable types of data."
 2 *Id.* at 174:21–175:8.

3 c. "[T]he definition of accuracy here," is that MA plans "would be paid
 4 consistently with how the model is calibrated." *Id.* at 182:6–8.

5 d. Q: "Well, I want you now to assume, sir, in this hypothetical world
 6 that the coding intensity adjuster that we talked about earlier, I want
 7 you to assume that it fully offsets any activities that the plan
 8 undertakes to code more completely, chart reviews, home visits,
 9 whatever, but they're completely offset by the coding intensity
 10 adjuster. If the plan were to submit only the codes of people who are
 11 truly sick, to use your presentation example [Exhibit 1017], then that
 12 plan would be underpaid."

13 . . .

14 A: "In a hypothetical word that you are creating . . . in that world, in
 15 theory, yes . . ."

16 . . .

17 Q: "Mr. Grant, I want you to again assume that the coding intensity
 18 adjuster fully offsets all the activities that a plan might undertake to
 19 code more fully. I also want you to assume that a plan audits every
 20 one of its charts and deletes every unsupported code. The problem
 21 that you highlight in your slide presentation, Exhibit 1017, would
 22 still exist in that scenario?"

23 . . .

24 A: "In my opinion, if you could have that scenario, yes."

25 Q: "The problem would still exist?"

26 A: "The problem would still exist if you have that scenario."

27 Q: "Okay. Now I'd like to change the assumption slightly. Once
 28 again, the coding intensity adjuster fully offsets all activities that the

1 plan undertakes that code more fully, but now the plan audits 50
 2 percent of a chart, of its charts, and deletes the unsupported codes in
 3 that set. Would the problem still exist?"

4 . . .

5 A: "Okay, we have multiple assumptions right? So we have the
 6 assumption that overcoding is the bias in the data. We have the
 7 assumption of perfect adjustment for plan coding activities. To a
 8 degree, it exists. It exists to a smaller amount."

9 Q: "Same assumption regarding the coding intensity adjuster, but
 10 now the plan is auditing 25 percent of its charts and deleting the
 11 unsupported codes. Does the problem still exist?" *Id.* at 274:22–
 12 277:16.

13 . . .

14 A: "Again, assumption of overcoding, endemic in fee for service,
 15 and assumption of plan – plan coding activities being 100 percent
 16 offset in theory it exists to the degree that diagnosis codes are
 17 deleted." *Id.* at 276:7–277:22."

18 e. Q: "Mr. Grant, I believe you testified earlier there was at least one
 19 plan for which you recall HRP performed a chart review while you
 20 were there; is this correct?"

21 A: "Well there's . . . more than one plan that we performed chart
 22 reviews for, yes."

23 Q: "Yeah. For the purpose of adding codes, you recall at least one
 24 plan?"

25 A: "Yes."

26 Q: "And do you recall the identity of the plan?"

27 A: "I do."

28 Q: "Okay. What is the identity?"

1 A: "It was Coventry."

2 Q: "And in connection with that project, were you the relationship
3 manager with Coventry?"

4 A: "I was the overall relationship manager for Coventry, like all
5 clients . . ."

6 Q: "Is it fair to say that you were involved in that engagement?"

7 A: "Right. And I oversaw all of our client engagements. I was the
8 senior vice president for client services. I had client services that
9 did the day-to-day for any client, and then if it was a special project
10 that involved special skills, we might have people that were further
11 managing the relationship with respect to that skill set because it
12 required specialized skill."

13 Q: "Understood. The one instance in which you recalled in which
14 there were review of charts to add codes, do you recall whether there
15 were any efforts to reconcile those codes against previously
16 submitted claims data?"

17 . . .

18 A: "So from a coding perspective, we did totally blind coding, so
19 the coders had no idea what was previously submitted. We did have
20 the capacity not to duplicate submit [sic] diagnoses. We weren't
21 going one for one and trying to look at claims data and see if every
22 claim was one-for-one backed by a diagnosis on that date."

23 Q: "As part of this effort, did HRP compare the codes identified in
24 the blind coding effort against the claims data that was submitted by
25 providers and delete codes that HRP's coders did not identify?"

26 . . .
27
28

1 A: "I'm not sure. I believe we may have done – not systematically,
2 not on a large-scale basis, but I believe there were cases where we
3 did."

4 Q: "And at that time, did you have a belief that not engaging in such
5 a systematic effort was improper?"

6 . . .

7 A: "At that time, no."

8 Q: "Okay. At that time, did you think it was fraud?"

9 A: "No, I did not knowingly participate in [a] fraudulent activity
10 [laughter]."¹ *Id.* at 307:11–310:16.

11 f. Q: "Mr. Grant, is that sort of what the purpose is of slide 2? You're
12 referencing a healthy personal mistakenly coded as sick and then
13 assigning the relative cost to that individual?"

14 . . .

15 "A. Yes. So this is again, with the God-like power to know
16 everybody's cost, I know that these healthy people coded as sick cost
17 the same as all the other healthy people and I magically already
18 know they all cost \$500, an unknowable fact when running a risk
19 adjustment calibration, but in this world I've created I know this.
20 And so I have two people thrown into the sick category from a
21 coding perspective, but from a cost perspective appropriately
22 residing in the healthy category . . . And as you see from this -- and
23 this is only -- by the way, it's a one-directional look at this, I will
24 point out too, just looking at the incorrect coding, not going the other
25 direction. The incorrectly -- incorrectly coded as sick, not healthy,
26

27 ¹ For a discussion of this portion of the transcript, please see United's Statement
28 of Genuine Disputes of Material Fact in Opposition to Plaintiffs' Motion for Partial
Summary Judgment at 44–45 n.8.

1 incorrectly coded as healthy. It's not a robust presentation that has
 2 both sides. It's a one sided -- . . . And then we just walk through it
 3 and say we haven't thrown any sick people into the healthy category
 4 erroneously, so healthy people still cost 500 bucks apiece. But by
 5 virtue [sic] adding two healthy people into the sick population, you
 6 lower the perceived average cost of the sick population....”

7 Q: “So what is the principle that you’re illustrating with this
 8 example?”

9 . . .

10 A: “That if there is a pattern of overreporting of diagnosis codes in
 11 fee for service, then that pattern would result in a underprediction of
 12 the disease-related factors in the model...” *Id.* at 229:3–231:15.

13 g. On cross-examination by Stephen Hasegawa, Grant testified as
 14 follows:

15 Q: “Does the existence of error within the MA Part C risk
 16 adjustment model mean that MA providers can submit knowingly
 17 incorrect data?”

18 A: “No.”

19 Q: “Have you ever held the opinion that it does?”

20 A: “No.”

21 Q: “Have you ever told anybody that the existence of error within
 22 the model means that MA providers can submit knowingly incorrect
 23 data?”

24 A: “And can we define terms?”

25 Q: “Okay.”

26 A: “When you say ‘knowingly incorrect,’ it is a *very* specific
 27 submission of a *very* specific data element saying[,] *that* I know is
 28 wrong.” *Id.* at 321:6–23 (emphasis in video transcript).

1 h. In response to additional questions from me on redirect, Grant
2 testified as follows:

3 Q: “Mr. Grant, if HRP in the instance that you highlighted did the
4 blinded review and didn’t do a systematic reconciliation with the
5 provider-submitted codes, is it your understanding that HRP knew
6 it was submitting specific bad codes?”

7 . . .

8 A: “We were not submitting any bad codes.”

9 Q: “Were you facilitating the submission of specific bad codes by
10 the plan in that instance?”

11 . . .

12 A: “No. I think – that’s not how we looked at it. We – the codes
13 were already in. We were not doing a review to systematically do a
14 complete audit of a plan and determine the accuracy of codes. We
15 were sometimes asked to do that, and if we were asked to do that,
16 we could do a very careful review. I mean, it’s a different style
17 review when you want to put in the effort that you need to do to
18 absolutely make sure that a code is backed up.” *Id.* at 322:18–
19 323:15.

20 33. United expects that additional depositions of other CMS officials
21 involved in creating and implementing the risk adjustment payment system will
22 provide facts further supporting the arguments in the Opposition.

23 I declare under penalty of perjury that the foregoing is true and correct.

24 Executed on July 23, 2018, in Washington, D.C.

25
26 By /s/ Abid R. Qureshi

27 Abid R. Qureshi

28 Attorney for United Defendants

EXHIBIT 1



U.S. Department of Justice

Civil Division

Washington, DC 20530

April 6, 2018

By Electronic Mail

David W. Rowe
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116

Re: Response to UnitedHealth's March 23, 2018 Letter Regarding the United States' Collection, Review, and Production Protocol and Schedule in *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*

Dear David:

We write to respond to your letter dated March 23, 2018, regarding the United States' collection, review, and production protocol and schedule, and to provide an update on our Technology Assisted Review ("TAR") process and additional information about our document custodians.

I. Document Production Schedule and TAR Metrics

On March 28, 2018, we delivered our third production of documents. Many of the documents within this production were coded for responsiveness by our TAR system during our first project, which is now complete. Consistent with the parties' prior agreement, we provide the following metrics from that project: (1) the non-responsive overturn rate is 4% at a calculated margin of error of 2.5%; (2) the TAR report calculating precision and recall demonstrates that the overall project efficacy has been met; (3) precision and recall are between 67.64% and 53.45% respectively, which indicates stabilization; and, (4) the F1 value, a weighted average of precision and recall, is 59.71%. We trust you will provide similarly detailed metrics once you complete your first TAR project.

As we stated in the cover letter to our March 28 production, we recently determined that we must manually review every document for privilege and confidentiality prior to production. Given this adjustment, all documents coded responsive (and their non-responsive family members) by any future TAR project will be folded into our current and ongoing review, and those documents that we determine are not privileged will be produced on a rolling basis

approximately every four weeks. You can therefore expect our fourth production by April 27, 2018.

II. Search Terms

Request No. 1

We respectfully disagree that the search strings we are using to identify documents responsive to Request No. 1 are “far too narrow and will not adequately capture the documents UnitedHealth is seeking.” While Request No. 1 seeks documents regarding prior RADV *methodologies*, your revision seeks documents unrelated to RADV methodologies. For example, adding the term “guid*” will hit on any RADV guidance or guidelines. Adding “process*” and “audit*” will hit on documents reflecting RADV processing and audits.

In an effort to reach a mutually agreeable resolution, we have added the following additional search string to identify documents responsive to Request No. 1: (RADV or “Risk Adjustment Data Validation”) and (“payment error calculat*” w/20 (guid* OR process* OR audit*)).

Request No. 21¹

It is our understanding that the risk scores contained in the bid pricing tool are only reviewed by OACT. We also note that certain of the bids included on Exhibit 1 of your December 22, 2017 letter are PDP (S contract) bids, and to our understanding do not involve Medicare Advantage. Please confirm that UnitedHealth intentionally included PDP (S contract) bids in Exhibit 1. Additionally, please confirm whether UnitedHealth seeks as part of this Request documents solely related to the Part D review of MAPD plans (H contract) bids included in Exhibit 1.

III. Direct Collections

Your statement that our decision to utilize direct collection, targeted searches, or a combination of both to identify documents responsive to each of UnitedHealth’s requests “suggests that [the United States] is refusing to satisfy its discovery obligations under Federal Rule of Civil Procedure 26” is contrary to both the facts and an understanding of what the Federal Rules require. As we stated in our letter dated March 2, 2018, we as the responding party are best situated to determine what is reasonable and proportional under the circumstances. *See* The Sedona Conference, Commentary on Defense of Process: Principles and Guidelines for Developing and Implementing a Sound E-Discovery Process, September 2016 at 11-13 (“Under the Federal Rules and similar state court rules, the responding party has the obligation and right to make decisions concerning the processes they will employ to comply with their discovery obligations.”) That includes the particular methods we use to collect documents. We are confident our collection efforts are reasonable and proportional under the circumstances and fully comply with the Federal Rules.

As we told you during our conversation on February 21 and reiterated in our March 2 letter, we are willing to consider collecting documents through direct collection in addition to

¹ In your March 23, 2018 letter, you mistakenly captioned this section Request No. 48.

targeted searches for particular requests, but we are only undertaking additional collection efforts when the direct collection sources are identifiable and the documents within those sources are not already being collected through a targeted search. That is why we are performing direct collections for Request Nos. 5 and 60. We are not performing a direct collection for Request No. 7 because we are confident our targeted search will identify the responsive material you are seeking and that we have agreed to produce. The specific documents you claim we should directly collect (*i.e.*, annual risk adjustment error rates) are publicly available, and thus equally available to you. *See* United States' Responses and Objections to UnitedHealth's Requests for Production (Set No. One) at 16.

We additionally will not perform a direct collection for Request No. 29 because we do not believe it will identify documents beyond those our targeted search will identify. And many of the documents you seek are publicly available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html>. Instead of a direct collection, we agree to include this additional search string to ensure we are collecting all documents responsive to this request: "Medicare Managed Care Manual" AND "rev." AND (("chapter 7" w/3 "risk adjustment") OR ("chapter 21" w/3 "Compliance Program Guidelines")) AND "table of contents".

We have previously informed you that we will perform direct collections of documents responsive to Request Nos. 12 and 13. We provide the following clarification about those productions for Request No. 12 for the years 2011-18 and Request No. 13 for the years 2013-15 (subject to and without waiving our prior objections):

- We will produce the following available data in CMS' Health Plan Management System ("HPMS") that is responsive to Request No. 12: templates for each contract from contract years 2011-18 and Excel spreadsheets for the same years which have information populated in the following fields: contract_id, contract_name, parent_org_name, document, cm_partc_signatory, cms_partc_signatory_date, cms_partd_signatory, organization_signatory, and organization_signatory_date.
- We will produce the following available data in HPMS that is responsive to Request No. 13: the template of language for the attestation for contract years 2013-15 and Excel spreadsheets for contract years 2013-15 entitled "Risk Adjustment Certification Reports" which include information that is stored in the HPMS system: MAOs' Contract ID, Contract Name, Certification Status, Certification Date, and Certified By.

IV. Materials Related to Other Investigations

We will not agree to produce documents concerning investigations unrelated to this action contained in the files of custodians from the Office of Investigations and Office of Counsel to the Inspector General of the U.S. Department of Health and Human Services. Discovery into investigations unrelated to this action is not "proportional to the needs of the case," Fed. R. Civ. P. 26(b)(1), and thus are well outside the bounds of permissible discovery, Fed. R. Civ. P. 26(b)(2)(C). Discovery into what the government has learned about the conduct of unrelated Medicare Advantage plans, whether the information was sufficient to demonstrate a violation of law, whether the government had "actual knowledge" of the violations, *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003-04 (2016), and what

action was taken, is well beyond what is proportionate to the needs of the case (and appropriate discovery). As you recognized in your letter of March 27, 2018, “a refined selection of custodians is required under the proportionality factors, where the burden and expense of the requested discovery outweigh the likely benefit.” *See* Mar. 27, 2018 Ltr. fr. Kirstin Scheffler Do (“Mar. 27, 2018 Ltr.”) to Carol Wallack, at 2 (citing *Oracle Am., Inc. v. Google, Inc.*, No. 10-CV-03561, 2015 WL 7775243 (N.D. Cal. Dec. 3, 2015)).

In an attempt to reach agreement on this issue and without waiving our objection to producing investigative material and the other objections set forth in our responses and objections to defendants’ requests for production of documents regarding the production of documents pertaining to other MA plans, we have agreed to search for and produce responsive, non-privileged documents contained in the files of CMS custodians that respond to particular requests for production outlined in the United States’ November 22, 2017 letter. Although UnitedHealth contends that the decision in *United States ex rel. Dean v. Paramedics Plus, LLC*, No. 4:14-CV-0023, 2018 WL 620776 (E.D. Tex. Jan. 20, 2018) controls all False Claims Act actions, the Advisory Committee notes to the 2015 amendments to the Federal Rules emphasize that the question of proportionality is a “case-specific determination.” But even if the non-binding decision in *Paramedics Plus* had any application here, our proposal is in line with that decision. As here, defendants requested “any communications” concerning the fraud alleged there (“a profit cap”). 2018 WL 620776 at *7. The court ordered the production of only those “documents pertaining to the Government’s continued payment of claims after discovery of a profit cap.” *Id* *7. Because neither the Office of Investigations and Office of Counsel to the Inspector General plays any role in the government’s payment decision that your client apparently seeks to probe in such discovery, we have appropriately objected to this discovery and limited it to CMS custodians, as CMS is the only entity responsible for the payment decision at issue.

Finally, virtually all of the investigative documents maintained by the Office of Investigations and Office of Counsel to the Inspector General would be subject to a claim of law enforcement or attorney-client privilege. UnitedHealth’s agreement (“at least at this time”) “not to seek the production of document related to currently sealed *qui tam* actions” fails to address the fundamental disagreement of the parties. And the government will not agree to produce purely investigative documents pursuant to the attorneys’ eyes-only protective order. While such procedures may be employed to protect trade secrets and other information, it is an inadequate mechanism to protect law enforcement sensitive information. *See e.g., In re City of New York*, 607 F.3d 923, 936 (2d. Cir. 2010) (recognizing that “[e]ven if ‘the attorneys’ eyes only’ procedure works in some commercial litigation, as well as some criminal cases, the consequences of accidental disclosure are too severe to employ the procedure” to protect law enforcement sensitive information) (emphasis & internal citations omitted). And your client has similarly refused to search and review communications from its attorneys on proportionality grounds, on the ground that all such communications are likely to be covered by the attorney-client privilege. Mar. 28, 2018 Ltr. at 2. We are doing likewise.

V. Custodians

After further analysis, including assessing the results of our document review to date, compiling our first privilege log, and in accordance with the above paragraph and principles of

proportionality within Fed. R. Civ. P. 26(b)(1), we have refined the custodians from the Office of Inspector General from whom we will produce documents responsive to certain of your requests (consistent with our Responses and Objections and subsequent letters), as reflected in Attachment A. We will not produce documents (other than those already produced) from anyone within the Office of Counsel to the Inspector General, including Julie Taitsman, Geeta Taylor, Lisa Veigel, Sarah Kessler, and Susan Gillin. Because these individuals are attorneys, the vast majority of their documents are privileged. Reviewing almost 200,000 documents simply to log them as privileged is overly burdensome and therefore inconsistent with Fed. R. Civ. P. 26. This adjustment is consistent with UnitedHealth's position not to include attorneys as custodians.²

For custodians from the Office of Investigations (Peggy Glenn and Kirin Hage), we will produce documents responsive to Request Nos.: 2, 3, 17, 18, 19, 20, 29, 31, 32, 40, 41, 49, 59, 60, 61, 2-10, 2-11, and 2-12 (subject to the limitations explained in the prior section of this letter). For custodians from the Office of Audit Services (Cheryl Oka, Chris Bresette, Dan Bittner, Dustin Litwiler, Jaime Saucedo, Juliet Lo, Lisa Lara, Mike McGuire, Nicole Freda, Steve Garrison, Stephen Conway, Tommy Lin, Vlada Hutton, and William Hill), we will produce documents responsive to Request Nos.: 2, 3, 5, 17, 18, 19, 20, 29, 31, 32, 40, 41, 59, 60, 61, 2-10, 2-11, and 2-12. We have revised several search strings for custodians within these two offices to better reflect what we have agreed to produce.

We have included in Attachment B additional information about our custodians. For current-employee custodians, we are providing relevant job titles and dates of employment. For former-employee custodians, we are providing each custodian's last job title. We will update this list as we identify additional information. We trust you will send us similarly detailed information about UnitedHealth's custodians.

Please let us know if you have any questions.

Sincerely,



Paul Perkins
Trial Attorney
Civil Division, Fraud Section

Attachments

CC: Counsel of Record

² UnitedHealth's March 27, 2018 proposal to include Thad Johnson as a custodian for the limited purpose of reviewing his records when he acted as a fact witness at the April 29, 2014 meeting between CMS and UnitedHealth does not diminish this fact. And as UnitedHealth knows, the United States has no similarly situated attorneys as UnitedHealth did not notify the Department of Justice about the April 29, 2014 meeting prior to its occurrence.

EXHIBIT 2



U.S. Department of Justice

Civil Division

Washington, DC 20530

April 27, 2018

By Electronic Mail

David W. Rowe
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116

Re: Response to UnitedHealth's April 23, 2018 Letter Regarding the United States' Collection, Review, and Production Protocol and Schedule in *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*

Dear David:

We write to respond to your letter dated April 23, 2018, regarding the United States' collection, review, and production protocol and schedule.

I. Technology Assisted Review

On April 6, 2018, we provided a number of metrics associated with our first Technology Assisted Review ("TAR") project. Your concerns about these metrics are misplaced. In addition to Recall, overall TAR project metrics are measured against Precision and F1, which were 67.64% and 59.71%, respectively. A number of other factors, such as control set richness (percentage of responsive documents) and volatility (changes in categorization from round to round) are also taken into consideration. Recall rate alone therefore is not indicative of flaws or deficiencies in a given TAR project—particularly where there is low richness, as the TAR tool must make relevancy decisions based on a narrow set of concepts.

For our first TAR project, we reached stabilization after performing numerous rounds of review (Training and Quality Control), evaluating the computer coding against the control set statistics after each round, monitoring volatility between rounds, and reducing the uncategorized document population to statistically insignificant levels (less than 1%). The estimated margin of error on our recall rate was +/- 5.24%. The sample size of our control set was 1,533 documents. These documents were drawn from the entire TAR population and selected using random statistical sampling (+/- 2.5% margin of error and 95% confidence level). 22.7% of the documents were identified as responsive and 77.3% were identified as not responsive.

It is also significant that in our Training and Validation rounds, there were very few increases in responsive records added (we saw fluctuations of less than 1% in the last few rounds). In reviewing the totality of statistics, the lack of growth in volume of responsive documents, and the statistical stability indicated the complete universe of responsive documents had been identified and the TAR project was complete. Our conclusions have been confirmed by Relativity.

While we have been transparent with our TAR process, we are concerned with your lack of transparency to date. You have not yet provided TAR metrics—or even indicated whether you have completed a TAR project. By May 4, please inform us of the status of your TAR process, and if you have completed a project, please also provide the agreed-upon metrics, including the additional information you requested and that we have now provided in this letter.

II. Searches

We reviewed your proposed revisions to our searches and accepted many of them. To several searches, we added the “within” limiter and made other revisions to better identify documents that are truly responsive. We did not accept your proposed revision to our search for Request No. 11, because that Request seeks documents “relating to Risk Adjustment,” and your revision seeks “emails to/from/cc/bcc broadcast@iceforhealth.org or domain iceforhealth.org” without limitation.

Our revised searches are included in Attachment A. We trust they are acceptable to UnitedHealth and it considers them final. We will proceed with these final searches unless we receive comments by May 4. We reserve our right to revise these searches to better identify documents we have agreed to produce and to conform to the proportionality requirement within Fed. R. Civ. P. 26(b). We will notify you of any revisions.

Request No. 1

We are disappointed that you have rejected our repeated efforts to reach a mutually agreeable solution to the parties’ disagreement about the searches necessary to identify documents responsive to Request No. 1. We reiterate that your revisions to our search capture documents beyond what we have agreed to produce. However, in order to resolve this disagreement, which as we have noted is delaying our document collection, review, and production efforts, we agree to your revised search.

Request No. 21

We appreciate your confirmation that you intentionally included PDP (S contract) bids in Exhibit 1 to your December 22, 2017 letter. Based on this information, we will also include the MAPD plans (H contract) bids that you included in Exhibit 1 as part of our collection for Request No. 21.

Collective Searches

More than eight months ago, we proposed relying upon collective searches to identify documents responsive to a number of your Requests in *United States ex rel. Swoben*. Aug. 14, 2017 Letter From J. Krieg and P. Perkins to A. Robinson, at 1. In your subsequent responses and during the parties’ numerous meetings regarding discovery you did not express concerns or raise questions about this issue. Therefore, to meet the discovery deadlines in that case, we proceeded

with our document collection and review process relying upon this technique. Three months later, we informed you that we would utilize the same technique to identify documents responsive to a number of your Requests in this case. Nov. 22, 2017 Letter From J. Krieg and P. Perkins to A. Qureshi, at 2. Again, you did not raise concerns or questions about this approach in your subsequent responses and during the parties' meetings. We therefore continued our document collection and review process unchanged.

Eight months after first informing you of our use of this collection method, you have inquired into the meaning of "collective searches." Your failure to challenge, let alone question, our use of collective searches over the past eight months forecloses your ability to demand a different method of identifying the universe of responsive documents. That point aside, to identify documents responsive to Request Nos. 38, 42, 43, 44, 46, 47, 52, 53, 54, 55, 56, 69, 70, 71, 72, 74, 75, 2-13, 2-14, and 2-17, we are relying upon all of our searches in Attachment A (*i.e.*, our collective searches). In other words, the searches we are using to identify documents responsive to your various Requests will also identify documents responsive to the above-Requests; therefore, unique searches are unnecessary.

As we have stated on numerous occasions, we as the responding party are best situated to determine what is reasonable and proportional under the circumstances. *See* The Sedona Conference, Commentary on Defense of Process: Principles and Guidelines for Developing and Implementing a Sound E-Discovery Process, September 2016 at 11-13 ("Under the Federal Rules and similar state court rules, the responding party has the obligation and right to make decisions concerning the processes they will employ to comply with their discovery obligations.") That includes the particular methods we use to collect and identify responsive documents. We are confident these efforts, including our use of collective searches, are reasonable and proportional under the circumstances and fully comply with the Federal Rules.

III. Collections

Request No. 8

More than five months ago, we informed you that we would collect documents responsive to Request No. 8 through a direct collection. Nov. 22, 2017 Letter From J. Krieg and P. Perkins to A. Qureshi, at 1. Now, five months later, you have asked us for the first time to "provide more information about how the government is collecting data responsive" to this Request. Again, your repeated failure to question our approach forecloses your ability to demand a different approach.

Despite the fact that we are under no obligation to provide this additional information, we note that information about the entire set of documents responsive to this Request (and the documents we will produce) is available on CMS's website¹. As you have requested, we will prioritize our production of documents responsive to this Request. Your demand that we produce ten years of data in less than three weeks, however, is clearly unreasonable. Not only is that date between our fourth and fifth rolling productions, requiring us to provide three productions in four weeks, it is far less time than you agreed to produce the data that we asked you to prioritize. In fact, we first requested that you prioritize the production of data on

¹ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/index.html>

December 14, 2017. Nearly a month later, UnitedHealth agreed to provide a limited set of this data by April. UnitedHealth still has not produced even this limited data, although you have committed to produce it today—over four-and-a-half months after we first requested it. Accordingly, we will try to produce this data by August, although we will endeavor to produce it before then.

Request Nos. 12 & 13

In our April 6, 2018 letter, we identified the specific documents for the specified time periods that we would produce responsive to Request Nos. 12 and 13. This is the only available data responsive to those Requests because, beginning in CY 2011, MA contracts were submitted online through the Health Plan Management System (“HPMS”) system. As we understand the process, an individual from a parent organization electronically signs a template for each contract associated with their plans. The individual signing the documents has the option to “create” a PDF of the signed document at any point after electronically signing the document. To create the PDF, the system populates the contract template with the signature information for the plan as well as the signature information for CMS. A copy of the signed document is not, however, stored separately in the HPMS system.

Additionally, CMS began accepting signed attestations electronically through HPMS in 2014. It is our understanding that representatives for MA Organizations access HPMS and sign the “Risk Adjustment Certification,” which includes standard template language, by selecting a box within HPMS that indicates certification for every MA plan for which the individual is authorized to sign. HPMS then saves in its system the MA Organizations’ contract information and certification date for all of the MA Organizations’ plans. However, a specific signed attestation is not stored as an individual document in the HPMS system.

IV. Custodians

In our April 6, 2018 letter, we stated, “[a]fter further analysis, including assessing the results of our document review to date, compiling our first privilege log, and in accordance with the above paragraph and principles of proportionality within Fed. R. Civ. P. 26(b)(1), we have refined the custodians from the Office of Inspector General from whom we will produce documents responsive to certain of your requests (consistent with our Responses and Objections and subsequent letters).” In particular, we removed OIG as a custodian for Request Nos. 7, 26, 27, 28, 33, 34, and 39, because those Requests do not seek documents in the possession of OIG-OAS and OIG-OI custodians, and to the limited extent they do, the burden of collecting and reviewing those documents is not proportional to the needs of the case. *See, e.g.*, Request No. 27 (“All Documents regarding CMS’s ‘Reporting and Returning of Overpayments’ proposal”); Request No. 33 (“All Documents reflecting discussion or analysis of CMS’s overpayment standard”).

We also stated in our April 6 letter that we “revised several search strings for custodians within [HHS-OAS and HHS-OI] to better reflect what we have agreed to produce.” We specifically narrowed our searches for custodians within OIG-OAS and OIG-OI for Request Nos. 2, 3, 17, 18, 19, 40, and 41 to require the presence of “Poehling,” “Swoben,” or variations of “UnitedHealth.” For custodians within OIG-OI, we have already informed you that we will not produce documents concerning investigations unrelated to this action. *See, e.g.*, April 6,

2018 Letter from P. Perkins to D. Rowe, at 3-5. Therefore, all documents responsive to these Requests will necessarily relate to UnitedHealth.

As you know, OIG-OAS conducts independent audits of HHS programs, grantees, and contractors. Custodians identified from this office have worked on audits of Medicare Advantage plans, including UnitedHealth's plans. Because we have agreed to produce OIG audit results only for UnitedHealth's plans in response to Request No. 5, we similarly will not produce documents related to OIG audit results for non-UnitedHealth plans in response to your other Requests. *See Responses and Objections*, at 14-15; Nov. 22, 2017 Letter From J. Krieg and P. Perkins to A. Qureshi, at 4. We also will not produce documents related to OIG-OAS's work concerning investigations unrelated to this action, including those under seal, for the same reasons we will not produce these documents from OIG-OI. And to the limited extent custodians within OIG-OAS possess documents responsive to the above Requests that do not relate to other investigations and do not relate to audits of non-UnitedHealth plans, the burden of collecting and reviewing those documents is not proportional to the needs of the case. Our revised searches therefore appropriately reflect our production agreements.

Please let us know if you have any additional questions or concerns.

Sincerely,



Paul Perkins
Trial Attorney
Civil Division, Fraud Section

Attachment

CC: Counsel of Record

EXHIBIT 3

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May 15, 2018

VIA EMAIL

Paul Perkins
Civil Division, Fraud Section
United States Department of Justice
175 N. St. N.E.
Washington, DC 20002

Re: Response to the Government's April 27 and May 9, 2018 Letters re: the United States' Collection, Review, and Production Protocol and Schedule and Memorialization of the Parties' May 1, 2018 Meet and Confer in *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*

Dear Paul:

We write to respond to your April 27, 2018 letter ("April 27 Letter") and May 9, 2018 letter ("May 9 Letter") regarding the United States' collection, review, and production protocol and schedule in response to UHC of California's Requests for Production of Documents to the Government (Set No. One) (hereinafter "Requests") and to memorialized the parties' May 1, 2018 meet and confer ("May 1 Meet and Confer").

A. Additional Collections

UnitedHealth continues to have concerns about the government's collection approach for certain Requests, despite the government's claim that its collection efforts are appropriate.

1. Request No. 8

The government continues to stall in the production of the data responsive to Request 8 and remains unwilling to commit to a date certain for production of this data before August¹—nearly one year after receiving this Request. *See* United States' Apr. 27 Ltr. at 3–4. The government's position appears to be based on a fundamental misconception that collecting and producing this data is a time-intensive task and that ten years of data "takes considerably more time" than collecting and producing a single year of data. ResDAC has confirmed that this is not the case. The requested data is *pre-packaged* data, not data that needs to be collected from multiple sources and compiled for the first time. ResDAC also confirmed that the only time required to produce this data is the time required to burn the information onto a hard drive, and that the number

¹ Even as to August, the government will commit only to "try" to produce this data by then.

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of years requested makes no material difference in how long it would take. If UnitedHealth wanted this data for research purposes, it could have obtained this data within weeks by paying ResDAC for it. There is no legitimate basis for the government's delay in providing this data, and this delay is highly prejudicial to UnitedHealth.

By contrast, UnitedHealth dedicated significant resources to prioritize the data responsive to the government's Requests 35–36, an effort far more labor-intensive than the data at issue in Request 8, and to meet the government's deadline for production. UnitedHealth requests that the government do the same. Please let us know next week whether you will produce this data in the month of May. If the government will not commit to a production date by the end of the May, UnitedHealth reserves its right to seek judicial intervention.

Finally, in its May 9 Letter, the government asked UnitedHealth to explain the relevance of LDS data prior to payment year 2009 (DOS 2008)—an issue raised for the first time in its letter and not included in the government's responses and objections. Data responsive to Request 8 for years prior to payment year 2009 is directly relevant to the claims and defenses in this litigation because, among other reasons, CMS uses data from prior years to calibrate the risk adjustment model. *See, e.g.*, Chapter 7, Medicare Managed Care Manual at 70.1 (Calibration of the CMS-HCC Risk Adjustment Models) (June 13, 2013). Therefore, UnitedHealth renews its request that the government produce data responsive to Request 8 for dates of service 2005 through 2015 (payment years 2006 through 2016).

2. Request Nos. 12 & 13

In its April 23, 2018 letter ("April 23 Letter"), UnitedHealth expressed its concern that the government's proposed direct collection efforts do not "provide a copy of the relevant contracts or attestations" responsive to Requests 12–13. While the government responded in its April 27 Letter that there are no copies of the signed contracts or attestations stored separately in the HPMS system, this response does not address UnitedHealth's concerns. Requests 12–13 are not limited to the data available in HPMS. *See* Request 12 (also seeking "any Documents related to such contracts"); Request 13 (also seeking "any Documents submitted by a Medicare Advantage Organization to qualify or explain their Risk Adjustment Attestations"). As stated on the May 1 Meet and Confer, UnitedHealth is concerned that the government's approach, as outlined in its April 6 and 27 letters, will not locate many of the documents responsive to Requests 12—13.

In its May 9 Letter, the government provided search terms it proposed using to identify documents responsive to Request 12. UnitedHealth has proposed revisions to these search terms in Attachment 1 to this letter. Further, the government stated that it planned to run these terms only across the custodians from the Medicare Drug & Health Plan Contract Administration Group ("MCAG"). On May 15, 2018, the government clarified that its May 9 Letter should have stated that it would run a search on "the Medicare Drug & Health Plan Contract Administration Group custodian(s) whose work responsibilities involved reviewing UnitedHealth's application and administering its contracts." May 15, 2018 Email from P. Perkins to Counsel of Record. Please clarify what the government means by "UnitedHealth's application."

Further, Attachment B to the government's April 6, 2018 letter contains only three custodians from MCAG, Kathryn Coleman, Marilyn Hunter, and Stacey Simmons. Please confirm that these are the only three individuals at MCAG that worked on UnitedHealth's contracts during the relevant time period, including reviewing "UnitedHealth's application" and administering UnitedHealth's contracts.

In its May 9 Letter, the government also indicated that it did not intend to run separate search terms for Request 13 because the search terms for Requests 14–15 were sufficient to locate documents responsive to Request 13. UnitedHealth reserves its rights to propose separate search terms for Request 13 at a later date if it becomes clear that the search terms for Requests 14–15 are not in fact sufficient to locate documents responsive to Request 13.

On the parties' May 1 Meet and Confer, the government indicated that it would produce documents dated prior to 2011 for Request 12 and documents outside of the time period 2013 to 2015 for Request 13. However, the government now states in its May 9 Letter that it will only produce documents responsive to Requests 12–13 relating to payment year 2009 forward and that it is "still evaluating whether to similarly limit [its] productions in response to other Requests." Please confirm that the government is not seeking damages for any claims prior to payment year 2009, which UnitedHealth assumes to be the basis for the government's position that documents and data from prior to payment year 2009 are not relevant.

3. Request 60

UnitedHealth needs additional clarification on the government's proposal before agreeing to the revised search for Request 60. Please confirm that the government's proposal would include the government's policies, practices, and procedures related to the retention of documents (electronic, hard copy, and otherwise), including, but not limited to, policies, practices, and procedures concerning the length of time documents were retained as a matter of practice—i.e., not deleted or destroyed absent affirmative action by any person.

4. Request 2-18

UnitedHealth disagrees with the government's assertion in its May 9 Letter that Request 2-18 and the government's Request 6 to UnitedHealth are not analogous requests: both Requests seek documents relating to the respective parties' meetings concerning risk adjustment. Further, the government's definitions of "Risk Adjustment Payments" and "Risk Adjustment Issues" are not narrowly defined. UnitedHealth does not interpret these definitions to request "documents related to only UnitedHealth's risk adjustment programs." However, if the government interprets this definition differently to include documents *only* related to UnitedHealth's risk adjustment programs, then UnitedHealth reserves the right to narrow the scope of what it is providing in response to all of the government's Requests that use this definition to account for the government's interpretation.

In any event, UnitedHealth appreciates and accepts the government's proposal to limit Request 2-18 to "documents relating to meetings between CMS and any Medicare Advantage Organization (MAO) about (a) chart review programs; (b) validation audits or reviews such as

RACCR or MAO-conducted RADVs; (c) MAO risk adjustment compliance programs.” The government’s proposed option (d)—“the deletion of diagnoses in RAPS and EDS because the diagnoses are unsubstantiated by beneficiary medical records”—is too narrow because it does not account for the deletion of diagnoses for other reasons. Further, the government already agreed that its productions in response to Requests 2-2 and 2-3—both of which request documents related to delete submissions—would “not be limited to deletes related to the submission of invalid diagnoses codes.” United States’ Apr. 20, 2018 Ltr. at 4. UnitedHealth therefore requests that the government produce documents responsive to Request 2-18 related to the deletion of diagnoses in RAPS and EDS for any reason.

B. Custodians

1. Office of the Secretary

The government recently revealed that, despite prior representations, it is “still evaluating whether [it] will produce documents from the Immediate Office of the Secretary, including the Secretary, Deputy Secretary, Chief of Staff, Executive Secretary, and other officials.” United States’ Apr. 20, 2018 Ltr. at 2. On the parties’ May 1 Meet and Confer, the government asserted that it still has yet to make this decision, including whether it will add the Secretary as a custodian for certain Requests. The government has had UnitedHealth’s request to add these custodians for nearly six months. UnitedHealth requests that the government notify UnitedHealth of its decision by May 22 so that UnitedHealth can seek judicial intervention, if necessary.

The government is now refusing to produce responsive documents from the Office of the Secretary that pre-date 2014 on the grounds that doing so purportedly would be burdensome. *See id.* During the May 1 Meet and Confer, the government indicated for the first time that all of the documents for the Office of the Secretary prior to 2014 are in hard copy and therefore overly burdensome to collect, review, and produce. The government is seeking damages beginning in payment year 2009, so limiting the production of such documents to 2014 and later would deprive UnitedHealth of documents for a 5-year span for which the government is seeking damages. Such an approach would be highly prejudicial to UnitedHealth and would be a flagrant violation of the government’s discovery obligations.

The government has failed to detail the purportedly prohibitive burden associated with producing these documents. Please provide more information regarding this burden, including, but not limited to:

- The number of hard copy documents from the Office of the Secretary that pre-date 2014.
- The estimated number of potential custodians from the Office of the Secretary for the pre-2014 time period whose custodial files the government claims consist only of hard copy documents.
- Confirmation that there are no electronic documents for the Office of the Secretary that pre-date 2014 and, if so, why.

- Whether the hard copy documents are printouts of electronic data, hard copy documents the custodians would have maintained, or a combination.
- The burden associated with collecting, scanning, running an OCR process for these documents and with running the government's search terms across these documents—a process the parties already contemplated and agreed to undertake as part of the parties' respective technology assisted review protocols.
- To the extent there are electronic documents for the Office of the Secretary that pre-date 2014, an explanation for why the government does not appear to be including these in its document collection, review, and production.

In its April 20, 2018 letter ("April 20 Letter"), the government suggests that many of the documents from the Office of the Secretary that pre-date 2014 "are likely already captured within CMS's 76 custodians." *Id.* On the parties' May 1 Meet and Confer, the government claimed that this was potentially because many of the documents in the Office of the Secretary would have originated at CMS. Please provide specific information about the current custodians at CMS who would have sent these materials to the Office of the Secretary and provide the basis for your assertion that "many" of the materials would have originated at CMS and thus "are likely already captured" within these custodians' files.

Furthermore, as we stated on the May 1 Meet and Confer, UnitedHealth is not asking the government to add every possible custodian from the Office of the Secretary and is willing to work with the government to develop a list of the relevant custodians for the pre-2014 time period. As UnitedHealth explained, however, the government is in a better position to identify potentially relevant custodians from the Office of the Secretary for the pre-2014 time period. Without more information about the potential custodians, UnitedHealth must rely on the government's efforts to identify relevant custodians. UnitedHealth expects the government to satisfy its discovery obligations and make a good-faith effort to identify potential custodians from the Office of the Secretary that pre-date 2014 and to fully assess the supposed burden involved with collecting and producing such documents.

2. Removal of OIG as a Custodian for Requests 7, 17–20, 26–28, 33–34, and 39

As explained in its April 23 Letter and during the parties' May 1 Meet and Confer, the government's removal of OIG as a custodian for Requests 7, 26–28, 33–34, and 39 is improper. The government argues that it did so because these Requests "do not seek documents in the possession of OIG-OAS and OIG-OI custodians, and to the limited extent they do, the burden of collecting and reviewing these documents is not proportional to the needs of the case." Apr. 27 Ltr. at 4. The government is incorrect. For example, Requests 27–28, 33–34 seek documents related to overpayment standards, guidance, and rules. The government itself has taken the position that OIG is the agency that has the authority to, among other things, impose penalties and assess treble damages on MA plans' failure to return and report overpayments under the Medicare Advantage program. *See, e.g.,* Def.'s Reply in Supp. of Mot. to Dismiss at 22, *UnitedHealthcare Ins. Co. v. Burwell*, No. 1:16-cv-00157-RMC, (D.D.C. Aug. 18, 2016), ECF No. 17; *see also* 42

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U.S.C. § 1320a-7a(a)(10) (authorizing OIG to impose civil monetary penalties of up to \$10,000, treble damages, and program exclusion on any participant in a federal healthcare program who “knows of an overpayment (as defined in [42 U.S.C. § 1320a-7k(d)(4)]) and does not report and return the overpayment in accordance with such section”).

On the parties’ May 1 Meet and Confer, the government proffered for the first time yet another purported reason for removing OIG as a custodian: the documents for OIG custodians responsive to Requests 7, 26–28, 33–34, and 39 would be found using the search terms for other Requests for which OIG is a custodian. As an initial matter, this assertion contradicts the government’s position in its April 27 Letter—that these Requests “do not seek documents in the possession of OIG-OAS and OIG-OI custodians” and that, to the extent they do, the burden is too great for the government to collect and review these documents for these requests. United States’ Apr. 27 Ltr. at 4.

The government has inexplicably refused to identify these overlapping search terms. UnitedHealth has expended time reviewing the proposed search terms for all Requests, and there are no such terms. For example, Requests 27–28, 33–34 all call for documents related to overpayments, yet the only search terms, other than those for Request 27, that specifically use terms like “overpayment*” or “overpay*” are those for Request 40. But the government has further limited the search terms for Request 40 related to OIG custodians by adding other search terms, including UnitedHealth-specific search terms, that do not target documents responsive to Requests 27–28, 33–34.

Further, in its May 9 Letter, the government indicated that it “removed OIG as a custodian for Request Nos. 17, 18, 19, and 20” because OIG does “not play a role in CMS’s payment decision,” and therefore documents responsive to these requests from OIG custodians are not relevant to the claims or defenses in this litigation. May 9 Ltr. at 3. The government’s decision to remove OIG as a custodian for these Requests is similarly unfounded in part because, as described further below, these Requests seek documents related to whether OIG previously prohibited conduct similar to the conduct at issue here. Further, Request No. 20 specifically seeks documents related to overpayments, and, as detailed above, the government itself has taken the position that OIG has the authority to impose penalties on MA plans’ failure to return and report overpayments.

Please let us know by May 22 if the government agrees to add OIG as a custodian for Requests 7, 17–20, 26–28, 33–34, and 39. If the government will not agree, UnitedHealth will seek judicial intervention.

C. Medical Loss Ratio (“MLR”)

Thank you for agreeing to produce certain categories of documents related to the MLR. Please identify how the government proposes to locate documents responsive to Requests 2-5 and 2-6 based on what the government has already agreed to produce in response to these Requests.

In the government’s April 20 Letter, the government stated that it will not produce documents regarding the development of the MLR standard or the development of the MLR Rebate because it believes such documents are not relevant to UnitedHealth’s damages theory. *See*

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United States’ Apr. 20, 2018 Ltr. at 3. The government also stated that it will not produce documents regarding CMS’s guidance regarding 42 C.F.R. Part 422, Subpart X, 42 C.F.R. Part 423, Subpart X, and 42 C.F.R. § 422.2470, CMS’s MLR Reporting Tool, or the MLR reports MAOs are required to submit to CMS for each contract year pursuant to 42 C.F.R. §§ 422.2460 and 423.2460. *Id.* The government similarly stated that “[t]hese documents are not relevant to UnitedHealth’s apparent damages theory.” *Id.*

The government is mistaken. The MLR is calculated one time per year and does not take into account changes to an MA plan’s revenue that may occur due to an MA plan’s submission of deletes or the results of RADV audits. Several MA plans provided comments regarding the proposed rule, published on February 22, 2013 in the Federal Register, Vol. 78, No. 36; 12428-12458, implementing the MLR requirements for the Medicare Advantage and Medicare Prescription Drug Benefit Programs. As CMS recognized when it published the final rule, “[s]everal commenters stated concerns about CMS’ proposal that the MLR would be reported once, based on the Medicare revenue for the year at the time of the report, and that neither reopening(s) of a reconciliation process nor any risk adjustment data validation (RADV) audits that could change the final revenue amount would result in a reopening of the MLR reported for a contract year.” 78 Fed. Reg. 31292-3. While CMS ultimately rejected these concerns in the final rule, documents regarding the topics MA plans raised in their comments to the proposed rule, CMS’s considerations of these comments, and communications between MA plans and CMS about these topics are directly relevant to UnitedHealth’s defenses.

In a good-faith effort to reach an agreement on this issue, UnitedHealth requests that the government produce documents concerning: (1) MA plans’ comments to the proposed rule related to reporting the MLR only once per year; (2) communications between MA plans and CMS in which MA plans express concerns about the MLR only being reported once per year and not taking into account changes to a plan’s revenue from deletes, RADV audits, and other reconciliation; and (3) CMS’s analysis of these comments and concerns.

Pursuant to this request, UnitedHealth proposes that the government add the below search terms for Requests 2-5 and 2-6—in addition to any other collection and search efforts the government plans to undertake to locate the categories of documents the government has already agreed to produce in response to these Requests:

- ((MLR or “Medical loss ratio”) w/10 (rebate* or report* or calculate* or penal*)) AND (“RADV*” or “risk adjustment data validation*” or reconciliation* or reconciled or (adjust* w/2 revenue*) or delete* or (final* w/2 pay*) or reopen* or (adjust* w/2 down*) or refund* or ((reduce* or eliminate* or decrease*) w/2 (penal* or rebate* or pay*))) AND (“medicare advantage” or “part C” or MAO* OR “MA Org*” OR “MA Plan”)

During the parties’ May 1 Meet and Confer, the government agreed to consider this proposal. UnitedHealth looks forward to working cooperatively with the government to reach an agreement on this issue.

D. Documents Related to Other Investigations

UnitedHealth previously explained that documents related to other investigation are highly relevant to its defenses, and has made a good-faith effort to reach a mutually agreeable resolution of this matter by agreeing to limit its requests for documents related to other investigations to Requests 17–20, 25, 38–41, and 43. *See, e.g.*, UnitedHealth’s Mar. 23, 2018 Ltr. at 3–4. In a further attempt to reach an agreement, UnitedHealth proposed that the government would not need to produce documents related to sealed *qui tam* cases at this time. *See id.* at 4. Despite UnitedHealth’s multiple good-faith efforts, the government still is refusing to produce plainly responsive documents concerning other investigations.

Notably, the government has not set forth any case law that contradicts the holding in *United States ex rel. Dean v. Paramedics Plus, LLC*, No. 4:14-CV-00203, 2018 WL 620776 (E.D. Tex. Jan. 30, 2018). And while *Paramedics Plus* does concern the government’s continued payment of claims after discovery of a profit cap, the court’s logic for ordering the government to produce responsive documents from investigation and litigation files from unrelated matters—because such information is relevant for discovery purposes under *United Health Services, Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016)—equally applies to the investigation files requested by UnitedHealth. Consistent with *Paramedics Plus*, the government cannot refuse to produce documents related to other relevant investigations and litigations as these documents are not subject to any investigative privilege.

The government stressed that UnitedHealth was already receiving payment information, but Requests 17–20, 25, 38–41, and 43 seek important information regarding government knowledge and are broader than the government’s continued payment. Under *Escobar*, evidence of non-materiality may be based on how the government responds to allegations of non-compliance generally, not just whether the government continued payment to the defendant despite knowledge of allegations of non-compliance. *Escobar*, 136 S.Ct. 1989 at *2003 (discussing how proof of materiality may include evidence regarding the government’s response to similar allegations of noncompliance in other cases). For example, courts applying *Escobar* have held that evidence that the government previously prohibited similar conduct is relevant to the materiality inquiry. *See, e.g.*, *United States ex rel. Scharff v. Camelot Counseling*, No. 13-cv-3791 (PKC), 2016 WL 5416494, at *17 (S.D.N.Y. Sept. 28, 2016) (complaint failed to allege sufficient facts to support materiality where it did not allege “whether the government had refused to reimburse clinics that have engaged in conduct similar” to defendant’s conduct); *United States ex rel. Worthy v. Eastern Maine Healthcare Systems*, No. 2:14-cv-00184-JAW, 2017 WL 211609, at *24 (D. Me. Jan. 18, 2017) (evidence regarding the government’s previous investigations of similar allegations and previous actions to prevent the same type of conduct at issue were relevant for materiality purposes). UnitedHealth is thus entitled to documents from OIG custodians evidencing such government knowledge.

Moreover, the government is simply incorrect that “CMS is the only entity responsible for the payment decision at issue.” United States’ April 6 Letter at 4. As discussed in Section B.2 above, the government itself has taken the position that OIG is the agency that has the authority to, among other things, impose penalties and assess treble damages on MA plans’ failure to return and report overpayments under the Medicare Advantage program. Documents related to OIG

investigations of other Medicare Advantage plans—including documents related to whether OIG previously prohibited conduct similar to the conduct at issue here—that are responsive to Requests 17–20, 25, 38–41, and 43 are therefore directly relevant to the claims and defenses in this litigation.

Please let us know by May 22 whether the government will search investigation files for Requests 17–20, 25, 38–41 and 43. UnitedHealth reserves its rights to proceed with an informal discovery conference before Magistrate Judge Segal and to file a motion and joint stipulation pursuant to Local 37-2 compelling the government’s production of documents related to other investigations.

Based on this disagreement and as stated in UnitedHealth’s May 4, 2018 letter, UnitedHealth does not agree to the government’s proposed search terms for OIG custodians for Requests 2–3 and 40–41.

E. Unofficial Interpretations of a Statute or Regulation

The government has objected to producing “unofficial interpretations of a statute, regulation, or rule, because such documents are not relevant to any claims or defenses in this action.” *See, e.g.*, United States’ Apr. 20 Ltr. at 3. The government also stated it would inform UnitedHealth if and when it withholds a document on the basis of this objection. On the parties’ May 1 Meet and Confer, UnitedHealth asked whether the government was actually intending to withhold documents on the basis of its objection and, if so, how it would inform UnitedHealth when it withheld documents. The government responded that it has yet to withhold a document based on this objection but will inform us immediately upon doing so by informing us in writing and/or by providing us a log of such documents withheld on this basis. As UnitedHealth has previously stated, the government’s objection is baseless and is not an appropriate grounds for withholding non-privileged, responsive documents.

UnitedHealth also expressed concern about timing because, if the government withholds documents on the basis of this objection, UnitedHealth will need time to seek court intervention, if necessary. On the parties’ May 1 Meet and Confer, the government provided assurances that it would notify UnitedHealth as soon as possible and well before the close of non-expert discovery.

F. Prioritization of Document Review and Production

In the government’s April 20 Letter and on the parties’ May 1 Meet and Confer, the government asked that UnitedHealth identify additional Requests or custodians that UnitedHealth would like the government to prioritize. UnitedHealth has requested that the government prioritize Request 8 and produce all responsive data by the end of May.

In response to the government’s offer to prioritize additional Requests and custodians, UnitedHealth requests that the government prioritize the collection, review, and production of documents for Jonathan Blum, Sean Cavanaugh, Jennifer Harlow, Tom Hutchinson, and Cheri Rice. UnitedHealth will make additional requests regarding the prioritization of additional Requests and custodians as appropriate moving forward.

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G. Production Schedule

The parties agreed that the parties' March 30, 2018 privilege log would be "followed by rolling installments approximately every four weeks." UnitedHealth produced a privilege log on April 30, in accordance with the parties' agreement. The government instead waited five weeks to produce its second privilege log on May 4.

As emphasized in UnitedHealth's prior correspondence, "[d]iscovery obligations must be mutual, and UnitedHealth expects that the government will meet its obligations in the future and will abide by the originally agreed-upon production schedule." UnitedHealth plans to produce its next privilege log no later than May 31, 2018 and expects the government will do the same.

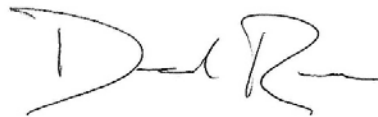
H. Technology Assisted Review ("TAR")

The government's assertion that UnitedHealth has somehow breached the parties' prior agreement to exchange metrics about its TAR process is simply untrue—the parties never agreed to exchange TAR metrics on specific dates. To be clear, UnitedHealth has never refused to provide its TAR metrics, and, in fact, has repeatedly assured the government—as it will do once again right now—that it will provide its TAR metrics to the government. In the future, if the government would prefer to set dates on which both parties will exchange their TAR metrics, UnitedHealth will consider such a proposal.

* * *

Please do not hesitate to contact me with any questions. Thank you.

Sincerely yours,



David W. Rowe
of LATHAM & WATKINS LLP

cc: Counsel of Record

EXHIBIT 4



U.S. Department of Justice

Civil Division

Washington, DC 20530

May 22, 2018

By Electronic Mail

David W. Rowe
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116

Re: Response to UnitedHealth's May 15, 2018 Letter Regarding the United States' Discovery Responses and Other Discovery-Related Issues in *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*

Dear David:

We write to respond to your May 15, 2018 letter and to address several discovery-related issues, including additional and continued deficiencies in your discovery obligations.

I. Request No. 8

Less than one month ago, you asked for the first time that we prioritize our production of data responsive to Request No. 8. This is now the third time we have confirmed that we will prioritize this production and do our best to provide it before August. It is not true that we are "stall[ing]" this production with "no legitimate basis." As we said in our May 9, 2018 letter, collecting and producing ten years of data, accounting for two billion claims with around seven billion line items, is a significant undertaking.

We understand that you believe you can get this data quicker by purchasing it from ResDAC. You are certainly free to do that. The government is utilizing CMS staff, however, to collect and produce the data you requested, and the timeframe we provided reflects that fact.

We appreciate the clarification that you offered in your May 15, 2018 letter regarding UnitedHealth's request for LDS data from payment year (PY) 2006 through 2008. We will plan to include this data in our production.

II. Request Nos. 12 & 13

We have incorporated your suggested revision to the search we are using to identify documents responsive to Request No. 12, albeit with one non-substantive edit. We now consider this search final.

As we stated in our May 9, 2018 letter, we are running this search on the Medicare Drug & Health Plan Contract Administration Group (“MCAG”) custodian(s) whose work responsibilities involved reviewing UnitedHealth’s application¹ and administering its contracts. You are correct that we have identified three custodians from MCAG: Kathryn Coleman, Marilyn Hunter, and Stacy Simmons. We will notify you if we identify additional MCAG custodians.

We also confirm, at your request, what we wrote in our May 9, 2018 letter: “Because this case focuses on PY 2009 and subsequent PYs, we will produce non-privileged documents relating only to PY 2009 forward for these two Requests.” This statement is consistent with the parties’ mutual understanding. *See* March 1, 2018 Letter from N. Hanna and J. Lee to D. Schindler and D. Meron (“the February 12, 2018 Order allows the Government to seek to recover, and does not preclude it from seeking to recover, damages for payment year 2009 and all subsequent years.”); March 3, 2018 Email from D. Schindler to J. Lee (“We understand Judge Fitzgerald to have held that our retroactivity argument precludes the government’s claims based on risk adjustment payments for payment years prior to 2009, but do not understand him to have held that our retroactivity argument precludes claims based on risk adjustment payments for payment year 2009 or subsequent payment years.”).

III. Request No. 60

Before we can agree to your revised Request No. 60, we must first understand that you interpret our Request No. 26 to seek UnitedHealth’s “policies, practices, and procedures related to the retention of documents (electronic, hard copy, and otherwise), including, but not limited to, policies, practices, and procedures concerning the length of time documents were retained as a matter of practice—i.e., not deleted or destroyed absent affirmative action by any person.” If you confirm this as your understanding, and additionally confirm that you have or are planning to produce documents consistent with this understanding, we will agree to do the same.

IV. Request Nos. 2-5, 2-6, 2-7 (Medical Loss Ratio)

In a further effort to reach agreement on Request Nos. 2-5, 2-6, and 2-7, we will produce MA plans’ comments to or concerns about the proposed rule related to reporting the Medical Loss Ratio (“MLR”) only once per year and not taking into account changes to a plan’s revenue from deletes, RADV audits, and other reconciliation, in addition to the three categories of documents we agreed to produce in our April 20, 2018 letter. CMS’s analysis of these comments and concerns are deliberative and pre-decisional, and as such, they are protected by the deliberative process privilege. We therefore will not agree to produce these documents, nor will we collect and review them for the sole purpose of including them on a privilege log. This

¹ You may learn more about the Medicare Advantage application process on CMS’s website (<https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.html>).

position is consistent with Fed. R. Civ. P. 26(b) and UnitedHealth's position elsewhere. *See* March 27, 2018 Letter from K. Scheffler Do to C. Wallack.

We have included in the Attachment a revised version of your proposed search for Request Nos. 2-5 and 2-6. We have also identified the methods of collection we are using to identify documents responsive to Request Nos. 2-5, 2-6, and 2-7.

V. Request No. 2-18

In a further effort to reach agreement on Request No. 2-18, we will agree to produce documents relating to meetings between CMS and any Medicare Advantage Organization (MAO) about (a) chart review programs; (b) MAO-conducted validation audits or reviews such as RACCR or MAO-conducted RADVs; (c) MAO risk adjustment compliance programs; and, (d) the deletion of diagnoses in RAPS and EDS. We will additionally agree to some, but not all, of your proposed revisions to our search for Request No. 2-18. We will not, for example, add to our search, "talk* or communicat* [or] confer* . . . or note* . . . or e-mail* or letter* or (follow w/2 up)" because those terms are overbroad and likely to capture irrelevant documents. We also will not remove "plan" from "Medicare Advantage plan" or add "Part C." These revisions are likely to identify documents beyond what you have requested and we have agreed to produce (*i.e.*, meetings between CMS and an MAO).

We disagree with your assertion that our May 9, 2018 letter justifies the narrowing of what you have previously agreed to produce in response to our Requests. To be clear, our Request No. 6 seeks, "All Documents relating to meetings and Communications between Defendant UnitedHealth Group, Inc. and any other Defendant or any other Person relating to Risk Adjustment Issues and Risk Adjustment Payments." The term, "Risk Adjustment Issues" includes within its definition "UnitedHealth's Risk Adjustment Programs." Our point in the May 9, 2018 letter is clear: your two versions of Request No. 2-18—the first, seeking "Documents relating to any meetings between CMS and *any Person related to Risk Adjustment*," and the second, seeking "documents or communications with or about *MA plans related to risk adjustment*"—are significantly broader than our Request No. 6. In addition to everything else covered by the term "risk adjustment," Request 2-18 effectively seeks documents related to "*all* MA plans' risk adjustment programs." In no way did we redefine the terms, "Risk Adjustment Issues" and "Risk Adjustment Payments," and your misrepresentation of our position is counterproductive to the parties' efforts to resolve and narrow areas of disagreement.

VI. Office of the Secretary

As we stated in our April 20, 2018 letter, "we are still evaluating whether we will produce documents from the Immediate Office of the Secretary, including the Secretary, Deputy Secretary, Chief of Staff, Executive Secretary, and other officials." This position is not inconsistent with prior representations, as you claim. *See, e.g.*, November 22, 2017 Letter from J. Krieg and P. Perkins to A. Qureshi (agreeing to identify whether custodians exist within the Office of the Secretary—not the Immediate Office of the Secretary). We continue to search for custodians within the Office of the Secretary and will notify you once we complete that process. But to date, we are still considering whether to offer custodians within the Immediate Office of the Secretary. We expect to finalize our decision shortly and will ensure you are notified when

we do. Until we make that decision, though, discussions about the burden of collecting and producing from the Immediate Office of the Secretary are premature.

We note, however, that while we initially believed the Immediate Office of the Secretary did not preserve files in electronic format prior to 2014, we now understand that it may have preserved certain files electronically for certain potential custodians as far back as the beginning of the discovery period. Where documents were not preserved electronically, they were preserved in hard copy format. We are therefore confident all documents were preserved in accordance with applicable document retention guidelines and requirements.

VII. Office of Inspector General

As explained in our April 6, 2018 letter, we will not produce documents concerning investigations unrelated to this action contained in the files of OIG custodians (*i.e.*, a subset of documents responsive to Requests No. 2, 3, 40, and 41). We also will not produce documents from OIG custodians related solely to OIG's independent enforcement authority and unrelated to the government's payment decision (*i.e.*, documents responsive to Request Nos. 7, 17, 18, 19, 20, 26, 27, 28, 33, 34, and 39). *See* April 6, 2018 Letter from P. Perkins to D. Rowe; April 27, 2018 Letter from P. Perkins to D. Rowe.

The vast majority of investigative material in OIG custodian files would be subject to a claim of law enforcement or attorney-client privilege. Indeed, the Office of Investigations conducts virtually all of its investigations in coordination with the Department of Justice, and the Office of Audit Services likewise coordinates with DOJ.

As the requesting party, UnitedHealth has the obligation under Fed. R. Civ. P. 26(b)(1) to articulate not only the potential relevance of any requested documents, but also the importance of the requested discovery given the burden of searching for and litigating discovery concerning such facially privileged information. *Oracle Am., Inc. v. Google, Inc.*, No. 10-03651, 2015 WL 7775243, at *2 (N.D. Cal. Dec. 3, 2015). UnitedHealth fails to do so, despite numerous letters and meetings on this issue.

UnitedHealth continues to rely on *United States ex rel. Dean v. Paramedics Plus, LLC*, No. 14-0023, 2018 WL 620776 (E.D. Tex. Jan. 20, 2018) to obtain discovery regarding OIG investigations. But, as explained in our April 6, 2018 letter, that decision permitted limited discovery—"information pertaining to the Government's continued **payment of claims** after discovery" of the alleged fraud (the profit cap). *Id.* at *7 (emphasis added). Consistent with that ruling, and in an effort to resolve this matter without court intervention, we offered to search for the requested information contained in the files of CMS custodians, as CMS (and not OIG) makes the payment decision in the Medicare Advantage program. *See* 5 U.S.C. App. 9(a)(2) ("there shall not be transferred to an Inspector General under paragraph (2) program operating responsibilities."). UnitedHealth has rejected our compromise.

UnitedHealth now points to two motion to dismiss rulings, *United States ex rel. Scharff v. Camelot Counseling*, No. 13-3791, 2016 WL 5416494 (S.D.N.Y. Sept. 28, 2016); *United States ex rel. Worthy v. Eastern Maine Healthcare Systems*, No. 14-00184, 2017 WL 211609 (D. Me. Jan. 18, 2017), in an effort to show that information outside the government's payment decision

is relevant and proportional to the needs of the case. Neither ruling mandated the discovery UnitedHealth seeks; each was a ruling on the pleadings, not discovery.

The passage UnitedHealth relies upon in *Scharff* regarding materiality, moreover, focuses on the government's "reimburse[ment]," 2016 WL 5416494 at *8. The decision thus likewise focuses on the government's payment decision.

Worthy, meanwhile, recognized that materiality differs in each case, but is determined by, among other things, looking at the "centrality of the requirements" at issue. 2017 WL 211609 at *26. Judge Fitzgerald has already recognized that "not only do various contractual and regulatory materials require Defendants to submit accurate diagnosis codes, but that data is *central* [to] the calculation of the amount of money CMS pays to Defendants." Dkt. 212 at 15 (emphasis added). UnitedHealth's knowing and improper avoidance of its obligation to correct invalid diagnosis data submitted for Medicare payment is material as a matter of law, and there are no remaining factual issues to resolve that would warrant discovery into law enforcement sensitive investigations. Here, moreover, the Department of Justice conducted an investigation into UnitedHealth's fraud that resulted in the FCA action, further demonstrating materiality.

The government has nonetheless sought to accommodate discovery concerning the government's payment decision in agreeing to search for investigative material within the custody and control of CMS, the component responsible for all payment decisions under the Medicare Advantage program. That OIG has independent enforcement authority is not a basis for broad searches into documents untethered to UnitedHealth or to the government's payment decision. We will not search for these documents and have appropriately removed OIG as a custodian under Fed. R. Civ. P. 26(b).

We have also repeatedly informed you, including during the meet and confer on May 1, 2018, that our searches will only identify documents responsive to Requests that we have agreed to produce. *See, e.g.*, May 10, 2018 Letter from P. Perkins to D. Rowe ("Our searches to these Requests are consistent with what we have agreed to produce"); March 2, 2018 Letter from P. Perkins to A. Robinson and D. Rowe ("Our search terms, however, should reflect to the extent possible what we have agreed to produce, and therefore they should not include terms clearly outside that universe"). Our searches will not, of course, *also* identify documents responsive to Requests that we have not agreed to produce. You apparently misunderstood this point during the meet and confer on May 1.

Finally, we have not accepted your proposed revision to our search for Request No. 5. Because the revision we provided on May 9, 2018, only expanded our prior search, we continue to consider this search final as of April 6, 2018.

VIII. Production Schedule

As we stated in our May 9, 2018 letter, we are planning to produce our next privilege log on June 1—27 days after our last privilege log. This is consistent with the parties' agreed upon schedule that the United States' privilege logs follow document productions by one week. We understand that UnitedHealth plans to produce its next privilege log only one day earlier—31 days after its last privilege log (not the four weeks required by the parties' production schedule for UnitedHealth).

IX. Jeffrey Grant Document Productions

It appears that UnitedHealth has violated the parties' agreement to produce, prior to the deposition of Jeffrey Grant, all responsive non-privileged communications or documents where Mr. Grant appears. On numerous occasions, you represented that you would fulfill this agreement. *See, e.g.*, March 16, 2018 Email from K. Scheffler to Counsel of Record. However, during Mr. Grant's deposition on May 16, 2018, Abid Qureshi introduced as Exhibit 1018 an email that included Mr. Grant. When Jessica Krieg asked if this document included bates numbers, Mr. Qureshi said, "No, it was not a document that was produced."

Please explain UnitedHealth's failure to produce this document prior to Mr. Grant's deposition in accordance with the parties' agreement.

X. Technology Assisted Review Metrics

The United States remains concerned by UnitedHealth's continued refusal to satisfy its discovery obligations by providing the Technology Assisted Review ("TAR") metrics the parties agreed to exchange. Consistent with our understanding of this agreement, we will continue to provide the agreed-upon TAR metrics after completion of any future TAR project. We understand that UnitedHealth claims it will provide its TAR metrics at some undefined point in the future. This position is both unfair and inconsistent with UnitedHealth's repeated insistence that "discovery obligations must be mutual."

We refer UnitedHealth back to our May 9, 2018 letter for the list of questions we expect it to answer and the metrics we expect it to provide, consistent with the parties' prior agreement. We trust UnitedHealth will reevaluate its position and immediately provide us with this information.

XI. Custodian Employment Information

On April 6, 2018, we provided a list of detailed employment information about each of our custodians. We asked that you provide a similar list about UnitedHealth's custodians, and you agreed. On April 20, 2018, we again asked you to provide this information, but you failed to do so. During the meet and confer on May 1, 2018, we asked you again to provide this information, and you committed to provide it within two weeks.

We still have not received a detailed list of employment information about UnitedHealth's custodians. We are perplexed by your failure to produce this information, particularly in light of your suggestion in both the Joint Rule 26(f) Report and the Amended Joint Rule 26(f) Report that you were ready to provide it in December 2017. Dkt. 191 at 19 ("While UnitedHealth proposed that the Parties exchange additional information, including custodians' job titles and employment history, regarding custodians on December 20, 2017, the United States was not prepared to do so."); Dkt. 224 at 34-35 (same).

Discovery obligations must be mutual, and the United States expects that UnitedHealth will meet its obligations. If you cannot by May 25, please explain your failure to provide this information in a timely manner and when you expect to produce it.

XII. Custodians

After further assessment, we have identified the following additional CMS custodian: Andrew Keenan. We have also determined that the following individuals do not, in fact, possess responsive material and therefore are not custodians: Victoria Beder, William Parham, Salve Massimini (Batu), Annette Brewer, Shaili Patel, Michele Edmondson-Parrott, Linda Abbott, and Nora Castro.

Please let us know if you have any questions.

Sincerely,



Paul Perkins
Trial Attorney
Civil Division, Fraud Section

Attachment

CC: Counsel of Record

EXHIBIT 5

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LATHAM & WATKINS LLP

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June 15, 2018

VIA EMAIL

Paul Perkins
Civil Division, Fraud Section
United States Department of Justice
175 N. St. N.E.
Washington, DC 20002

Re: Government's Unsupported Assertions of the Deliberative Process Privilege

Dear Paul:

UnitedHealth is concerned that the government is improperly invoking the deliberative process privilege to shield highly relevant documents from discovery. As discussed below, the deliberative process privilege is a narrow, qualified privilege that the government cannot invoke to prevent discovery of documents critical to UnitedHealth's ability to defend itself. Please let us know by June 22 if you will reconsider your position or, if necessary, your availability for a meet and confer.

The government's reliance on the deliberative process privilege is improper in at least three respects. *First*, the government is refusing even to collect documents from certain sources it believes may contain a high percentage of documents protected by the deliberative process privilege. Such an approach ignores the qualified and limited nature of the deliberative process privilege. *Second*, the government is taking an overly broad view of the privilege, and its privilege logs do not provide the requisite support for an assertion of the deliberative process privilege. *Third*, even if the government properly asserted the deliberative process privilege, UnitedHealth's need for the requested information far outweighs the government's interest in non-disclosure.

A. The Government's Refusal To Collect Documents Based On The Deliberative Process Privilege

The deliberative process privilege is a qualified privilege that is narrowly construed and applies only in limited circumstances. *See FTC v. Warner Commc'ns. Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984) (holding that the deliberative process privilege applies only to documents that are "predecisional" and "deliberative in nature" and stating that "[p]urely factual material . . . is not protected"); *N. Pacifica, LLC v. City of Pacifica*, 274 F. Supp. 2d 1118, 1121 (N.D. Cal. 2002) (stating that "the privilege is strictly confined within the narrowest possible limits consistent with the logic of its principles") (internal quotation and citation omitted). The government has the burden of establishing that the deliberative process privilege protects the material at issue. *N.*

Pacifica, LLC, 274 F. Supp. 2d at 1121. As discussed below, an appropriate agency official must personally consider each document, detail the information over which the privilege is asserted, and explain why such information properly falls within the scope of the deliberative process privilege. By refusing even to collect various categories of documents, *see, e.g.*, United States’ Apr. 20, 2018 Ltr. at 3, the government cannot satisfy its obligations for asserting this narrow, qualified privilege. We believe that the government’s refusal to collect documents and undertake an individualized review of each document is improper and fails to comply with relevant law. If you have any relevant authority that would support the government’s blanket refusal to collect responsive documents, please forward to us immediately.

B. The Government’s Expansive And Unsupported Assertions Of The Deliberative Process Privilege

The government has produced approximately 30,300 documents and logged approximately 6,700 documents in this litigation. Remarkably, the government is asserting privilege over about 5,900 of these documents solely on the basis of the deliberative process privilege—about 19.5% of the documents produced by the government and over 88% of all documents on the government’s privilege logs. When including privileges asserted simultaneously with this privilege, this number rises to over 6,300—nearly 21% of the documents produced by the government and nearly 95% of the documents on the government’s privilege log. These staggering statistics suggest that the government is taking an inappropriately expansive view of the deliberative process privilege.

The government’s privilege logs do not provide adequate support for its expansive assertions of the deliberative process privilege. A proper assertion of the privilege requires: “(1) a formal claim of privilege by the head of the department possessing control over the requested information; (2) an assertion of the privilege based on actual personal consideration by that official; and (3) a detailed specification of the information for which the privilege is claimed, along with an explanation of why it properly falls within the scope of the privilege.” *Coleman v. Schwarzenegger*, 2008 WL 2237046, at *4 (E.D. Cal. May 29, 2008) (internal quotation and citation omitted).

Additionally, to qualify for protection under the deliberative process privilege, materials must be both “predecisional” and “deliberative.” *Hongsermeier v. Comm’r of Internal Revenue*, 621 F.3d 890, 904 (9th Cir. 2010) (quoting *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975)). A document will be considered “predecisional” if it was “prepared in order to assist an agency decisionmaker in arriving at his decision.” *Carter v. U.S. Dep’t of Commerce*, 307 F.3d 1084, 1089 (9th Cir. 2002) (holding that adjusted census data held back based on accuracy concerns was not “predecisional” because it was originally prepared for the purpose of dissemination to the public) (quotations and citation omitted). To be deemed deliberative, the statement or document must have been a direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters. *See Vaughn v. Rosen*, 523 F.2d 1136, 1144 (D.C. Cir. 1975) (“[P]redecisional materials are not exempt merely because they are predecisional; they must also be a part of the agency give-and-take of the deliberative process by which the decision itself is made.”); *see also Allen v. Woodford*, No. CV-F-05-1104, 2007 WL 309945, at *5, *9 (E.D. Cal. Jan. 30, 2007) (stating that, to qualify for the deliberative process privilege, the document must relate to a larger policy formulation, not a single, trivial decision,

such as whether to fire a single employee). Additionally, the “privilege only applies to significant policy decisions, rather than factual material,” *Dominguez v. Schwarzenegger*, 2010 WL 3341038, at *5 (N.D. Cal. Aug. 25, 2010) (internal quotation and citation omitted) (ordering production of all documents for which government invoked solely deliberative process privilege where government failed to identify specific policy decisions at issue).¹ For example, discussions about CMS’s own error rates and what impact the underlying errors had on CMS’s calculations of risk adjustment coefficients would not qualify for the deliberative process privilege because these discussions would involve purely factual information, not questions of policy.

The government has not properly satisfied the requirements to assert the deliberative process privilege. The government has not identified a formal claim of privilege by any official of any relevant agency, let alone a high-ranking official. There also does not appear to be any indication that an appropriate agency official asserted the privilege based on his or her actual personal consideration of the documents. Rather, it appears that the privilege assertions to date have been made by lawyers at the Department of Justice.

Furthermore, the basic descriptions provided by the government fail to satisfy the requirement that the government provide a “detailed specification of the information for which the privilege is claimed, along with an explanation of why it properly falls within the scope of the privilege.” *Id.* Nor do the government’s privilege log descriptions even detail whether or how each document is both pre-decisional and deliberative.

For example:

- Document “reflecting internal agency deliberations regarding RADV audit methodology.” *See, e.g.*, USBPPRIV00000239. The government has used this description for approximately 1,742 documents that span from September 2003 to July 2017.
- Document “reflecting calculation of RA error rate.” *See, e.g.*, USBPPRIV00001566. The government has used this description for approximately 743 documents that span from September 2004 to November 2016.
- Document “reflecting internal agency deliberations regarding Advance Notice and/or Announcement and Call Letter.” *See, e.g.*, USBPPRIV00000410. The government has used this description for approximately 429 documents that span from March 2005 to April 2017.

¹ The government should not be withholding in full documents that contain factual (or other) materials that do not qualify for this narrow privilege. This does not appear to be the case, however, considering the government is withholding in full approximately 95% of documents over which it is asserting solely the deliberative process privilege and is only redacting approximately 5% of these documents.

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- Document “reflecting internal agency deliberations regarding RA supporting documentation requirements.” *See, e.g.*, USBPPRIV00002198. The government has used this description for approximately 413 documents that span from August 2004 to May 2017.
- Document “reflecting internal agency deliberations regarding medical coding in support of RA payments.” *See, e.g.*, USBPPRIV00005095. The government has used this description for approximately 315 documents that span from March 2004 to May 2017.
- Document “reflecting internal agency deliberations regarding FFS adjuster.” *See, e.g.*, USBPPRIV00001545. The government has used this description for approximately 214 documents that span from June 2005 to March 2017.

These generic, widely used descriptions do not adequately describe the content of the purported deliberations and do not provide the requisite level of detail for UnitedHealth to determine whether such documents properly fall within the scope of the deliberative process privilege. And, as noted above, the government has not indicated that any high-ranking agency official reviewed any of these documents before including them on the logs.

Because the government has not provided the requisite level of detail about the exact agency decisions at issue and how each document contributed to those decisions, UnitedHealth cannot properly assess whether any purported deliberations were ultimately adopted by the agency. *See Nat’l Resources Def. Council v. U.S. Dep’t of Defense*, 388 F. Supp. 2d 1086, 1098 (C.D. Cal. 2005) (“Even if the document is predecisional at the time it is prepared, it can lose that status if it is adopted, formally or informally, as the agency position on an issue or is used by the agency in its dealings with the public.” (quoting *United States v. Rozet*, 183 F.R.D. 662, 666 (N.D. Cal. 1998))); *Assembly of State of Cal. v. U.S. Dept. of Commerce*, 968 F. 2d 916, 920 (9th Cir. 1992) (noting that a “predecisional” document is one “prepared in order to assist in an agency decisionmaker in arriving at his decision” and that “documents deemed ‘postdecisional’ do not enjoy the protection of the deliberative process privilege”) (quoting *Sears, Roebuck & Co.*, 421 U.S. at 153).

The government has also logged documents that were circulated to numerous individuals — far more than one would expect from a document that properly fell within the deliberative process privilege. For example, USBPPRIV00000183 is purportedly an “[e]mail reflecting internal agency deliberations regarding RADV audit methodology.” The privilege log lists approximately 114 individuals in the “To” field and another approximately 64 in the “cc” field. It is doubtful that this type of mass email, which was sent to around 180 people, would properly fall under the deliberative process privilege. *See also* USBPPRIV00000177 (“Email reflecting internal agency deliberations regarding RADV audit methodology” sent to approximately 125 recipients); USBPPRIV00000288 (“Email, with attachments, reflecting internal agency deliberations regarding calculation of RA error rate” sent to approximately 108 recipients).

In sum, the government has not properly invoked the deliberative process privilege for the approximately 6,300 responsive documents it seeks to shield from production in this matter based on that privilege. The government chose to bring this lawsuit. It cannot now hide behind the deliberative process privilege to skirt its discovery obligations and deprive UnitedHealth of highly relevant documents to which it is entitled.

II. UnitedHealth's Need For The Requested Information Outweighs The Government's Interest In Non-Disclosure

Even if the government had properly invoked the deliberative process privilege—which it has not—the privilege is qualified and can be overcome by a sufficient showing of need outweighing the harm that might result from disclosure. *Warner Commc'ns Inc.*, 742 F. 2d at 1161 (“A litigant may obtain deliberative materials if his or her need for the materials and the need for accurate fact-finding override the government's interest in non-disclosure.”) (citations omitted). Here, the government is alleging over a billion dollars in damages; UnitedHealth's need for arguably privileged documents far outweighs the government's interest in non-disclosure.

The Ninth Circuit has set forth four non-exclusive factors that may be considered in balancing of the competing interests: “(1) the relevance of the evidence; (2) the availability of other evidence; (3) the government's role in the litigation; and (4) the extent to which disclosure would hinder frank and independent discussion regarding contemplated policies and decisions.” *Id.* (citations omitted). These factors overwhelmingly weigh in favor of overcoming any assertion of deliberative process privilege in this case.

First, as UnitedHealth has explained in numerous letters and meet and confers, the requested documents are crucial for its defenses to the misconduct charges made by the government in this case. For example, under *United Health Services, Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016), documents related to the government's interpretations of the requirements imposed on MA plans by CMS statutes, rules, regulations, and guidance—requirements the government now claims UnitedHealth violated—are directly relevant to UnitedHealth's defenses. Thus, documents related to, among other things, the government's understanding of whether MA plans were required to “look both ways,” whether other MA plans were conducting “one-way looks,” and how the government responded to any allegations of non-compliance are all relevant to whether any alleged misconduct by UnitedHealth satisfies *Escobar*'s demanding materiality standard. These documents—as well as documents such as those relating to the government's views on how to measure overpayments—are also relevant to whether UnitedHealth's interpretation of relevant statutes, guidelines, and communications with CMS officials was reasonable. *See, e.g., United States v. Pac. Gas & Elec. Co.*, 178 F. Supp. 3d 927, 963 (N.D. Cal. 2016) (holding that evidence of government's or other regulated entities' interpretation of regulations was relevant to reasonableness of defendant's interpretation). Furthermore, documents related to the government's own error rates are relevant to UnitedHealth's theory of the proper calculation of any potential damages.

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The government appears to be asserting the deliberative process privilege over these types of documents and depriving UnitedHealth of these crucial documents. For example, the government is asserting privilege over approximately 743 documents related to the “calculation of RA error rate,” approximately 278 documents related to the “calculation of coding intensity adjuster,” approximately 257 documents related to “non-UHG MAO RA activities,” and approximately 214 documents related to the “FFS adjuster.”

Second, UnitedHealth cannot obtain this crucial evidence related to government knowledge and interpretations of MA requirements from other sources—the government is the sole custodian of this information.

Third, the government chose to bring this lawsuit, so its role in the litigation weighs heavily toward disclosure of these documents.

Fourth, because there is a protective order in place, the risk that disclosure of these documents will have a chilling effect on future deliberations by government employees is minimal. *See, e.g., In re McKesson Governmental Entities Average Wholesale Price Litig.*, 264 F.R.D. 595, 602–03 (N.D. Cal. 2009) (holding that the protective order in place would sufficiently protect the government’s interest); *Noble v. City of Fresno*, No. 1:16-cv-01690, 2018 WL 1381945, at *9 (E.D. Cal. Mar. 19, 2018) (same).

Thus, even if the government had properly invoked the deliberative process privilege (which it has not), the privilege would be overcome in this case because UnitedHealth’s need for the documents outweighs the government’s interest in non-disclosure.

* * *

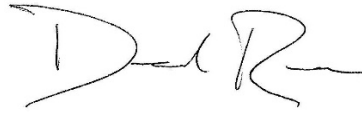
Please let us know by June 22 if you will reconsider your position or, if necessary, your availability the following week for a meet and confer.

If the government continues to assert the deliberative process privilege over any documents, UnitedHealth requests that the government (1) collect any documents it has previously refused to collect, produce non-privileged documents, and log any purportedly privileged documents; (2) revise its privilege logs to provide the requisite detail about the information over which the government claims the privilege applies; and (3) provide a formal claim of privilege by an appropriate agency official who has personally reviewed any documents over which the government is asserting the deliberative process privilege.

Please do not hesitate to contact me with any questions. Thank you.

LATHAM & WATKINS LLP

Sincerely yours,

A handwritten signature in black ink, appearing to read "D. Rowe". The signature is fluid and cursive, with a large "D" and a stylized "R" followed by a horizontal line.

David W. Rowe
of LATHAM & WATKINS LLP

cc: Counsel of Record

EXHIBIT 6



U.S. Department of Justice

Civil Division

Washington, DC 20530

June 29, 2018

By Electronic Mail

David W. Rowe
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116

Re: UnitedHealth's June 15, 2018 Letter Regarding the United States' Discovery Responses in *United States ex rel. Poehling v. UnitedHealth Group, Inc., et al.*

Dear David:

We write in response to your June 15, 2018 letter concerning the government's assertion of the deliberative process privilege. That the government has asserted privilege over many documents reflects the overbreadth of UnitedHealth's discovery requests and not any impropriety with the privilege assertions. Before privilege questions are addressed, UnitedHealth has the initial burden of demonstrating the relevance of agency deliberations. *See e.g., Gulfstream Park Racing Ass'n Inc.*, 399 F.3d 391, 400 (1st Cir. 2005) ("discovery of both privileged and unprivileged information is subject to the limitations imposed by Rule 26(b)); *accord Freeman v. Seligson*, 405 F.2d 1326, 1338 (D.C. Cir. 1968) ("matters of privilege can appropriately be deferred for definitive ruling until after the production demand has been adequately bolstered by a general showing of relevance and good cause"). UnitedHealth's letter fails to do so.

Contrary to the suggestion in your letter, moreover, the government has carefully asserted the privilege to protect documents necessary to ensuring free and frank agency deliberations. UnitedHealth's letter unfortunately reflects a misunderstanding of the deliberative process privilege, incorrectly criticizes the government for purportedly refusing to conduct searches for documents, and unfairly criticizes the government's privilege log when the descriptions of privileged material on the government's log are far more specific and compliant with the demands of Fed. R. Civ. P. 26(b)(5) than UnitedHealth's log.

I. United's Purported Need for Deliberative Material

First, there is no merit to UnitedHealth's argument that it needs deliberative process documents related to the government's interpretation of statutory, regulatory, and contractual requirements imposed on MA Organizations by CMS. UnitedHealth has not identified any statute, rule, regulation, or guidance for which privileged information is needed to discern any government interpretation that is probative of factual issues that remain in this case. Nor has UnitedHealth even identified an issue in need of "interpretation." Since the inception of the MA program, agency-issued documents such as the Medicare Managed Care Manual, the Participant

Guides, Federal Register comments, announcements, and call letters have extensively set forth the agency's understandings of MA Organizations' obligations under the relevant statutes, regulations, and contracts. In any event, any issue concerning the agency's understanding are resolved by official pronouncements, not privileged deliberations. *See, e.g., United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (holding that any interpretive issue relating to a regulation is resolved through reference to the official public record). "[N]on-public or informal understandings of agency officials concerning the meaning of a regulation are . . . not relevant." *Id.*; *see also United States ex rel. Wright v. Agip, et al.*, No. 03-Cv-00264 at 7-9 (E.D. Tex. June 29, 2007) (denying motion to compel deposition of Government personnel in FCA case regarding their understanding of regulations, and holding that "personal opinions of agency employees that were never communicated to a Defendant are simply irrelevant to either issues of falsity or knowledge").¹

Second, UnitedHealth has failed to explain any legitimate need to explore the government's position on whether MA Organizations were required to "look both ways," whether other plans were conducting "one-way looks," and how the government responded when and if it learned that plans were conducting "one-way" looks. UnitedHealth's contentions regarding the obligation of MA plans to 'look both ways' has already been addressed in the Ninth Circuit's decision in *United States ex rel. Swoben v. UnitedHealthgroup, Inc.*, 848 F.3d 1161, 1167-68 (9th Cir. 2016). In the *Swoben* appeal, UnitedHealth argued that there was no "authority indicat[ing] that a [MAO] was obligated to undertake affirmative steps to unearth potentially unsupported codes" in claims by medical providers. *Id.* at 1173. The appellate court recognized that UnitedHealth's argument was a red herring, noting that the *Swoben* matter was "not a case about whether [MAOs] have to take affirmative steps to verify risk adjustment data. [UnitedHealth] indisputably took such steps by conducting retrospect chart reviews." *Id.* at 1179.

As with *Swoben*, the question in this case is not *whether* UnitedHealth was obligated to verify diagnostic data in provider claims, but rather *what* UnitedHealth was required to do after it "indisputably . . . conduct[ed] retrospective chart reviews." The Ninth Circuit has already answered that question and held that UnitedHealth had an obligation to correct unsupported diagnoses submitted for risk adjusted payments. *Id.* at 1174-75. UnitedHealth's attempt to relitigate this issue is not a legitimate basis to obtain privileged agency deliberations.

Third, although UnitedHealth contends that the referenced deliberations are relevant to the question of materiality, that issue too has been decided as a matter of law. Both the Ninth Circuit and Judge Fitzgerald have recognized the direct link between the invalid diagnoses submitted by defendants and the risk adjusted payments by Medicare. *Swoben*, 848 F.3d at 1167-68 ("diagnoses codes contribute to an enrollee's risk score, which is used to adjust a base payment rate"); Order on MTD at 15 ("not only do various contractual and regulatory materials require Defendants to submit accurate diagnostic data, but that data is central to the calculation of the amount of money CMS pays to Defendants"). Furthermore, Judge Fitzgerald has already ruled that CMS' continued payments "despite generalized knowledge of 'one-way' Chart Reviews and problematic diagnosis codes" is not relevant to whatever "materiality" issue there might be with respect to United's obligation to delete invalid diagnoses. Order on MTD at 21.

¹ These principals apply in other, similar, contexts such as APA litigation. *See, e.g., Maritel, Inc. v. Collins*, 422 F. Supp. 2d 188, 196 (D.D.C. 2006) ("agency generally may exclude material that reflects internal deliberations" from administrative record).

The diagnosis data UnitedHealth submitted to the Center for Medicare and Medicaid Services (CMS) is material by design. As UnitedHealth well knows, CMS uses an automated system (RAPS) to process both the codes and the deletes submitted by MA Organizations. There is no factual issue left regarding materiality that would warrant discovery of privileged, or non-privileged, documents.

Fourth, there is no merit to the argument that UnitedHealth requires agency deliberations to understand whether the government's views on "overpayments" are consistent or inconsistent with unspecified interpretations by unidentified officials at UnitedHealth. The issue of scienter in this case involves whether UnitedHealth "knew," as that term is defined in the False Claims Act, that submitted diagnosis codes were unsupported by patient charts. Evidence pertaining to that issue can come only from UnitedHealth. None of the discovery against the government referenced in your letter will shed light on what the defendants knew about the diagnosis codes that were unsubstantiated by patient charts that only UnitedHealth had reviewed. To the extent that scienter focuses on UnitedHealth's knowledge of its legal obligation to delete unsupported diagnosis codes, UnitedHealth's privileged documents (not those of the agency) are relevant.

Finally, with respect to your statement that "documents related to the government's own error rates" are relevant to UnitedHealth's damages calculations, to the extent the agency has non-privileged factual information about coding error rates, we have already agreed to produce it. That said, we do not concede the relevancy of this category of material and we reserve the right to revisit this issue in the event production is burdensome or we encounter issues concerning proprietary information.

II. UnitedHealth Misapprehends the Deliberative Process Privilege

Even assuming UnitedHealth could establish the relevancy of agency deliberations, the government has withheld pre-decisional and deliberative documents in accordance with Ninth Circuit and other authority governing the privilege. The deliberative process privilege is an ancient common law privilege designed to protect predecisional agency deliberations from public scrutiny. *Hongsermeier v. C.I.R.*, 621 F.3d 890, 904 (9th Cir. 2010). "It was developed to promote frank and independent discussion among those responsible for making government decisions" and "to protect against premature disclosure of proposed agency policies or decisions." *F.T.C. v. Warner Commc'ns, Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984) (internal citations omitted). To meet the substantive requirements of the privilege, documents must be both predecisional and deliberative. *Carter v. U.S. Dep't of Commerce*, 307 F.3d 1084, 1089-90 (9th Cir. 2002). "[A] document is predecisional if it was "'prepared in order to assist an agency decisionmaker in arriving at his decision,'" and is deliberative if its release would "'expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions.'" *Id* (internal citations omitted).

UnitedHealth's letter misconstrues the privilege. Contrary to UnitedHealth's assertion, the distinction between whether the nature of materials is factual or opinion is not dispositive of whether material is deliberative. *See Nat. Wildlife Fed'n v. U.S. Forest Serv.*, 861 F.2d 1114, 1118-19 (9th Cir. 1988) (holding that opinions or recommendations regarding facts or consequences of facts are not automatically ineligible from protection; courts have interpreted the exemption "to protect documents that would reveal the *process* by which agency officials

make these determinations, whether or not the documents themselves contain facts or non-binding recommendations regarding law or policy”) (emphasis in original).

We also take issue with the assertion of UnitedHealth that an agency must perfect the privilege at this stage of the proceedings. *See In re Consol. Litig. Concerning Int'l Harvester's Disposition of Wis. Steel*, 1987 WL 20408, at *7 (N.D. Ill. Nov. 20, 1987) (rejecting assertion that declaration must be submitted when privilege is first invoked).

And contrary to UnitedHealth’s assertion, the adoption of a policy by an agency does not remove privilege protection over pre-decisional deliberations. *See Fed. Open Mkt. Comm. of the Fed. Reserve Sys. v. Merrill*, 443 U.S. 340, 360 (1979) (documents protected by “the privilege for predecisional deliberations . . . remain privileged even after the decision to which they pertain may have been effected, since disclosure at any time could inhibit the free flow of advice, including analysis, reports, and expression of opinion within the agency.”).

III. The Government’s Invocation of Privilege Stands in Stark Contrast to UnitedHealth’s Failure to Sufficiently Invoke or Establish Privilege

Finally, it is unclear what “various categories of documents” UnitedHealth believes the government has “refus[ed] to collect” and review, presumably on the basis that they are protected by the deliberative process privilege. The one citation you provide relates to UnitedHealth Request Nos. 2-5, 2-6, and 2-7. In our June 18, 2018 letter, however, we agreed to collect, review, and log privileged documents responsive to these Requests. UnitedHealth, by contrast, still refuses to collect, review, and log categories of documents because, even though such documents are responsive, it “is an overly burdensome request that does not account for proportionality principles.” *See* March 27, 2018 Letter from K. Scheffler to D. Wallack. UnitedHealth must reconsider its position, particularly in light of your contrary assertions.

Consistent with Fed. R. Civ. P. 26(b)(5), moreover, the government has described the material withheld on its privilege logs in a manner that adequately describes the privilege matter “without revealing information itself privileged.” The privilege descriptions by the government are far more detailed than UnitedHealth’s descriptions of purportedly privileged information. Of particular concern are several categories of inadequate, catch-all document descriptions in your logs. While some entries indicate that withheld documents regard specific risk adjustment programs (for example, “development or operation of Claims Verification program” or “RACCR/IDV program”), nearly a third (599 of 1,679 as of May 31) indicate, without elaboration, that the withheld documents regard “other risk adjustment services.” Worse, many descriptions are so generic they could apply to almost any document UnitedHealth has withheld as privileged. For example, 150 entries describe withheld documents as “regarding compliance with legal and/or regulatory requirements.” Similarly, many descriptions relate to routine legal activities that may, or may not, involve privileged communications and that may, or may not, have anything to do with this case. For example, 72 entries describe withheld documents as “regarding internal audit,” and 24 entries describe withheld documents as “regarding draft contract.” The United States is entitled to know, at minimum, what “other risk adjustment services,” what “legal and/or regulatory requirements,” what “audit,” and what “contract.” The above examples are illustrative only and not intended to capture the full extent to which UnitedHealth’s privilege logs are severely deficient.

* * * * *

While we are available to confer on these issues during the week of July 2, UnitedHealth must narrow its overly-broad requests in accordance with the relevance and proportionality principles set forth in Fed. R. Civ. P. 26(b)(1). Further, UnitedHealth should also examine and revise its own privilege assertions before reconvening with the government.

Sincerely,

/s/

Justin Draycott
Trial Attorney
Civil Division, Fraud Section

CC: Counsel of Record

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Attorneys for United Defendants

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

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

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et*
al.,

Defendants.

CASE NO. CV 16-08697-MWF (SSx)

**NOTICE OF LODGING EXCERPTS
OF VIDEO CLIPS OF DEPOSITION
TESTIMONY**

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

1 **TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

2 PLEASE TAKE NOTICE that, pursuant to Central District of California
3 Local Rule 11-5.1, Defendant UnitedHealth Group, Inc. (“United”) hereby lodges
4 as Exhibit 1 video excerpts of the videotaped deposition of Jeffrey Grant dated
5 May 16, 2018.

6 Exhibit 1 is a CD that contains excerpts of video clips from the deposition
7 testimony of Jeffrey Grant on May 16, 2018, referenced as Exhibit 59 to United’s
8 Statement of Genuine Disputes of Material Fact in Opposition to Plaintiffs’ Motion
9 for Partial Summary Judgment (“Statement of Genuine Disputes”). United cannot
10 attach this physical media as an exhibit to its Statement of Genuine Disputes.
11 United respectfully submits this designation in the attached Exhibit.

12
13 Dated: July 23, 2018

14 LATHAM & WATKINS LLP
15 DAVID J. SCHINDLER
16 DANIEL MERON
17 KATHRYN H. RUEMLER
18 ABID R. QURESHI

19 By /s/ David J. Schindler
20 David J. Schindler
21 Attorneys for United Defendants
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23
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EXHIBIT 1

1 IN THE UNITED STATES DISTRICT COURT

2 CENTRAL DISTRICT OF CALIFORNIA

3 Case No. CV 16 08697 MFW (SSx)

4 _____
5 UNITED STATES OF AMERICA,)

6 ex rel. BENJAMIN POEHLING,)

7 Plaintiffs,)

8 v.)

9 UNITEDHEALTH GROUP, INC., et al.,)

10 Defendants.)

11 _____)

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14
15 (Volume 2)

16 DEPOSITION OF JEFFREY GRANT

17 Washington, D.C.

18 May 16, 2018

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24 Reported by: Mary Ann Payonk

25 Job No. 140253

Exhibit 1 contains:

- 1 clip from the videotaped deposition of Jeffrey Grant dated May 16, 2018, running 10:02:20 to 10:04:07
- 1 clip from the videotaped deposition of Jeffrey Grant dated May 16, 2018, running 15:29:59 to 15:34:48

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

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

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-MWF(SSx)

**DECLARATION OF DAVID J.
SCHINDLER IN SUPPORT OF
UNITED'S OPPOSITION TO
PLAINTIFFS' MOTION FOR
PARTIAL SUMMARY
JUDGMENT**

*[Opposition to Motion for Partial
Summary Judgment; Statement of
Genuine Disputes and Declaration of
Abid R. Qureshi filed Concurrently
Herewith]*

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

DECLARATION OF DAVID J. SCHINDLER

I, David J. Schindler, hereby declare as follows:

1. I am a partner at Latham & Watkins LLP, the law firm which represents Defendant UnitedHealth Group Incorporated and its affiliated entities named as Defendants in this action (collectively, “United”). I submit this Declaration in support of United’s Opposition to Plaintiffs’ Motion for Partial Summary Judgment. I have personal knowledge, information, or belief of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

2. Attached as **Exhibit 1** is a true and correct copy of an excerpt from Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (Apr. 6, 2009) (“2010 Announcement” or “2010 Rate Announcement”). A non-excerpted version of this document was produced as part of the administrative record in *UnitedHealthCare Ins. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C.) (“APA United administrative record”) at AR4316–AR4356. A non-excerpted version of this document was marked as Exhibit 1015 at the May 16, 2018 deposition of Jeffrey Grant in this litigation.

3. Attached as **Exhibit 2** is a true and correct copy of an excerpt from Government Accountability Office (“GAO”), *Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments* (January 2013). A non-excerpted version of this document was produced as part of the APA United administrative record at AR12039–AR12064. A non-excerpted version of this document was marked as Exhibit 1010 at the March 20, 2018 deposition of Jeffrey Grant in this litigation.

4. Attached as **Exhibit 3** is a true and correct copy of an excerpt from Gregory C. Pope et al., *Evaluation of the CMS-HCC Risk Adjustment Model: Final*

1 *Report* (March 2011). A non-excerpted version of this document was produced as
 2 part of the APA United administrative record at AR11880–AR12006.

3 5. Attached as **Exhibit 4** is a true and correct copy of an excerpt from
 4 Medicare Payment Advisory Commission, Issues for Risk Adjustment in Medicare
 5 Advantage, in *Report to Congress: Medicare and Health Care Delivery System*
 6 (June 2012).

7 6. Attached as **Exhibit 5** is a true and correct copy of an excerpt from
 8 Richard Kronick & W. Pete Welch, Measuring Coding Intensity in the Medicare
 9 Advantage Program, *Medicare & Medicaid Research Review*, 4(2), (2014). A non-
 10 excerpted version of this document was marked as Exhibit 1011 at the March 20,
 11 2018 deposition of Jeffrey Grant in this litigation and was marked as Exhibit 1002
 12 at the February 28, 2018 deposition of Marilyn Tavenner in this litigation.

13 7. Attached as **Exhibit 6** is a true and correct copy of transcript excerpts
 14 from the deposition of Jeffrey Grant, taken on March 20, 2018, during the course
 15 of this litigation.

16 8. Attached as **Exhibit 7** is a true and correct copy of the transcript from
 17 the deposition of Jeffrey Grant, taken on May 16, 2018, during the course of this
 18 litigation.

19 9. Attached as **Exhibit 8** is a true and correct copy of Brad Piper &
 20 Hillary Millican, *Medicare Advantage Risk Score Primer: What You Need to Know*
 21 *About Diagnoses Supporting Risk Scores and Revenue Payment Timing*, Milliman
 22 White Paper (Oct. 2017).

23 10. Attached as **Exhibit 9** is a true and correct copy of an excerpt from
 24 the Centers for Medicare and Medicaid Services (“CMS”), *2012 Regional*
 25 *Technical Assistance Participant Guide: Encounter Data* (August 6–7, 2012).

26 11. Attached as **Exhibit 10** is a true and correct copy of CMS, *Guidance*
 27 *for Reporting and Returning Medicare Advantage Organization and/or Sponsor*
 28

1 *Identified Overpayments to the Centers for Medicare & Medicaid Services (CMS),*
 2 (Feb. 18, 2015).

3 12. Attached as **Exhibit 11** is a true and correct copy of an excerpt from
 4 the Medicare Managed Care Manual (February 10, 2017) (“2017 Manual”).

5 13. Attached as **Exhibit 12** is a true and correct copy of an email from
 6 Steve Nelson to Cheri Rice dated April 30, 2014, which was produced by United
 7 during the government’s investigation of this matter and is Bates labeled
 8 MARA1296259.

9 14. Attached as **Exhibit 13** is a true and correct copy of an email from
 10 Steve Nelson to Cheri Rice dated June 26, 2015, which was produced by United
 11 during the government’s investigation of this matter and is Bates labeled
 12 MARA2152278–MARA2152279.

13 15. Attached as **Exhibit 14** is a true and correct copy of an email from
 14 Cheri Rice to Johanna Kreisel dated June 7, 2016, which was produced by the
 15 United States during the course of this litigation and is Bates labeled
 16 USBP000498420–USBP000498421.

17 16. Attached as **Exhibit 15** is a true and correct copy of a slideshow
 18 entitled Model Calibration Factor, authored by Jennifer Harlow, Lateefah Hughes
 19 and Jonathan Smith, which I understand was first produced by CMS pursuant to
 20 Freedom of Information Act (“FOIA”) request 05240137007 and is Bates labeled
 21 CMS0005881-CMS0005891. This document was marked as Exhibit 1004 at the
 22 February 28, 2018 deposition of Marilyn Tavenner in this litigation.

23 17. Attached as **Exhibit 16** is a true and correct copy of a document
 24 entitled “Agenda” which I understand was first produced by CMS pursuant to
 25 FOIA request 05240137007 and is Bates labeled CMS0006198-CMS0006203.
 26 This document was marked as Exhibit 1019 at the May 16, 2018 deposition of
 27 Jeffrey Grant in this litigation.

28

1 18. Attached as **Exhibit 17** is a true and correct copy of an excerpt from
2 Pope et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-*
3 *HCC Model*, Health Care Financing Review, 25(4), (Summer 2004). A non-
4 excerpted version of this document was produced as part of the APA United
5 administrative record at AR11857–AR11879. A non-excerpted version of this
6 document was marked as Exhibit 1009 at the March 20, 2018 deposition of Jeffrey
7 Grant in this litigation.

8 19. Attached as **Exhibit 18** is a true and correct copy of Policy and
9 Technical Changes to the Medicare Advantage and the Medicare Prescription Drug
10 Benefit Programs, 75 Fed. Reg. 19,678 (Apr. 15, 2010) (Final Rule) (“2010 Rule”
11 or “2010 RADV Rule”). This document was produced as part of the APA United
12 administrative record at AR2817–AR2830.

13 20. Attached as **Exhibit 19** is a true and correct copy of a PowerPoint
14 presentation sent as an attachment to Exhibit 20, which was produced by the
15 United States during the course of this litigation and is Bates labeled
16 USBP000011428–USBP000011433. This document was marked as Exhibit 1017
17 at the May 16, 2018 deposition of Jeffrey Grant in this litigation.

18 21. Attached as **Exhibit 20** is a true and correct copy of an email from
19 Jeffrey Grant to Thomas E. Hutchinson dated May 29, 2009, which was produced
20 by the United States during the course of this litigation and is Bates labeled
21 USBP000011424–USBP000011427. This document was marked as Exhibit 1016
22 at the May 16, 2018 deposition of Jeffrey Grant in this litigation.

23 22. Attached as **Exhibit 21** is a true and correct copy of an excerpt from
24 Advance Notice of Methodological Changes for Calendar Year (CY) 2009 for
25 Medicare Advantage (MA) Capitation Rates and Part D Payment Policies (Feb. 22,
26 2008) (“2009 Advance Notice”). A non-excerpted version of this document was
27 produced as part of the APA United administrative record at AR4220–AR4255.

28

23. Attached as **Exhibit 22** is a true and correct copy of an excerpt from the Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5301(b)(2), 120 Stat. 4, 51 (Feb. 8, 2006).

24. Attached as **Exhibit 23** is a true and correct copy of an excerpt from Announcement of Calendar Year (CY) 2014 Medicare Advantage and Part D Payment Policies and Final Call Letter (April 1, 2013) (“2014 Announcement” or “2014 Rate Announcement”). A non-excerpted version of this document was produced as part of the APA United administrative record at AR4829–AR4914.

25. Attached as **Exhibit 24** is a true and correct copy of the Declaration of Mary Murley, dated July 23, 2018, made in support of United’s Opposition to the Plaintiffs’ Motion for Partial Summary Judgment.

26. Attached as **Exhibit 25** is a true and correct copy of an excerpt from Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 2, 2012) (“2013 Rate Announcement”). A non-excerpted version of this document was produced as part of the APA United administrative record at AR4688–AR4749.

27. Attached as **Exhibit 26** is a true and correct copy of Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) (“RADV Methodology” or “Final RADV Methodology”). This document was produced as part of the APA United administrative record at AR5311–AR5315. This document was marked as Exhibit 1005 at the February 28, 2018 deposition of Marilyn Tavenner in this litigation.

28. Attached as **Exhibit 27** is a true and correct copy of an excerpt from Public Comments of Aetna on the 2009 Proposed RADV Rule. A non-excerpted version of this document was produced as part of the APA United administrative record at AR2608–AR2652.

29. Attached as **Exhibit 28** is a true and correct copy of an excerpt from Public Comments of AHIP on the 2009 Proposed RADV Rule. A non-excerpted version of this document was produced as part of the APA United administrative record at AR2718–AR2764.

30. Attached as **Exhibit 29** is a true and correct copy of Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits; Request for Comment (Dec. 20, 2010) (“Proposed RADV Methodology”). This document was produced as part of the APA United administrative record at AR5020–AR5022.

31. Attached as **Exhibit 30** is a true and correct copy of an excerpt from Public Comments of Aetna on the Proposed RADV Methodology, dated January 21, 2011. A non-excerpted version of this document was produced as part of the APA United administrative record at AR5036–AR5071.

32. Attached as **Exhibit 31** is a true and correct copy of an excerpt from Public Comments of Humana on the Proposed RADV Methodology, dated Jan. 21, 2011. A non-excerpted version of this document was produced as part of the APA United administrative record at AR5102–AR5162.

33. Attached as **Exhibit 32** is a true and correct copy of an excerpt from Public Comments of United on the Proposed RADV Methodology, dated Jan. 21, 2011. A non-excerpted version of this document was produced as part of the APA United administrative record at AR5193–AR5224.

34. Attached as **Exhibit 33** is a true and correct copy of Public Comments of American Academy of Actuaries on the Proposed RADV Methodology, dated Jan. 21, 2011. This document was produced as part of the APA United administrative record at AR5235–AR5236.

35. Attached as **Exhibit 34** is a true and correct copy of an excerpt from Public Comments of Humana on the Contract Year 2015 Policy and Technical

Changes to the Medicare Advantage and the Medicare Prescription Drug Benefits Programs, 79 Fed. Reg. 1918 (January 10, 2014) (the “Proposed Overpayment Rule”). A non-excerpted version of this document was produced as part of the APA United administrative record at AR865–AR918.

36. Attached as **Exhibit 35** is a true and correct copy of an excerpt from Public Comments of United on the Proposed Overpayment Rule, dated Mar. 7, 2014. A non-excerpted version of this document was produced as part of the APA United administrative record at AR1009–AR1056.

37. Attached as **Exhibit 36** is a true and correct copy of an excerpt from Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014) (Final Rule) (“Overpayment Rule”). A non-excerpted version of this document was produced as part of the APA United administrative record at AR1235–AR1354.

38. Attached as **Exhibit 37** is a true and correct copy of *UnitedHealthcare Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Oct. 17, 2017) (ECF No. 47-1) (United’s Motion for Summary Judgment) (“APA United Opening Brief”).

39. Attached as **Exhibit 38** is a true and correct copy of *UnitedHealthcare Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Dec. 4, 2017) (ECF No. 58) (Defendants’ Memorandum in Support of Their Cross-Motion for Summary Judgment and in Opposition to Plaintiffs’ Motion for Summary Judgment) (“APA CMS Opening Brief”).

40. Attached as **Exhibit 39** is a true and correct copy of *UnitedHealthcare Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Jan. 18, 2018) (ECF No. 60) (United’s Opposition to the Government’s Motion for Summary Judgment and Reply in Support of United’s Motion for Summary Judgment) (“APA United Response Brief”).

41. Attached as **Exhibit 40** is a true and correct copy of *UnitedHealthcare Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Feb. 12, 2018) (ECF No. 64) (Defendants' Reply in Support of Their Cross-Motion for Summary Judgment) ("APA CMS Reply Brief").

42. Attached as **Exhibit 41** is a true and correct copy of an excerpt from the Medicare Managed Care Manual (July 2, 2001) ("2001 Manual"). A non-excerpted version of this document was produced as part of the APA United administrative record at AR5316–AR5558.

43. Attached as **Exhibit 42** is a true and correct copy of an excerpt from Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 2000 (January 10, 2014) (Proposed Rule). A non-excerpted version of this document was produced as part of the APA United administrative record at AR1–AR157. A non-excerpted version of this document was marked as Exhibit 1006 at the February 28, 2018 deposition of Marilyn Tavenner in this litigation.

44. Attached as **Exhibit 43** is a true and correct copy of an excerpt from Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (Apr. 7, 2008) ("2009 Rate Announcement"). A non-excerpted version of this document was marked as Exhibit 1014 at the May 16, 2018 deposition of Jeffrey Grant in this litigation.

45. Attached as **Exhibit 44** is a true and correct copy of transcript excerpts from the deposition of Larry Renfro, taken on May 6, 2016, pursuant to Civil Investigative Demand No. 16-13, as part of the government's investigation of this matter.

46. Attached as **Exhibit 45** is a true and correct copy of notes from a conversation between Larry Renfro and Marilyn Tavenner dated April 8, 2014, which was produced by United during the government's investigation of this matter and is Bates labeled MARA2160500.

47. Attached as **Exhibit 46** is a true and correct copy of an email from Larry Renfro to Janis Leafgren dated April 28, 2014, which was produced by United during the government's investigation of this matter and is Bates labeled MARA1998459.

48. Attached as **Exhibit 47** is a true and correct copy of a CMS meeting notes document dated April 29, 2014, which was produced by United during the government's investigation of this matter and is Bates labeled MARA2157039–MARA2157040.

49. Attached as **Exhibit 48** is a true and correct copy of transcript excerpts from the deposition of Marilyn B. Tavenner, taken on February 28, 2018, during the course of this litigation.

50. Attached as **Exhibit 49** is a true and correct copy of UHC of California, Inc., Contract No. H0543-001-000, MA Supporting Documentation for CY 2015 Bid, dated Aug. 5, 2014 (CONDITIONALLY UNDER SEAL).

51. Attached as **Exhibit 50** is a true and correct copy of Pacificare of California, Contract No. H0543-007-000, MA Supporting Documentation for CY 2012 Bid, dated June 5, 2011 (CONDITIONALLY UNDER SEAL).

52. Attached as **Exhibit 51** is a true and correct copy of an excerpt from CMS, Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2014 (April 5, 2013).

53. Attached as **Exhibit 52** is a true and correct copy of the Declaration of Jon Bird, dated July 23, 2018, made in support of United's Opposition to the Plaintiffs' Motion for Partial Summary Judgment.

54. Attached as **Exhibit 53** is a true and correct copy of an excerpt from Advance Notice of Methodological Changes for CY 2004 Medicare+Choice (M+C) Payment Rates (Mar. 28, 2003) ("2004 Advance Notice"). A non-excerpted version of this document was produced as part of the APA United administrative record at AR3888–AR3921. A non-excerpted version of this

1 document was marked as Exhibit 1012 at the March 20, 2018 deposition of Jeffrey
2 Grant in this litigation.

3 55. Attached as **Exhibit 54** is a true and correct copy of *UnitedHealthcare*
4 *Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Apr. 14, 2017) (ECF No. 28)
5 (“APA U.S. Motion to Stay”).

6 56. Attached as **Exhibit 55** is a true and correct copy of *UnitedHealthcare*
7 *Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Apr. 28, 2017) (ECF No. 31)
8 (“APA United Opposition to Motion to Stay”).

9 57. Attached as **Exhibit 56** is a true and correct copy of *UnitedHealthcare*
10 *Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. June 14, 2017) (ECF No. 38)
11 (“APA Motion to Stay Order”).

12 58. Attached as **Exhibit 57** is a true and correct copy of *UnitedHealthcare*
13 *Insur. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C. Mar. 31, 2017) (ECF No. 25)
14 (“APA Motion to Dismiss Order”).

15 59. Attached as **Exhibit 58** is a true and correct copy of an excerpt from
16 Advance Notice of Methodological Changes for CY 2014 for Medicare Advantage
17 (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter
18 (Feb. 15, 2013) (“2014 Advance Notice”). A non-excerpted version of this
19 document was produced as part of the APA United administrative record at
20 AR4752–AR4828.

21 60. Filed as Exhibit 1 to United’s Notice of Lodging Excerpts of Video
22 Clips of Deposition Testimony and referenced here as **Exhibit 59** is a true and
23 correct copy of a video excerpt from the deposition of Jeffrey Grant, taken on May
24 16, 2018, during the course of this litigation.

25
26 I declare under penalty of perjury under the laws of the United States that
27 the foregoing is true and correct.
28

Executed: July 23, 2018, at Los Angeles, California.

/s/ David J. Schindler

David J. Schindler

EXHIBIT 1

April 6, 2009

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2010, and the risk and other factors to be used in adjusting such rates. The capitation rate tables for CY 2010 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/> under Ratebooks and Supporting Data. The spreadsheet that shows the statutory component of the regional benchmarks is also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2010. These growth rates will be used to update the 2010 rates, except for the ESRD State rates, which are subject to a 2 percent minimum increase under Section 1853(a)(1)(H). As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 0.81 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2007 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2010 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). We received 66 submissions in response to CMS' request for comments on the Advance Notice, published on February 20, 2009. Three of the comments were from advocacy groups, three were from Congress (members or agencies of Congress), seven were from associations, nine were from consultants, and forty-four were from health plans.

Attachment IV contains tables with the Part D benefit parameters.

Key Changes from the Advance Notice

Attachment I provides the final estimates of the National MA Growth Percentages (growth trends) and information on deductibles for MSA standard and demonstration plans, and on the maximum out-of-pocket amount for MSA demonstrations plans.

Attachment III, Section E announces the policy decision on the MA coding pattern differences adjustment for 2010. After consideration of comments, CMS has modified the methodology proposed in the Advance Notice. Section D includes the Budget Neutrality factor for 2010. Attachment IV announces the final version of the update to the Part D Benefit Parameters.

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Announcement supersede materials in the Advance Notice.

Proposals Adopted as Issued in the Advance Notice:

Frailty Adjustment Transition for PACE organizations. Frailty adjustment scores will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2010 will be calculated using a blend of 50% of the frailty factors in use prior to 2008 and 50% of the recalibrated frailty factors implemented in 2009.

Frailty Adjustment Transition for Certain Demonstrations. Frailty adjustment scores will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/ Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans. The phase out schedule for 2010 is 25% of the pre-2008 frailty factors. 2010 will be the final year in the phase out for these MA plan types.

Normalization Factors. Normalization factors for 2010 are as follows:

- The final 2010 normalization factor for the aged-disabled model is 1.041.
- The final 2010 normalization factor for the ESRD dialysis model is 1.039.
- The final 2010 normalization factor to be applied to the risk scores of enrollees in functioning graft status is 1.072.
- The final 2010 normalization factor for the RxHCC model is 1.146.

ESRD Payment. For payment year 2010, CMS' payments for ESRD dialysis and transplant enrollees will be based on State rates calculated using a blend of 25% of the old State ratebook (in use through 2007) and 75% of the revised State ratebook (implemented in 2008).

IME Phase Out. For 2010, CMS will begin phasing out indirect medical education (IME) amounts from MA capitation rates (including ESRD).

Location of Network Areas for PFFS Plans in Plan Year 2011. The list of network areas for plan year 2011 can be downloaded from the following website: <http://www.cms.hhs.gov/PrivateFeeforServicePlans/> The list has not changed since the publication of the Advance Notice.

Continuation of Clinical Trial Policy. In 2010, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Adjustment to FFS Per Capita Costs for VA-DOD Costs. For payment year 2010, OACT concludes that there is insufficient evidence to incorporate any VA adjustment into the rate making process.

Calculation and Source Data of MSP Factor. For payment year 2010, CMS no longer requires that MA organizations conduct, nor will we use the results of, plan surveys conducted in 2009. Rather, CMS will adjust for MSP status using Coordination of Benefits (COB) data.

Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM). In accordance with the January 12, 2009 Final Rule with Comment, “Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions”, Part D sponsors must use the amount paid to the pharmacy (or other dispensing provider) when calculating beneficiary cost sharing, developing their Part D bids, and reporting drug costs to CMS. For Part D sponsors that contract with a PBM, amounts paid to the PBM for Part D drugs that exceed the amounts paid to the pharmacy (or other dispensing provider) must be included in the administrative expense component of the bid. Starting in 2010, Part D sponsors will not be required to submit an Attestation of Pricing Approach.

Reinsurance Payment Demonstration Plans. 2010 is the last scheduled year for the Part D Reinsurance Payment Demonstration. CMS will not accept any new or expanded applications for reinsurance demonstration plans to be offered in 2010. Reinsurance demonstration plans which were offered in 2009 may continue through 2010. The budget neutrality offsets applied to the capitated reinsurance payments for these plans will be \$10.77 per member per year for contract year 2010.

Payment Reconciliation. The 2010 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2009. The risk percentages for the first and second thresholds remain at 5% and 10% respectively of the target amount for 2010. The payment adjustments for the first and second corridors are 50% and 80% respectively.

Questions can be directed to:

Paul Spitalnic at (410)-786-2328) or Paul.Spitalnic@cms.hhs.gov for Attachments I and II

Deondra Moseley at (410) 786-4577 or Deondra.Moseley@cms.hhs.gov, Rebecca Paul at (410) 786-0852 or Rebecca.Paul@cms.hhs.gov, or Meghan Elrington at (410)786-8675 or Meghan.Elrlington@cms.hhs.gov for Attachments III and IV.

/ s /

Jonathan D. Blum
Acting Director
Center for Drug and Health Plan Choice

/ s /

Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

The BN factor estimate for 2010 is 0.10%. This factor was calculated based on a full BN factor of 2.0%, multiplied by the BN phase-out percentage of 5 percent. 2010 is the fourth and final year of the phase-out required by the DRA, and 5 percent of the full BN factor is applied to the rates, as the same percentage for all counties.

Section E. Adjustment for MA Coding Pattern Differences

In the Advance Notice, we proposed a coding difference adjustment of 3.74%. This adjustment was based on adjusting for three years of differential coding between MA and FFS, i.e., from 2007 to 2010. This adjustment factor was calculated based on beneficiaries who were enrolled for seven months or more in any given year, using data for three cohorts (2004-2005, 2005-2006, and 2006-2007). In the Notice, we stated our intention to update the adjustment factor with data for an additional cohort (2007-2008) for the Rate Announcement.

Our analysis of the 2007-2008 cohort showed that coding pattern differences have accelerated and this finding has strengthened our conclusion that coding pattern differences between MA and FFS are having a notable impact on payment. Because this is the first year that CMS is implementing this MA coding adjustment under the provisions of the DRA, however, CMS is taking a conservative approach and implementing an adjustment factor using a coding difference factor based on the earliest three cohorts (2004-2005, 2005-2006, and 2006-2007). CMS will consider the 2007-2008 data and later cohort data for future MA coding pattern difference factors.

CMS received a number of comments suggesting that the stayer percentage and enrollment duration factor used to calculate the MA coding pattern difference adjustment factor should be based only on beneficiaries who are enrolled in MA for a full 12 months in any given year, rather than seven months or more. CMS concurs with these comments; in finalizing the 2010 MA coding pattern difference adjustment factor, CMS is basing the stayer percentage and enrollment duration factor on 12 months of continuous MA enrollment.

Based on these changes in methodology, the final 2010 MA coding intensity adjustment will be 3.41%. Table 1 summarizes the calculation of the adjustment.

Table 1: Calculation of Difference Factor

Calculation of difference factor for 2010 Cohorts between 2004 and 2007 EDF = 2.38 Stayer percentage = 81.8%	
Weighted average of Year 2 MA risk scores	0.9806
Weighted average differences in disease score growth	0.0171
Difference factor as a percent of risk score	1.75%
Apply EDF to obtain adjustment factor (2.38)	4.16%
Adjust for percent of stayers to allow application of adjustment factor to all enrollees' risk scores (81.8%)	3.41%

Comment: A number of commenters offered CMS strong support for our determination in the Advance Notice that we were required to apply a coding pattern difference adjustment in 2010. Several commenters cited several reasons why the adjustment was appropriate. They agreed with CMS that the adjustment will improve payment accuracy, reduce unnecessary Medicare expenditures, and better assure financial neutrality between FFS and MA. Some commenters opined that the adjustment was long overdue. Commenters noted that MA organizations had an incentive to identify and code diseases, whether the diseases were treated or not, and that as a result unadjusted risk scores show MA enrollees to be sicker than they actually are. Several commenters noted that the increased MA payments resulting from coding pattern differences are in addition to the 14% payment differential resulting from MA benchmarks being set above Medicare FFS levels. One commenter noted that because physicians in FFS do not have a financial incentive to code as intensely, MA plan risk scores can increase at a greater rate than FFS risk scores, making MA enrollees look less healthy and more costly without any change in their actual health status.

Response: We concur with these comments.

Comment: Several commenters argued that the coding pattern difference adjustment was being made on the assumption that coding observed in the FFS program is accurate, and argued that CMS should not penalize MA organizations for differing from FFS coding patterns if, in fact, these FFS patterns were somehow inaccurate or inadequate. One commenter expressed concern that the adjustment would penalize many organizations for doing what CMS and Congress intended when they implemented risk adjustment payments (invest resources to improve data collection and educate providers on proper documentation). One commenter contended that a significant differential should be expected between FFS and SNPs for SNPs that code accurately. Another commenter claimed that risk scores of beneficiaries in Original Medicare are depressed by the inadequate coding of chronic conditions on FFS claims. One commenter does not believe that it is in keeping with Congressional intent for CMS to make a negative adjustment to all plans regardless of whether improper or inaccurate coding has been identified; another commenter thought that an across-the-board adjustment conflicted with Congressional intent to adjust payments for “differences resulting from inaccurate coding.”

Response: As we stated in the 2009 Advance Notice, we do not assume that the coding pattern differences that we found in our study are the result of improper coding. As documented in the 2009 Announcement, CMS believes that the statutory language in the DRA provision at issue provides for a payment adjustment if CMS establishes that there are “differences in coding patterns between Medicare Advantage plans and providers under part A and B.”

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MA organizations are coding “accurately” when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, “differences” in coding patterns, regardless of the source, would make the MA plan coding “inaccurate” for purposes of implementing risk adjustment.

This reading of the word “inaccurate” is supported by floor statements made by Senator Grassley, Congressman Barton, and Congressman Thomas. Senator Grassley made the following floor statement; the other two committee chairs made very similar statements:

“Section 5301 and the joint statement which accompanied the conference report in the Senate requiring adjustments for differences in coding patterns is intended to include adjustments for coding that is inaccurate or incomplete for the purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings, even if such coding is accurate or complete for other purposes. This will ensure that the goal of risk adjustment—to pay plans accurately—is met.”

Comment: One commenter argued that, since CMS did not make adjustments in 2008 and 2009, this necessarily must mean that data available to CMS as late as April 2008 did not demonstrate that the changes in risk scores were the result of differences in coding patterns, and that CMS accordingly should not apply an adjustment based on 2007 to 2008 data. Under this argument, CMS cannot now state that a change in risk score trends can be conclusively attributed to differences in coding patterns based on pre-April, 2008 dates. This commenter argued that CMS can adjust the capitation rates only to compensate for that one year of differential. In other words, the commenter argued that CMS implicitly had previously found that prior years of risk score trends can be explained based on factors other than coding patterns, and thus should not rely on the data to make an adjustment. Another commenter opined that the information in the 2010 Advance Notice fails to present substantive new evidence free of technical concerns.

Response: While, in previous years, CMS has delayed the application of a coding patterns difference adjustment in order to conduct further research, this did not mean that we had concluded that risk score trends were caused by factors other than coding pattern. Our most recent analysis – discussed below – has resulted in our decision to apply a coding pattern differences adjustment in 2010. We believe that, having concluded that the differences we have observed are in fact attributable to differences in coding patterns, it is appropriate to use data from the beginning of the program, as deemed necessary to better ensure appropriate and accurate payments.

Comment: Several commenters, noting that CMS had indicated in last year’s Announcement that we would use the results from the risk adjustment data validation (RADV) audits to inform our assessment of whether risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees, inquired about our findings and how they supported the coding pattern difference adjustment. A number of commenters were concerned that CMS would be making an adjustment twice for the same coding effects if it applied both a coding pattern difference adjustment and made adjustments as a result of its RADV audits. Several commenters expressed concern that a prospective coding intensity adjustment in combination with future 2010 risk score audits could result in duplicate adjustments. A few commenters asked if CMS was adjusting the 2007 risk scores used in developing the MA coding pattern difference adjustment factor for adjustments made as a result of the RADV audits. Some commenters suggested that, instead of implementing a coding pattern difference adjustment, we rely on the RADV audits. They contended that the current risk score validation audit process was the appropriate system to determine coding accuracy and payments should only be adjusted for the subset of plans in which coding problems can be documented.

Response: CMS' strategy for determining the correct MA coding pattern difference for 2008 and 2009 was to ensure that we thoroughly understood the dynamics behind the coding pattern differences between MA and FFS. In this spirit, we agreed to assess whether the new annual medical record audits would be able to inform our study of MA coding pattern differences. Medical record audits serve the purpose of determining whether diagnosis codes submitted to CMS for risk adjustment payment purposes have a basis in the documented medical record, while our study of MA coding pattern differences has resulted in a better understanding of the differential growth in the number of diagnosis reported by MA plans and FFS providers. The results of the medical record audits supported our approach to calculating the MA coding pattern differences adjustment by failing to show a systematic correlation between coding pattern differences and errors in the reporting of documented coding.

Comment: Several commenters argued that CMS was not authorized to make a retroactive coding pattern difference adjustment. Another commenter asked if the adjustment would be used for 2010 alone, or would also be used to make retroactive adjustments. Several commenters opined that the DRA did not require a retroactive adjustment and that, since the MA payment methodology is fundamentally a prospective system, that absent an explicit statutory direction to impose a retroactive adjustment, CMS should not apply adjustments it now deems appropriate for 2008 and 2009 into 2010 payments. A couple commenters argued that the DRA established coding intensity to be a single annual adjustment made for each coverage year, if supported by the data, and felt that the MA coding pattern difference adjustment described in the Advance Notice was intended to retroactively apply an adjustment for 2008 and 2009. One commenter felt that this was not the intent of Congress and the other commenter felt that this adjustment would be made for years when CMS found that it did not have adequate information to justify an adjustment.

Response: CMS is not making a retroactive adjustment. We estimated the cumulative coding pattern difference in MA and FFS stayers' disease scores in 2010. We calculated this adjustment by applying a three-year enrollment duration factor (EDF) to the annual average difference in disease score growth, essentially calculating the adjustment to account for three years of coding pattern differences. As a result, the coding adjustment is an estimate of how much lower risk scores would be in 2010 if they rose at the same rate as FFS risk scores over the period 2007-2010. We note that some commenters supported using six years (2004-2010) in the calculation based, taking into account all measured differences since risk adjusted payments were begun.

Comment: One commenter believed that using a 2-year stayer cohort captures a large proportion of MA stayers that are new to MA with no coding history in year-one with potentially larger coding increases in the second year as the plan gains accurate diagnosis data. Another commenter opined that the calculation of the adjustment does not seem to acknowledge a trend observed by MA organizations in which a beneficiary's risk score increases more quickly during the second year that the beneficiary is enrolled in an MA plan and that, therefore, the enrollment effect that the agency attempts to isolate may be larger than assumed in the notice. One commenter suggested studying 3-and 4-year stayer cohorts; they also recommend that CMS study the cohort of individuals that would not qualify as stayers due to being in MA or FFS for only a single year over the examined time period.

Response: The method by which CMS constructs its two-year stayer cohorts ensures that the experience of beneficiaries newly enrolled in MA are not included in the difference measurement. Requiring enrollees to have been enrolled for thirty months results in first-year disease scores that were coded exclusively by either MA plans or FFS providers and, thus, CMS is comparing year-after-year disease scores that were coded exclusively by a single sector. These cohorts will capture some enrollees' second and third years in MA, but it will also capture differential disease score changes for enrollees who have been enrolled in either sector for longer periods of time. Therefore, the difference factor is calculated over all beneficiaries who have been enrolled in a sector over varying periods of time, thereby obtaining an average difference across all continually-enrolled beneficiaries.

The use of cohorts over more than two years would result in smaller cohorts of non-representative beneficiaries in that they were alive much longer and they were enrolled in their respective sector for longer than beneficiaries in the two-year cohorts. For example, beneficiaries who are in MA for at least 3 or 4 years are not identical to those who are enrolled for at least two years. Two-year cohorts capture the information needed while keeping the largest number of enrollees in the cohorts.

Comment: One commenter stated that, since CMS acknowledges that a significant portion of Medicare beneficiaries who join MA plans are switching from FFS, and that the vast majority of beneficiaries joining FFS are newly eligible and have very low risk scores, basing an adjustment of risk scores on a comparison of FFS to MA enrollees will overstate the differences between the two groups.

Response: CMS constructs the cohorts in such a way that “joiners” and “leavers” – beneficiaries who switch from one sector to the other – are excluded from the population on whom we calculate the difference factor. The cohorts only include beneficiaries who have been in MA or FFS for several years – at least 30 months.

Comment: A couple commenters expressed interest in having CMS recognize that MA plans' effort to “catch up” with FFS in the coding pattern difference adjustment factor. One commenter felt that changes in coding due to “catch up” fell outside the purview of the DRA and strongly suggested that the agency consider changes to the calculation of the adjustment to exclude “catch up” to more directly address the statutory requirement. Another commenter felt that, after seeking to take “catch up” into account last year, CMS should recognize it in the 2010 adjustment factor. One commenter offered an example of a way to adjust for “catch up” that involved applying a ratio of the amount by which the average MA risk score was below the FFS 1.0 when risk adjusted payments started, relative to the amount by which the average MA risk score was greater than the FFS 1.0 in later years.

Response: While we are using cohorts starting with 2004-2005 to calculate the average difference factor, we are only taking into account three years of experience in the enrollment duration factor (EDF). Any catch up occurring in the first three years (2004-2007) of risk adjusted payments is not factored into the duration factor and, therefore, not included in the coding pattern difference adjustment. In other words, by adjusting the annual average difference by the average enrollment over the past three years, CMS is only adjusting 2010 risk scores by

the cumulative effect of coding pattern differences over three years, and not over all six years since the start of risk adjusted payments.

Comment: One commenter stated that the enrollment duration factor (EDF) seems intended to reflect the number of beneficiaries to whom a coding intensity adjustment would have been appropriately applied in 2008 and 2009 (if the agency had made a determination to apply such an adjustment in time to affect payments in those years) and prospectively in 2010. Another commenter questioned why CMS was using an enrollment duration factor and felt that an adjustment based on the disease scores would take differences into account. This commenter argued that CMS had not established that there was a link between length of MA enrollment and higher risk scores or explained how the EDF meets with the intent of the DRA.

Response: The enrollment duration factor (EDF) is used to adjust the annual difference factor in order to approximate the experience of stayers in 2010. In other words, the EDF creates a single year, prospective estimate of cumulative difference between MA and FFS disease scores (not just the marginal growth in the difference from the previous year). A less nuanced way to calculate the cumulative difference would simply be to multiply the average annual difference (the difference factor) times the number of years being taken into account. The EDF allows CMS to adjust the annual average difference by the estimated enrollment experience of the beneficiaries in MA during the payment year.

Comment: Several commenters recommended that the adjustment incorporate an analysis of coding pattern differences in four cohorts available at the time the Announcement is published: 2004-2005, 2005-2006, 2006-2007, and 2007-2008. They felt that doing so would permit the agency to more precisely determine the appropriate magnitude of the adjustment while considering data from the 2004-2005 data collection year, when risk adjustment was first a significant component of MA plan payments. One commenter felt that, since the coding difference experience seems to be volatile and unpredictable, using four cohorts would add some stability to the calculation. They cited OACT's use of 5-year moving averages of the ratio of the county FFS per capita costs to national per capita costs when estimating the FFS costs in each county.

Response: Because 2010 is the first year that CMS is applying the MA coding pattern difference factor under the provisions of the DRA, we have decided to take a conservative approach and calculate the difference factor using only the first three cohorts, as described in the Advance Notice. After applying the new enrollment duration factor (EDF) (see below), the MA coding pattern difference factor for 2010 is 3.41.

Comment: Several commenters disagreed with the use of seven months enrollment in the prior year to determine whether someone is a stayer for purposes of the enrollment duration factor (EDF) and felt that twelve months would be a more appropriate measure. Commenters contended that an MA organization needed at least one full year of enrollment experience with a beneficiary to credibly calculate a member's risk score and that 12 months was in alignment with the idea that the adjuster should be applied to "stayers." One commenter understood that the EDF makes the assumption that the adjustment factor would be the same for members with between 7 and 30 months of plan membership, and believed that this was highly unlikely, and that the effect of relative coding intensity are likely to increase over time. One commenter asked

how CMS had validated that a 7 month time period is sufficient to capture the HCC diagnoses for a member.

Response: The objective of the enrollment duration factor (EDF) is to capture the average number of years a population of enrollees has had their diagnoses submitted by the MA sector; for this factor, we are not trying to capture change in disease score, but exposure to MA coding patterns. In response to industry concerns regarding the adequacy of seven months of enrollment in capturing and reporting enough diagnoses codes to establish a pattern, CMS will use twelve months in previous years as a criteria for calculating the EDF. Using twelve months, applied to the same time period as in the Advance Notice – 2007-2010 – the EDF that CMS will use in calculating the adjustment factor will be 2.38.

Comment: One commenter noted that plans with more turnover will have lower EDFs. Other commenters asked if an analysis had been done to see how much variance there is in enrollment duration from plan to plan.

Response: CMS recognizes that enrollment duration may differ among plans. Because we have determined that it is most appropriate to apply an industry-wide adjustment, the EDF used in the calculation will, by its construct, be an industry average.

Comment: One commenter wanted CMS to use the same definition of “stayer” when determining the stayer percentage as we do when developing the cohorts used for measuring the coding pattern difference (30 months of continuous enrollment).

Response: Because CMS will apply the adjustment to all enrollees’ risk scores, not just stayers, we need to reduce the adjustment proportionately so that the aggregate effect is the same, whether we applied the adjustment to stayers only or to all enrollees. To calculate the actual adjustment to use in payment, we reduce it by the proportion of stayers in MA for the most current period available. In applying the twelve month enrollment criteria in calculating previous-year enrollment for the EDF, we also changed the calculation of the stayer percentage that we will use to reduce the adjustment factor for application in payment. The stayer percentage we will use is 81.8%.

Comment: Commenters suggested a number of additional factors that they thought CMS should adjust for in calculating the coding pattern difference adjustment factor. The additional factors suggested are: age, gender, originally disabled, Medicaid eligibility, institutional status, hospice status, beneficiaries with multiple chronic conditions, duration in managed care, health status, type of plan, plan size, socio-economic status, racial/ethnic differences, and enrollment in the Veterans Affairs or Department of Defense health programs. A number of commenters requested that CMS adjust for regional differences in FFS coding differences. One commenter felt that plans with a high proportion of recent FFS members or in regions where MA coding changes are not greater than FFS are disadvantaged. One commenter suggested that possible anti-selective effects in MA were resulting in an overestimate of MA’s rising risk scores. One commenter asked how CMS knew that measured differences in coding changes between MA and FFS were really coding pattern changes and not changes in health status.

Response: CMS did take into account factors that we believed would have an important influence on the rate of change in disease score growth between MA and FFS. For example, we adjusted the difference factor (the annual average difference in disease score growth between MA and FFS) for age and survivor status variations between MA and FFS. Because a greater proportion of disabled beneficiaries are enrolled in FFS than in MA, and because disabled beneficiaries risk scores tend to grow more slowly than aged beneficiaries' risk scores, adjusting for age reduced the differences in disease score growth between the two sectors. In addition, the enrollment duration factor (EDF) takes into account the average duration of enrollment in the MA sector of those who are present in the year prior to the payment year. We believe that age and survivor status are correlated to the differential change in disease scores between MA and FFS, and that duration of enrollment in the MA sector directly affects how long a beneficiary's disease score has been exposed to this differential. It is not clear that other factors would affect differential changes in disease score.

Comment: One commenter inquired about which version of the CMS-HCC model we used to calculate the coding pattern differences.

Response: CMS used the version of the CMS-HCC model that was used in payment from 2004 through 2006 to calculate the difference factor. We ran all cohorts through the same version of the model, so that measurements of differences would not be affected by model changes.

Comment: One commenter wanted CMS to establish an appeals mechanism that would allow plans to demonstrate that their coding patterns are correct.

Response: As discussed above, the MA coding pattern difference adjustment is not adjusting for coding that is incorrect, but for coding that differs from FFS and is therefore inaccurate for payment. Further, the industry-wide adjustment factor will not be modified for individual plans.

Comment: In the 2010 Advance Notice, CMS invited comments on the decision to adjust for differences in disease growth for the three-year period prior to 2010, as well as on alternative approaches involving a greater or smaller number of years. A number of commenters wanted CMS to adjust for one year instead of three. One commenter states that using the annual rate going back to 2004 would be the most reasonable approach. One commenter stated that CMS should make an adjustment on a prospective basis only, which they took to mean a single year adjustment. Several commenters argued that the DRA requires CMS to adjust for all differences in coding patterns, and suggested that CMS should adjust for all measured and projected differences, including those attributable to the excluded period for 2004-2007. Another commenter noted that, while one alternative was to make an adjustment for all years during which comprehensive risk adjustment has been in place – that is, 2004 to 2010 -- on balance they were inclined to think that the methodology described in the Advance Notice was appropriate.

Response: The difference factor, which takes into account coding pattern differences from 2004 to 2007, is an average annual difference in the growth of disease scores between MA and FFS. Based on the data that we have, it is clear that coding pattern differences have continuously grown since 2004 and that 2010 risk scores will incorporate repeated years of coding pattern differences. We have decided to maintain for 2010 the use of three cohorts as proposed in the Advance Notice.

Comment: One commenter expressed concern that the MA coding difference adjustment would reduce the disease score, causing a greater portion of the risk score to be based on demographic factors, which would introduce limitations and problems of the old AAPCC approach.

Response: CMS is calculating the MA coding pattern differences adjustment factor based on disease scores because that is the portion of the risk score that plans have control over. However, the adjustment is being applied simply as an overall proportional reduction to the risk scores, leaving the proportion of the risk score that is determined by diseases intact.

Comment: One commenter suggested that FFS normalization and MA coding pattern difference adjustment should be subtractive, not additive, or plans will be penalized twice for coding practices observed in the FFS program.

Response: The two adjustments address two different measures of coding changes: the FFS normalization factor adjusts risk scores for underlying changes in FFS coding and the MA coding pattern difference adjustment factor adjusts for coding patterns above and beyond the FFS changes.

Comment: One commenter asked if the three-year adjustment discussed in the Advance Notice would lead to a restatement of the historical budget neutrality adjustments for those years.

Response: As discussed above, the 2010 MA coding pattern differences adjustment is not a retroactive adjustment, but an estimate of the cumulative difference between MA and FFS stayers' disease score in 2010. CMS will take the projected reduction in 2010 risk scores into account when calculating the 2010 budget neutrality factor.

Comment: One commenter expressed concern that the extent of the adjustment may cause health plans to consider withdrawing from the market given the short time to prepare the 2010 bids. A couple commenters expressed concern that the proposed across-the-board 3.74% reduction would have a major negative effect and is a departure from last year's proposal to gather plan-specific coding changes through targeted audits.

Response: While we appreciate that the application of the MA coding pattern difference adjustment will need to be taken into account in MA plan bids, we believe that the final 3.41 percent adjustment is an appropriate correction that will result in more accurate payments. In addition, the adjustment is consistent with the statutory requirement that we study whether there are different diagnoses coding patterns between MA and FFS and, if we find differences, that we adjust MA risk scores accordingly.

Comment: A number of commenters did not support an industry-wide coding pattern difference adjustment and either wanted CMS to implement a more targeted adjustment or delay or phase in the adjustment. Some commenters wanted CMS to apply the coding pattern difference adjustment to a defined subset of plans that fail the risk validation audit or plans with larger differences in risk score growth. Commenters felt that an industry-wide adjustment would be unfair to plans that have under-coded and create an incentive of promoting coding intensity by those plan that have previously under-coded. Commenters suggested that CMS use a plan-specific EDF, or apply an adjustment in tiers to take into account different levels of turnover. A few commenters felt that SNPs would be at a disadvantage because there was an increased

volume of encounters for their members and because the percent of stayers was likely to be less than the average MA plan rate. A number of commenters supported an industry-wide adjustment; one commenter cited the following advantages: (1) industry-wide adjustments were the practice in other sectors of Medicare, (2) all MA plans should be paying close attention to coding and documentation and it was reasonable to expect coding changes to be widespread, (3) coding behavior of a particular provider does not necessarily affect just one plan, (4) beneficiaries move from one plan to another and retain the diagnosis codes assigned; and (5) when using MA data, a system-wide adjustment will ensure that baseline information is accurate.

Response: In addition to the reasons given by commenters, CMS was also persuaded by comments on the 2009 proposal – which proposed an adjustment on a subset of contracts – that an industry-wide adjustment provides an even playing field when plans compete: newer plans may be able to code just as intensely as older plans, but would not have been in existence long enough for CMS to calculate an adjustment factor for them. Further, applying an adjustment factor to a subset, or tiered adjustment factors across contracts, results in cut offs that can potentially appear unfair, especially if one contract falls just above and another just below a cutoff. To avoid these problems, as well as for the reasons cited by the more recent comments, we have decided that an industry-wide adjustment is the most efficient and effective approach to making an adjustment for MA coding pattern differences.

Comment: One commenter suggested that CMS should review and compare samples of MA plan member medical records with a FFS control group and that the difference in risk scores derived from the medical records could support an across-the-board coding pattern adjustment in a subsequent year.

Response: While a comparison of diagnostic coding captured on medical records in MA and FFS would indicate differences in documentation of diagnoses coding in the medical record, there are two key shortcomings of this approach in calculating an MA coding pattern difference adjustment factor. The key comparison in studying the impact on payment of differences in coding patterns between MA and FFS is the codes that are submitted and codes that are reflected in the model. In addition, CMS is taking into account changes in disease scores over time and taking a sample of medical records will not provide that information.

Comment: One commenter did not agree that CMS should calculate coding pattern differences for each individual and, instead, recommended that the difference be calculated by dividing the MA growth in risk scores by the FFS growth in risk scores for each age and survivor status grouping in each cohort.

Response: CMS did not calculate individual differences in disease score growth; we calculated the difference between the average growth in disease scores among MA stayers and the average growth in disease scores among FFS stayers for each cohort. This difference calculation was adjusted for each age and survivor grouping in each cohort. It is not clear how CMS would use the ratio of MA growth to FFS growth in applying an adjustment.

Comment: A number of commenters requested that CMS release all relevant information and calculations concerning the MA coding pattern difference adjustment factor in order to make sure that the adjustment is fully explained and transparent to the public to the same extent that

they are for the FFS program through regulation. A couple commenters believed that CMS has not provided enough transparency in the methodology used to calculate the coding pattern differences for the public to properly evaluate the calculation CMS has completed.

Response: We would be happy to provide additional information about the steps and results of our MA coding pattern differences analysis to interested stakeholders.

Section F. Encounter Data Reporting

Comment: One commenter encouraged CMS to continue its efforts to collect additional data from MA plans, including data relating to all medical encounters between beneficiaries and providers, to improve the accuracy of the risk adjustment system, and to measure the effectiveness and integrity of MA plan benefits.

Response: CMS will release guidance in 2009 regarding the collection and use of MA encounter data. As we discussed in the final IPPS rule in August 2008, CMS will provide opportunity for stakeholders to provide feedback on our plans for implementation.

Comment: One commenter expressed concern about the burden of collecting and reporting encounter data and asked that plans be given a long lead time to implement this new requirement; the commenter suggested that CMS phase in the changes.

Response: CMS is sympathetic to plans' desire for adequate lead time to implement encounter data requirements. We will explore options for the start up of reporting and will provide opportunity for feedback on our approach.

Section G. IME Phase Out

Comment: Related to CMS 4138-IFC –42 CFR 422.306(c) and the phase-out in MIPPA of the IME portion of the MA capitation rate, one commenter asked how a plan calculates the phase-out of the IME in a county and the role of 0.6% in determining the phase-out.

Response: To help plans identify the impact, CMS has separately identified the amount of IME for each county rate in the 2010 rate book. We intend to publish the rates with and without the IME reduction in future years as well. The role of 0.6% is that it is the maximum reduction possible to the FFS per capita costs in a county in 2010.

Section H. Location of Network Areas for PFFS Plans in Plan Year 2011

Comment: A commenter questioned CMS's interpretation of the statutory definition of "having" a network-based plan to mean offering a plan "that is generally open to enrollment," and asked CMS to clarify whether such plans are "open to enrollment" as of January 2009.

Response: First, CMS believes Congress intended to eliminate non-network PFFS plans only in those areas where at least two coordinated care plan options are available. Limited enrollment

EXHIBIT 2

GAO

United States Government Accountability Office

Report to Congressional Requesters

January 2013

MEDICARE ADVANTAGE

Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments



G A O

Accountability * Integrity * Reliability



United States Government Accountability Office
Washington, DC 20548

January 31, 2013

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

In 2012, the federal government will spend an estimated \$134.7 billion on the Medicare Advantage (MA) program, an alternative to the original Medicare fee-for-service (FFS) program, in which private health plans offer health care coverage to Medicare beneficiaries. The Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, pays private plans a monthly amount per beneficiary to provide health care services for each beneficiary enrolled in these plans. CMS adjusts this payment to account for a beneficiary's health status, a process known as risk adjustment, and assigns to each MA beneficiary a risk score—a relative measure of expected health care costs.¹

Risk scores for beneficiaries with the same diagnoses and characteristics should be identical, regardless of whether the beneficiaries are in an MA plan or Medicare FFS. However, MA plans have a greater incentive than FFS providers to make sure that all medical diagnoses are comprehensively coded, as this can increase beneficiaries' risk scores and ultimately the payments plans receive. This is not the case for FFS providers, who are generally paid for the services they provided and whose payments do not vary based on the diagnoses of the beneficiaries

¹Information on a beneficiary's age, sex, Medicaid enrollment status, original reason for Medicare entitlement (i.e., age or disability), and major medical conditions all generally factor into the calculation of the risk score. To gather information on medical diagnoses for beneficiaries in Medicare FFS, CMS analyzes the claims that FFS providers submit for payment. For beneficiaries enrolled in MA plans, instead of submitting claims, CMS requires plans to submit certain diagnosis codes for each beneficiary. Medical diagnoses are not used to calculate risk scores for beneficiaries who were not enrolled in Medicare for all of the previous year.

who received the services.² Consequently, risk scores for beneficiaries in MA plans may tend to be higher relative to the risk scores of beneficiaries in FFS who are in similar health and have identical characteristics. To ensure that MA plans are not overpaid as a result of these differences in diagnostic coding patterns, CMS makes a separate adjustment to MA plan payments.

In January 2012, we reported that CMS's adjustments to account for differences in diagnostic coding were inadequate and resulted in excess payments to MA plans.³ In 2010, CMS estimated that 3.4 percent of MA beneficiary risk scores were attributable to diagnostic coding differences between MA plans and Medicare FFS providers. CMS reduced MA beneficiaries' 2010 risk scores by 3.4 percent, which resulted in the agency saving \$2.7 billion in excess payments to MA plans. However, on the basis of the information available when we did our study, we estimated that the difference in diagnostic coding between MA plans and Medicare FFS providers was greater—4.8 percent to 7.1 percent—depending on the assumptions made about trends in risk score growth. Our estimate differed from CMS's because we used more recent data, incorporated the trend of coding differences over time, and accounted for additional beneficiary characteristics.

We also found that the impact of coding differences increased over time and noted that this trend suggested that the cumulative impact of coding differences in 2011 and 2012 could be larger than in 2010. However, CMS applied the same 3.4 percent adjustment to risk scores it used in 2010 to risk scores in 2011 and 2012. To help ensure appropriate payments to MA plans, we recommended that CMS take steps to improve the accuracy of the adjustment made for differences in diagnostic coding practices between MA plans and Medicare FFS.

Since we completed the analysis for our January 2012 report, risk score data for 2 additional years have become available. You asked us to update and extend our work on differences in diagnostic coding practices

²One important exception is hospital acute inpatient services, for which Medicare payment is based on Medicare severity diagnosis-related groups rather than services.

³See GAO, *Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices*, [GAO-12-51](#) (Washington, D.C.: Jan. 12, 2012).

EXHIBIT 3

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March 2011

Evaluation of the CMS-HCC Risk Adjustment Model

Final Report

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**Evaluation of the CMS-HCC
Risk Adjustment Model**

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SECTION 1 ACA-MANDATED EVALUATION OF CMS-HCC MODEL

1.1 Introduction

The 2010 Patient Protection and Affordable Care Act (Public Law No: 111-148) includes several sections affecting the Medicare Program. Specifically, Sec. 3205 focuses on Medicare Advantage (MA) plans for special needs individuals. Within that section of the legislation, "item (f) Risk Adjustment" contains revisions to the Social Security Act, including a new clause that mandates 1) an evaluation of the Centers for Medicare & Medicaid Services (CMS) risk adjustment system used to account for medical expenditures and care coordination costs for specified subsets of beneficiaries; and 2) a publication of that evaluation and any changes occurring as a result of the evaluation:

... "(III) Evaluation.—For 2011 and periodically thereafter, the Secretary shall evaluate and revise the risk adjustment system under this subparagraph in order to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions.

"(IV) Publication of evaluation and revisions.—The Secretary shall publish, as part of an announcement under subsection (b), a description of any evaluation conducted under subclause (III) during the preceding year and any revisions made under such subclause as a result of such evaluation."

The CMS hierarchical condition categories (CMS-HCC) model, implemented in 2004, adjusts Medicare capitation payments to Medicare Advantage health care plans for the health expenditure risk of their enrollees. Its intended use is to pay plans appropriately for their expected relative costs. For example, MA plans that disproportionately enroll the healthy are paid less than they would have been if they had enrolled beneficiaries with the average risk profile, while MA plans that care for the sickest patients are paid proportionately more than if they had enrolled beneficiaries with the average risk profile.

Although this Affordable Care Act legislative mandate for an evaluation of the CMS-HCC risk adjustment model is new, the evaluation process is well established. CMS conducts comprehensive evaluations of its CMS-HCC model on a regular basis, including evaluating the model on the dimensions specified in the Affordable Care Act.

This report is a record of the 2011 evaluation of the CMS-HCC model. It contains three major sections: a primer on the CMS-HCC model and more generally the use of risk adjustment within a health insurance market; an evaluation of the CMS-HCC model, including an evaluation of the predictive accuracy of the CMS-HCC model for individuals and groups; and an analysis to determine if there are integral differences between the individuals in MA Chronic Condition

Special Needs Plans (C-SNPs) and fee-for-service (FFS) beneficiaries with similar diagnostic profiles on whom the CMS-HCC model is calibrated.

For information on how the risk adjustment model addresses frailty, please refer to Section 2, where extensive research on the frailty model and potential methods for more effectively capturing these costs are summarized. For information on how the risk adjustment model performs in capturing the costs of individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, please refer to Section 3 and the extensive discussion of model performance over a wide range of diagnoses, combinations of diagnoses, and range of risk given a number of serious conditions. Finally, for discussion of an assessment of the ability of the risk adjustment model to capture the scale of morbidity among beneficiaries enrolled in C-SNPs, please refer to Section 4.

SECTION 2 PRIMER ON THE CMS-HCC MODEL

In this section we present an introduction and overview on the CMS-HCC risk adjustment system. Risk adjustment is a method of adjusting capitation payments to health plans, either higher or lower, to account for the differences in expected health costs of individuals. Insurers determine their revenue needs based on a variety of factors, including trends in medical expenditures and anticipated enrollment, and determine how much to vary the premium charged to individuals or small groups of enrollees using population characteristics such as age, smoking habits, and past history of illness. The risk adjustment models used in the MA program function as more comprehensive methods of underwriting in which diagnoses and demographic information are used to set each enrollee's monthly capitation rate. As with any insurance product, the system is intended to be accurate at the group level. At the individual level, predicted medical costs can be lower or higher than actual medical costs, but at the group level, below-average predicted costs balance out above-average predicted costs. Below, we first present relevant background on key characteristics of health insurance and then we describe the main components of the CMS-HCC models.

2.1 Health Insurance

In general, insurance is a form of risk management primarily used to hedge against the risk of a contingent, uncertain loss. Insurance can be defined as the equitable transfer of the risk of a loss, from one entity to another, in exchange for payment. Health insurance is an agreement between an organization and an individual to provide or pay for at least part of the costs of medical services for the individual and to protect that person against the risk of high-cost medical care in the case of a serious accident or illness. Not everyone will experience high-cost medical events; but for those who do, the financial impact could be devastating.

The concept of pooling risk is fundamental for all types of insurance because a large risk pool is needed to produce stable and measurable characteristics that can be used to accurately estimate future costs (AAA, 2006). Health insurance is designed to pool the financial risk of a high cost medical event across a large group of people. The majority of individuals in the risk pool pay more than their actual health services cost—they are willing to accept a small loss to guard against the risk of a major loss. The excess payments are pooled to cover the cost of individuals who do experience high-cost events.

Medicare is one of the world's largest health insurance programs, providing insurance to approximately 47 million beneficiaries. About one-fourth of Medicare beneficiaries receive their Medicare health benefits through private health care plans, a program known as Medicare Advantage (MA). Medicare pays these participating health plans a monthly capitation rate to provide health care services for their enrollees.

Medicare beneficiaries vary greatly in terms of their health status, which in turn affects their utilization and costs. Those with serious illnesses, multiple chronic conditions, or who are frail will require more care and will have higher medical costs than their healthier counterparts. If a MA health plan selected only the highest-cost beneficiaries (high risk), it would have difficulty remaining viable with unadjusted capitation rates. In contrast, if it selected a healthier-than-average pool in its enrollment (low risk), it would make excess profits at the expense of the

MA program if capitation rates were unadjusted. Risk selection can occur by chance or by practices implemented by health plans (AARP, 2009). For example, if a health plan were to set high copayment rates for office visits to specialists, beneficiaries needing care from specialists might select not to enroll in that plan. To address this issue of risk selection and accurately compensate MA health plans for accepting the risk of enrolling beneficiaries of varying health statuses, the MA program uses risk adjustment and administrative policies.¹

2.2 Risk Adjustment

The Medicare risk adjustment models use data from a large pool of beneficiaries (full sample sizes over 1 million for the CMS-HCC models) to estimate predicted costs on average for each of the component factors (e.g., age-sex, low income status, individual disease groups). This method of risk assessment is in accordance with the Actuarial Standard Board's Actuarial Standard of Practice for risk classification—the risk characteristics are related to expected outcomes and the risk classes are large enough to allow credible statistical inferences (ASB, 2005). The predicted costs from the risk adjustment models are then converted to relative risk factors so that payment adjustments can be made relative to the average Medicare beneficiary. It is important to understand that the underlying risk assessment is designed to accurately explain the variation at the group level, not at the individual level, because risk adjustment is applied to large groups (AAA, 2010). As the American Academy of Actuaries notes:

“... Determining average experience for a particular class of risk is not the same as predicting the experience for an individual risk in the class. It is both impossible and unnecessary to predict expenditures for individual risks. If the occurrence, timing, and magnitude of an event were known in advance, there would be no economic uncertainty and therefore no reason for insurance.” (AAA, 1980)

By risk adjusting the payments to MA plans—beneficiaries with lower-than-average predicted costs have their payments decreased incrementally based on their risk profile and beneficiaries with higher-than-average predicted costs have their payments increased incrementally based on their risk profile—CMS reduces the incentives for these plans to risk select only the healthiest beneficiaries and avoids indirectly penalizing plans that provide care for the most seriously ill beneficiaries.

The suitability of a risk adjuster depends on the nature of the groups to be paid using the adjuster. The MA program now allows not only general population health plans to participate, but specialty plans as well, in particular plans enrolling beneficiaries with a specified subset of chronic diseases. Sections 2.3 to 2.8 describe that characteristics and ability of the CMS-HCC risk adjustment model to account for the costs of these conditions as well as the comorbidities

¹ Risk adjustment is one of a set of techniques CMS implements to compensate MA plans and to protect beneficiary access to these plans. Other techniques include these: a Total Beneficiary Cost metric, which beginning in CY2011 evaluates changes from year to year in a plan's cost-sharing or benefits and denies bids that propose significant increases in cost-sharing or decreases in benefits; and Discriminatory Cost-Sharing Assessments, which beginning in CY2012 provide three benefit discrimination assessments—Per Member Per Month Actuarially Equivalent Cost Sharing Maximums, Service Category Cost Sharing Standards, and Discriminatory Pattern Analysis. (Advance Notice, CY2012)

and complications related to these conditions. The evaluation of its ability to predict risk for enrollee groups that have concentrations with particular medical conditions, as well as other atypical profiles, are in Section 3.

2.3 History of Risk Adjustment Models for Medicare Managed Care

CMS has developed its risk adjustment methodology over time, modifying it to better account for differences in expected health expenditures. **Table 2-1** presents a summary of the Medicare managed care risk adjustment models and their explanatory power as measured by R^2 . It is followed by a description of each of the models.

Table 2-1
Medicare Managed Care historic risk adjustment model R^2 statistics¹

Risk adjustment model	Payment years	R^2
Adjusted Average Per Capita Cost (AAPCC) ²	pre-2000	0.0077
PIP-DCG ²	2000-2003	0.0550
CMS-HCC ^{2,4}	2004-2008	0.0997
Version 12 CMS-HCC (2005 recalibration) ^{3,4}	2009-current	0.1091
Version 21 CMS-HCC (2007 recalibration; 2009 clinical revision) ^{3,4}	proposed	0.1246

NOTES:

- ¹ The R^2 statistic refers to the percentage of variation in individual expenditures predicted.
- ² The R^2 statistics for the three earliest models are based on the 1999-2000 calibration sample which included both community and institutional beneficiaries.
- ³ These models are estimated on the recalibration samples and include community continuing enrollees only, no months of institutional status are included.
- ⁴ The CMS-HCC models include payment model HCCs only.

SOURCE: RTI analysis of Medicare claims and enrollment data—1999-2000, 2004-2005, and 2006-2007 5% sample.

Historically, capitation payments to Medicare managed care plans were linked to FFS expenditures by geographic area, with payments set at 95 percent of an enrollee's county's Adjusted Average Per Capita Cost (AAPCC). The AAPCC actuarial rate cells were defined by age, sex, Medicaid enrollment (indicating poverty), institutional status (for nursing home residents), and working aged status (for beneficiaries with employer-based insurance where Medicare is a secondary payer). Separate county factors were calculated for the aged and nonaged (under 65 years) disabled. Due to small numbers, only state-level factors were calculated for end-stage renal disease (ESRD)-entitled beneficiaries.

The AAPCC payment methodology explained only about 1 percent of the individual variation in expenditures for Medicare beneficiaries and, for beneficiaries with similar

demographic profiles, did not pay more for sicker people. Research showed that the managed care program was increasing total Medicare expenditures because its enrollees were healthier than FFS enrollees and the AAPCC did not account for this favorable risk selection (Brown et al., 1993; Riley et al., 1996; Mello et al., 2003). Also, this payment methodology was not appropriately compensating plans enrolling sicker beneficiaries or plans specializing in treating high-cost populations, such as beneficiaries with particular chronic diseases or high levels of functional impairment.

The 1997 Balanced Budget Act (BBA) modified the Medicare managed care and other capitated programs, then collectively known as Medicare+Choice (M+C). The BBA included a mandate for health-based Medicare capitation payments by 2000. In 2000, CMS implemented the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as its health-based payment risk adjuster (Pope et al., 2000a). This model estimated beneficiary health status (the expected cost) from AAPCC-like demographics and the most serious principal inpatient diagnosis (principal reason for inpatient stay) associated with any hospital admission from the prior year.

The PIP-DCG model was an improvement over the AAPCC payment methodology, increasing explanatory power of individual variation in beneficiaries' expenditures from about 1 percent to about 5.5 percent. The PIP-DCG model was intended as a transition model, a feasible way to implement risk adjustment based on the readily available: already adjudicated inpatient diagnostic data. However, relying on inpatient diagnoses was the PIP-DCG model's major shortcoming because only illnesses that result in hospital admissions were counted. Therefore, managed care organizations that reduced admissions (e.g., through good ambulatory care) could end up with apparently healthier patients and be penalized through lower payments. Congress's Benefits Improvement Protection Act (BIPA 2000) addressed the PIP-DCG limitations by requiring the use of ambulatory diagnoses in Medicare risk-adjustment, to be phased in from 2004 to 2007.

CMS evaluated several risk-adjustment models that use both ambulatory and inpatient diagnoses and ultimately chose the DCG-HCC model for Medicare risk-adjustment partly because it "...would lend itself most easily to necessary modifications that would be clear to analysts and physicians" (CMS, 2003). The model, part of the same DCG family of models as the PIP-DCG, was developed with CMS funding by researchers at RTI International and Boston University, with clinical input from physicians at Harvard Medical School (Pope, Kautter, Ingber, et al., 2004). Prior to its 2004 implementation, the model was modified to fit Medicare subpopulations and CMS' data collection system and became the CMS-HCC risk adjustment model. (The structure of the current model is described thoroughly in the next sections.) The CMS-HCC model was again an improvement over previous methodology, increasing explanatory power of individual variation in beneficiaries' expenditures to about 10 percent (compared to 5.5 percent in the PIP-DCG model).

One of the CMS-HCC model's strengths is its facility to be modified for improvements. CMS updates the software annually to account for changes in ICD-9-CM diagnosis codes. It recalibrates the model regularly on more recent diagnosis and expenditure data. Additionally, the CMS-HCC model underwent a major clinical revision in 2009 to adjust for changes in disease patterns, treatment methods, and coding practices, as well as compositional changes within the Medicare population. These modifications have again increased the CMS-HCC

model's explanatory power, raising it to 11 percent for the version of the model used in payment from 2009-current (Version 12 model) and then to 12.5 percent for the version of the model that will be implemented for PACE starting in 2012 (Version 21 model).²

2.4 Principles for Risk Adjustment Model Development

The CMS-HCC risk adjustment model is prospective—it uses demographic information (age, sex, Medicaid dual eligibility, disability status) and a profile of major medical conditions in the base year to predict Medicare expenditures in the next year. It is calibrated on the FFS population because this population, unlike the MA population, submits complete Medicare claims data, including both diagnoses and expenditures. Determining which diagnosis codes should be included, how they should be grouped, and how the diagnostic groupings should interact for risk adjustment purposes was a critical step in the development of the model. The following 10 principles guided the creation of the CMS-HCC diagnostic classification system:

Principle 1—Diagnostic categories should be clinically meaningful. Each diagnostic category is a set of ICD-9-CM codes (Centers for Disease Control and Prevention [CDC], 2010). These codes should all relate to a reasonably well-specified disease or medical condition that defines the category. Conditions must be sufficiently clinically specific to minimize opportunities for gaming or discretionary coding. Clinical meaningfulness improves the face validity of the classification system to clinicians, its interpretability, and its utility for disease management and quality monitoring.

Principle 2—Diagnostic categories should predict medical expenditures. Diagnoses in the same HCC should be reasonably homogeneous with respect to their effect on both current (this year's) and future (next year's) costs.

Principle 3—Diagnostic categories that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures. Diagnostic categories used in establishing payments should have adequate sample sizes in available data sets. Given the extreme skewness of medical expenditure data, the data cannot reliably determine the expected cost of extremely rare diagnostic categories.

Principle 4—In creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, while the effects of unrelated disease processes accumulate. Because each new medical problem adds to an individual's total disease burden, unrelated disease processes should increase predicted costs of care. However, the most severe manifestation of a given disease process principally defines its impact on costs. Therefore, related conditions should be treated hierarchically, with more severe manifestations of a condition dominating (and zeroing out the effect of) less serious ones.

² Throughout this report, we refer to V12 and V21 of the CMS-HCC risk adjustment model. These shorthand names refer to the versions of the model. Model versions are updated for a variety of reasons, including changes in valid diagnoses mapping to the HCCs, updates to accommodate more recent years of data, as recalibrations to incorporate clinical and other updates. Not all model versions are used for payment.

EXHIBIT 4

J U N E 2 0 1 2

REPORT TO THE CONGRESS

Medicare and the
Health Care
Delivery System

MEDPAC Medicare
Payment Advisory
Commission



The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105–33) to advise the U.S. Congress on issues affecting the Medicare program. In addition to advising the Congress on payments to health plans participating in the Medicare Advantage program and providers in Medicare’s traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission’s 17 members bring diverse expertise in the financing and delivery of health care services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts, who typically have backgrounds in economics, health policy, and public health.

MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress. In the course of these meetings, Commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. (Meeting transcripts are available at www.medpac.gov.) Commission members and staff also seek input on Medicare issues through frequent meetings with individuals interested in the program, including staff from congressional committees and the Centers for Medicare & Medicaid Services (CMS), health care researchers, health care providers, and beneficiary advocates.

Two reports—issued in March and June each year—are the primary outlets for Commission recommendations. In addition to annual reports and occasional reports on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

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REPORT TO THE CONGRESS

Medicare and the
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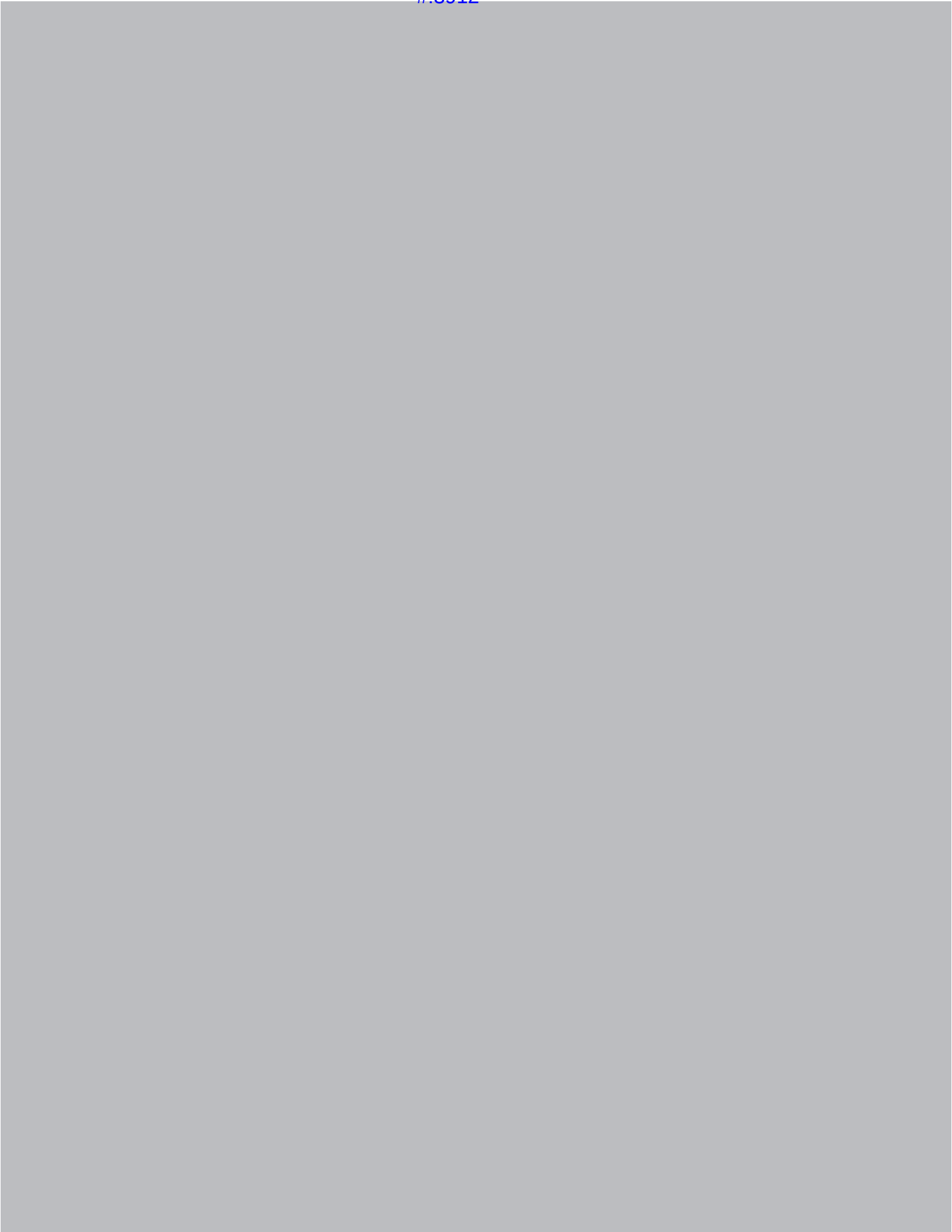
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C H A P T E R

4

**Issues for risk adjustment
in Medicare Advantage**



CHAPTER 4

Issues for risk adjustment in Medicare Advantage

Chapter summary

Health plans that participate in the Medicare Advantage (MA) program receive monthly capitated payments for each Medicare enrollee. Each capitated payment is the product of two general parts: a base rate, which reflects the payment if an MA enrollee has the health status of the national average beneficiary, and a risk score, which indicates how costly the enrollee is expected to be relative to the national average beneficiary. The purpose of the risk scores is to adjust MA payments so that they accurately reflect how much each MA enrollee would be expected to cost. In this chapter, we examine the performance of the risk-adjustment system in the MA program and offer alternatives for improving it.

Improving payment accuracy of the CMS–hierarchical condition category model

Currently, CMS uses the CMS–hierarchical condition category (CMS–HCC) model to risk adjust each MA payment. This model uses enrollees’ demographics and medical conditions collected into 70 HCCs to predict their costliness. It has been shown to be a much better predictor of a beneficiary’s costliness than the demographic-based model that preceded it. Analysis of the CMS–HCC model and the demographic model indicates that the CMS–HCC model explains about 11 percent of the variation in costliness among individual beneficiaries, whereas the demographic model explains only about 1 percent (Pope et al. 2004).

In this chapter

- Evidence that MA enrollees tend to be lower cost than FFS beneficiaries
- Improving predictive accuracy of the CMS–HCC model
- Issues related to financial neutrality between FFS Medicare and the MA program

The demographic model did not include factors that are important for predicting beneficiaries' costliness—such as conditions. Consequently, it systematically overpredicted costs for healthy beneficiaries and systematically underpredicted costs for beneficiaries in poor health. Because the CMS–HCC model includes beneficiaries' conditions as well as their demographic information, it explains more of the variation in beneficiaries' costliness and predicts costs more accurately than the demographic model. However, systematic overpredictions and underpredictions may remain under the CMS–HCC model. For example, for all beneficiaries who have the same condition, the CMS–HCC model adjusts MA payments by the same proportion. But the severity of a condition varies across beneficiaries, and those with greater severity tend to be more costly. In addition, research suggests that a minimum of 20 percent to 25 percent of the variation in beneficiaries' costliness may be predictable, so the CMS–HCC may leave half or more of the predictable variation unexplained (Newhouse et al. 1997). Therefore, for a given condition it is possible that plans can be financially advantaged or disadvantaged based on the risk profile (overall health status) of their enrollees.

To the extent that systematic prediction errors occur under the CMS–HCC model, we explored several policy options for reducing these errors:

- Add measures of income and indicators for race to the model. If beneficiaries in certain income categories or racial groups tend to have greater severity for given conditions, these additional variables could reduce prediction errors.
- Include measures for the number of conditions in the model. The cost of treating a certain condition may increase as more comorbidities are present.
- Use two years of beneficiaries' diagnoses to determine their condition categories. CMS currently uses one year of beneficiaries' diagnoses to determine their conditions, but we have found that providers often do not consistently code conditions on claims from year to year. Using two years of diagnosis data (when available) would help to fully identify beneficiaries' conditions.

Our analysis indicates that including beneficiaries' race and measures of income would not improve predictive accuracy. However, including the number of conditions would improve predictive accuracy for beneficiaries who have many conditions. Using two years of diagnoses to identify beneficiaries' conditions also would improve predictive accuracy for beneficiaries who have many conditions but to a lesser extent than adding the number of conditions. In addition, using two years of diagnoses would reduce year-to-year fluctuations in beneficiaries' risk scores, which would result in more stable revenue streams for MA plans.

Because adding the number of conditions and using two years of diagnosis data both have beneficial effects, but in different ways, we also examined the effects of adding both features to the CMS–HCC model. It resulted in more accurate predictions for high-risk beneficiaries and smaller year-to-year fluctuations in beneficiaries’ risk scores.

Other issues for MA risk adjustment

On several occasions, the Commission has taken a position that payments for MA enrollees should equal what they would be expected to cost in FFS Medicare (financial neutrality) (Medicare Payment Advisory Commission 2001, Medicare Payment Advisory Commission 2002, Medicare Payment Advisory Commission 2004, Medicare Payment Advisory Commission 2005). An underlying rationale for this policy is that it encourages beneficiaries to enroll in whichever sector (MA or FFS) is more efficient in their local health care market. Two recently published papers have implications for the interaction between risk adjustment and financial neutrality. One paper shows that in FFS Medicare, regions that have high per capita service use also have high average risk scores, and areas that have low per capita service use have low average risk scores (Song et al. 2010). At least some of the regional difference in risk scores is due to differences in service use that do not reflect differences in health status; that is, risk scores are high in some regions simply because beneficiaries get more health care, not because they are sicker. If these same regional differences in service use and risk scores occur in the MA program, they drive MA payments higher in high-use regions. Adjustments could be made to eliminate these differences.

A second paper shows there are differences between FFS Medicare and a large MA plan in the relative costliness of treating conditions (Newhouse et al. 2011). If these cost differences between FFS Medicare and MA plans are widespread, risk adjustment underpredicts MA costs for some conditions and overpredicts MA costs for other conditions. An issue to consider is whether it is more appropriate for CMS to estimate the CMS–HCC model by using cost and diagnosis data from MA enrollees rather than FFS beneficiaries.

Both papers have implications for equity in the MA program: Adjusting MA risk scores to reduce the effects of regional differences in risk scores would reduce regional variations in MA payments, and using data from MA enrollees to estimate the CMS–HCC model would reduce incentives for plans to attract beneficiaries who have some conditions and avoid beneficiaries who have other conditions. However, both issues are inconsistent with the concept of financial neutrality between MA and FFS Medicare. These issues will have to be discussed in the future.

A final issue regarding risk adjustment is that analyses by CMS and the Government Accountability Office (GAO) both indicate that risk scores have increased at a faster rate in the MA program than in FFS Medicare (Centers for Medicare & Medicaid Services 2009, Government Accountability Office 2012). The higher growth rate in MA has resulted in MA enrollees having higher risk scores than they would have in FFS Medicare. In an effort to bring MA risk scores in line with those in FFS Medicare, CMS has made adjustments to MA risk scores, but GAO believes that larger adjustments should be made. ■

Health plans that participate in the Medicare Advantage (MA) program receive monthly capitated payments for each Medicare enrollee. Each capitated payment is the product of two general parts: a base rate, which reflects the payment if an MA enrollee has the health status of the national average Medicare beneficiary, and a risk score, which indicates how costly the enrollee is expected to be relative to the national average beneficiary.

Over the years, CMS has employed various methods for determining MA enrollees' risk scores. Currently, CMS uses the CMS–hierarchical condition category (CMS–HCC) risk-adjustment model, which uses enrollees' demographics and condition categories (such as diabetes and stroke) to predict their costliness. The demographic variables include age, sex, Medicaid status, institutional status, eligibility based on being disabled, and eligibility based on age but originally eligible because of disability.

All demographic variables are from the year for which beneficiaries' costs are to be predicted (the prediction year). The condition categories are based on diagnoses recorded on physician, hospital outpatient, and hospital inpatient claims in the year before beneficiaries' costs are to be predicted (the base year). This makes the CMS–HCC a prospective model, as opposed to a concurrent model, which would use conditions from the prediction year. It is logical to use a prospective model in the MA program because the express purpose of MA plans is to provide care to manage their enrollees' conditions. If concurrent risk adjustment were used, MA plans would be reimbursed as their enrollees' conditions occur, rather than being paid to manage existing chronic conditions.

An underlying feature of a prospective risk-adjustment model for beneficiaries with a given set of conditions is that it underpredicts costs for some beneficiaries, overpredicts for others, but predicts accurately on average. However, when prediction inaccuracies occur systematically with identifiable beneficiary characteristics, plans can benefit if their enrollees have characteristics predictive of lower-than-average costs (favorable selection) or be disadvantaged if their enrollees have characteristics predictive of higher-than-average costs (adverse selection). An ideal risk-adjustment system would eliminate all opportunities for favorable selection, but a risk adjuster can be less than ideal and still be effective if it makes efforts by plans to identify favorable risks prohibitively costly.

To the extent that favorable selection occurs in the MA program, it could be caused by the behavior of plans

or beneficiaries. Plans can attract favorable risks by structuring benefits that are attractive to relatively healthy beneficiaries or by marketing their products so that they attract healthy enrollees. Alternatively, relatively healthy beneficiaries may find the structure of managed care plans more attractive than do beneficiaries in poor health.

Selection problems can be reduced by improving risk adjustment to reduce the extent of systematic prediction errors. An alternative method for reducing selection problems is partial capitation, which would pay plans partly on the basis of capitated rates and partly on the actual costs of providing care. This would reduce the likelihood of plans experiencing large losses from very sick enrollees or large profits from healthy enrollees. However, it is not clear what fraction of the payments should be capitated and what fraction should be based on costs.

For each MA enrollee, CMS obtains from the enrollee's plan the condition codes from encounters with physicians, hospital outpatient departments, and hospital inpatient departments. CMS maps the condition codes into hierarchical condition categories (HCCs), which define broad condition categories, such as diabetes and congestive heart failure. All condition codes fall into one of the 189 CMS-defined HCCs. However, CMS uses only 70 HCCs in the CMS–HCC model, so many conditions have no effect on beneficiaries' risk scores.¹ Some conditions, such as diabetes and cancer, are actually represented by groups of several HCCs, which differ according to severity. CMS has determined that a beneficiary cannot have more than one HCC indicated in each of these condition groups. If CMS finds that a beneficiary has conditions that map into more than one HCC within a condition group, only the highest cost HCC is used in predicting the beneficiary's costliness. For example, the CMS–HCC model has five diabetes HCCs. If CMS finds that a beneficiary has condition codes that fit the HCC “diabetes with acute complications” and the HCC “diabetes without complications,” CMS drops the HCC “diabetes without complications.”

CMS calibrates the additional costliness associated with each demographic variable and each HCC in the model using cost, demographic, and diagnosis data from beneficiaries in fee-for-service (FFS) Medicare, but CMS has begun collecting data on MA beneficiaries and intends to use those data to calibrate the CMS–HCC model.² CMS applies linear regression methods to obtain coefficients on each variable in the model. If a beneficiary has a particular

variable represented in the CMS–HCC model, the coefficient on that variable indicates its marginal cost.

A model that CMS used before the CMS–HCC model included only beneficiaries’ demographic data (demographic model). The demographic model does not include important observable characteristics of beneficiaries that affect their costliness, such as medical conditions. Consequently, the demographic model explains a small fraction of the variation in beneficiaries’ Medicare costliness (about 1 percent) and, within a given demographic category, systematically overpredicts costs for relatively healthy beneficiaries and underpredicts costs for the sickest beneficiaries, leaving the potential for selection problems.

The CMS–HCC model has been shown to be a much better predictor of a beneficiary’s costliness. For example, it explains about 11 percent of the variation in beneficiaries’ costliness. Therefore, the CMS–HCC model likely mitigates selection problems in the MA program.

However, the CMS–HCC model has shortcomings such that it may not have fully eliminated systematic prediction inaccuracies:

- Research on variation in individual-level health care spending suggests that at least 20 percent to 25 percent of the variation in spending can be predicted, with the remaining being random and, hence, unpredictable (Newhouse et al. 1997). Because the CMS–HCC model explains about 11 percent of the variation in spending, it may leave half or more of the predictable variation unexplained.
- For all enrollees with a given health condition, the CMS–HCC model adjusts MA capitated payments by the same rate. For example, the CMS–HCC model increases capitated payments for all MA enrollees with acute myocardial infarction by 35.9 percent above the base rate. However, within condition categories, some beneficiaries are healthier and less costly than others, while some are sicker and more costly.

Because of these shortcomings of the CMS–HCC model, there is a potential for MA plans to benefit financially if they have a relatively healthy beneficiary profile or to be disadvantaged if they have a sicker beneficiary profile. This is especially relevant to plans that specialize in managing the care for the sickest beneficiaries, such as special needs plans (SNPs) and plans in the Program of All-Inclusive Care for the Elderly (PACE), because

payments may not be adequately adjusted to effectively provide care.

We have done an analysis that suggests that MA enrollees are healthier and less costly than their FFS counterparts, meaning that favorable selection may be occurring in the MA program. In this chapter, we discuss this analysis as well as options for modifying the CMS–HCC model to mitigate systematic prediction errors.

This chapter discusses two other issues concerning risk adjustment in the MA program:

- Research indicates that geographic differences in per capita service use in FFS Medicare lead to geographic differences in risk scores that do not reflect differences in health status among FFS beneficiaries (Song et al. 2010). If regional differences in service use also lead to regional differences in risk scores in the MA program, then plans in regions where service use is high have higher risk scores, which drive capitated payments in those regions above the level in lower use regions.
- The coefficients on the conditions in the CMS–HCC model indicate the relative costliness of treating those conditions in FFS Medicare. However, the CMS–HCC model is used to risk-adjust payments in the MA program, where the relative costs of treating conditions may differ from costs in FFS Medicare (Newhouse et al. 2011). This raises questions of whether it is more appropriate to continue to calibrate the CMS–HCC model using data on FFS beneficiaries, or to switch to data on MA enrollees.

Evidence that MA enrollees tend to be lower cost than FFS beneficiaries

Recently, there has been renewed interest in examining the extent to which favorable selection occurs in the MA program. One study found a substantial amount of favorable selection (Brown et al. 2011). Another study used cost data from a large MA plan and found little correlation between how costly a condition is to treat in FFS Medicare and the extent to which beneficiaries with that condition are profitable to that plan (Newhouse et al. 2011). This gives the plan little incentive to try to select against the sickest, highest cost beneficiaries.

Within a given HCC, the severity of the condition and hence the cost of treating it can vary. For example, we examined FFS beneficiaries who were grouped into

the HCC for congestive heart failure (CHF) in 2008 and had no other HCCs. In 2008, the beneficiary at the 95th percentile of costliness had more than \$37,000 in Medicare spending, while the beneficiary at the 5th percentile had \$115 in Medicare spending. Despite these large cost differences for beneficiaries who have the same condition, the CMS–HCC model adjusts the payment rate for each beneficiary who has CHF by the same proportion (41 percent). Therefore, it is possible that, for beneficiaries in a given HCC, some will be profitable to MA plans because they are low-severity cases while others will not be profitable because they are high-severity cases.

If beneficiaries who have the same condition are randomly selected into MA plans in sufficiently large numbers, those who are profitable will be offset by those who are unprofitable, resulting in no financial gain or loss for the plan. However, if the selection of these beneficiaries is not random, it is possible that those who enroll in MA plans are on average profitable. This could occur either through the actions of plans—perhaps through benefits that are attractive to healthier beneficiaries or marketing techniques that target those beneficiaries—or because relatively healthy beneficiaries find the structure of MA plans more attractive than do sicker beneficiaries.

We conducted a study using two measures that may suggest, but not confirm, whether MA enrollees are, on average, lower risk than FFS beneficiaries. We divided the beneficiaries who were in FFS Medicare in 2007 into two groups: those who stayed in FFS Medicare in 2008 (stayers) and those who enrolled in MA plans in 2008 (joiners). For each group, we calculated the mean FFS costliness in 2007 in each HCC and used beneficiaries' risk scores to adjust for differences in health status. We reasoned that, for each HCC, if the risk-adjusted mean cost of the joiners was below that of the stayers, it indicates that lower cost beneficiaries are more likely to enroll in the MA program. We also identified the beneficiaries who were in FFS Medicare in 2008 and divided them into two groups: those who were in FFS Medicare throughout 2007 and those who left an MA plan in 2007. For both groups, we calculated the mean FFS costliness in 2008 of the beneficiaries who had conditions in each HCC and used beneficiaries' risk scores to adjust for differences in health status. We reasoned that, for each HCC, if the risk-adjusted mean cost of the beneficiaries who left an MA plan in 2007 was above that of beneficiaries who were in FFS Medicare throughout 2007 and 2008, it indicates that beneficiaries who stay in MA plans tend to be lower cost than those who leave MA for FFS Medicare.

Our results from both analyses suggest that MA enrollees are, on average, lower cost than FFS beneficiaries. In the first analysis, for 68 of the 70 HCCs, beneficiaries who joined an MA plan in 2008 had lower FFS costs in 2007 than the beneficiaries who stayed in FFS Medicare in 2008. On average, the joiners had costs that were 15 percent lower than the stayers. In the second analysis, beneficiaries who left an MA plan in 2007 had FFS costs in 2008 that averaged 16 percent higher than beneficiaries who were in FFS Medicare throughout 2007. Moreover, for 69 of the 70 HCCs, beneficiaries who disenrolled from MA in 2007 had higher average costs in 2008 than those who were in FFS Medicare throughout 2007.

Although these results suggest that MA enrollees are lower cost than FFS beneficiaries, we emphasize that they are not conclusive. It is possible that beneficiaries with relatively low costs are more likely to enroll in an MA plan but that their costs increase after enrollment. Possible reasons this may occur include that their costs regress to the mean over time, they lacked supplemental coverage while in FFS Medicare, or they have low incomes and the more comprehensive coverage that often occurs in MA plans encourages them to increase their service use.

Improving predictive accuracy of the CMS–HCC model

We have evaluated three alternatives for improving the predictive accuracy of the CMS–HCC model so that systematic prediction errors are reduced. All three options involve using more data than are currently used in the CMS–HCC model:

- Add socioeconomic variables such as race/ethnicity and income to the model. This model includes all variables in the current CMS–HCC model plus race/ethnicity indicators (African American, Hispanic, White, other race) and income level, which we approximated by the per capita income in the beneficiary's county of residence.
- Add indicators for the number of conditions beneficiaries have. This model includes all variables in the current CMS–HCC model plus indicators of whether beneficiaries have zero, one, two, three, four, or five or more HCCs.³
- Use two years of diagnosis data (when available) to determine each beneficiary's HCCs rather than one

**TABLE
4-1****Adding indicators of race and measure of income has little effect on predictive accuracy of CMS-HCC model**

Category	Predictive ratio	
	Standard model	Race/income model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	0.99
Cancer	0.99	0.99
Mental illness	1.00	1.00
Schizophrenia	1.00	1.00
AMI	1.03	1.02
Unspecified stroke	1.01	1.00
All strokes	1.01	1.00
Number of conditions		
0	0.94	0.94
1	1.02	1.02
2	1.03	1.03
3	1.03	1.02
4	1.02	1.02
5 or more	0.98	0.98
8 or more	0.95	0.94

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. Both models use one year of diagnosis data to determine beneficiaries' conditions.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

year of diagnosis data, which CMS currently uses. Obviously, two years of diagnosis data would not be available for beneficiaries in their first or second year of Medicare eligibility. For those in the first year of Medicare eligibility, the demographic model that CMS currently uses for new enrollees is a viable option. For those in the second year of eligibility, we could use the current version of the CMS-HCC model.

Adding socioeconomic variables does not improve predictive accuracy of CMS-HCC model

We calibrated a model that has all the variables of the current version of the CMS-HCC model, which has 70 HCCs (standard model). We also calibrated a version that has the same variables as the standard model plus race/

ethnicity indicators (African American, Hispanic, White, and other race) and income level, which we approximated by the per capita income in the beneficiary's county of residence (race/income model). For a description of the method we used to calibrate the models presented in this chapter, see the text box (pp. 106–107).

We evaluated the predictive accuracy of the standard and race/income versions using two measures:

- R^2 , a statistical measure of how much of the variation in costliness among individuals is explained by the model: The closer the R^2 is to 1.0, the more of the variation the model has explained.
- Predictive ratio: For a group of beneficiaries, it is the total costliness predicted by the model divided by the total actual costliness of the group. The closer the predictive ratio is to 1.0, the better the model has predicted the actual costs. Predictive ratios less than 1.0 indicate the predicted costs are below the actual costs (underprediction); predictive ratios greater than 1.0 indicate the predicted costs are above actual costs (overprediction).

The R^2 gives a general sense of how well a model accounts for variations in costs across individuals. However, strategies to attract favorable risks are typically based on characteristics such as conditions that define groups of beneficiaries, not on specific individuals. Therefore, many analysts prefer to use predictive ratios to evaluate the predictive accuracy of risk-adjustment models (Frogner et al. 2011, Pope et al. 2004, Pope et al. 2011). For beneficiaries with a given attribute, the predictive ratio indicates (on average) the extent to which a model overpredicts or underpredicts the costliness of the beneficiaries with the attribute and by how much.

The addition of race and income variables to the standard model did very little to enhance its predictive accuracy. Using the standard CMS-HCC model, we obtained an R^2 of 0.1100. Adding race and income variables had no effect on the R^2 .

We also used predictive ratios to examine how accurately these two models predict beneficiaries' costliness for nine condition categories. For most of these conditions, both models predict beneficiaries' costliness quite well, but they overpredict costs to some degree for acute myocardial infarction (AMI). Within each of these conditions—as well as all conditions represented in the CMS-HCC model—some beneficiaries are relatively healthy and have no other

conditions, while other beneficiaries are much sicker and have many other conditions. We analyzed categories of beneficiaries identified by number of conditions: zero, one, two, three, four, five or more, and eight or more. We found that both models underpredict costliness to some degree for beneficiaries who have five or more conditions and by a larger degree for those who have no conditions or eight or more conditions. Also, both models overpredict costliness to some degree for categories defined by one condition, two conditions, three conditions, and four conditions (Table 4-1).

These prediction errors can be seen when we parse the beneficiaries who have diabetes by how many other conditions they have. For diabetics who have one other condition (and would be in the two conditions group in Table 4-1), the predictive ratio is 1.03; for diabetics who have at least seven other conditions (and would be in the eight or more conditions group in Table 4-1), the predictive ratio is 0.93. However, these deviations from 1.0 are a concern only if there is systematic selection into MA plans of the beneficiaries who are in categories for which the predictive ratio is above 1.0.

The important points to take away from Table 4-1 are:

- The CMS–HCC model accurately predicts costs, on average, for most conditions that are represented in the model.
- However, among beneficiaries who have the same condition, some are relatively healthy and have no other conditions or only a few other conditions, while others are sicker and have many other conditions. For those who have only a few conditions, the CMS–HCC model slightly overpredicts costs, and for those who have many conditions, the model underpredicts costs, and the underprediction increases as the number of conditions increases. Consequently, SNPs and plans in PACE, which focus on the sickest beneficiaries, may be at a disadvantage, while plans that are able to attract the healthiest beneficiaries with a given condition may benefit.
- Adding race and income to the CMS–HCC model does little to improve the model’s predictive accuracy.

Including number of conditions improves predictive accuracy

We used 2007 diagnosis data and 2008 demographic and program cost data to calibrate two versions of the CMS–

HCC model. One is the standard model that CMS uses in the MA program and is the same standard model in Table 4-1. The other is the conditions model, which adds to the standard model six indicators for how many conditions each beneficiary has, as determined by the beneficiary’s diagnoses: zero, one, two, three, four, and five or more conditions. We define number of conditions as the number of HCCs that each beneficiary’s conditions map into.

This standard model has an R^2 of 0.1100, indicating that it explains 11 percent of the variation in beneficiaries’ Medicare costs. When we add the six measures indicating the number of conditions, the improvement in the R^2 is nearly imperceptible, 0.1105.

We also calculated predictive ratios for nine condition categories using both the standard and conditions models. For all nine conditions, the predictive ratios show little or no change between the two models. For most conditions, both predict reasonably well, with the exception being AMI, where there is some degree of overprediction under both models. As we saw in Table 4-1, the standard model underpredicts for beneficiaries who have zero conditions, five or more conditions, and eight or more conditions and overpredicts for one, two, three, and four conditions. In contrast, the conditions model predicts quite accurately for each of those groups (Table 4-2, p. 104). Because the conditions model predicts accurately for the sickest beneficiaries (those who have many conditions), it may be beneficial for SNPs and PACE plans.

Using two years of diagnosis data stabilizes risk scores and improves predictive accuracy

Previous research indicates that in FFS Medicare, a beneficiary who has a chronic condition indicated on a claim in one year often will not have that condition appear on a claim in the following year (Frogner et al. 2011, Medicare Payment Advisory Commission 1998). If this inconsistent coding of beneficiaries’ chronic conditions also occurs among MA plans, beneficiaries’ risk scores will often have large year-to-year changes.

We evaluated the extent to which beneficiaries who were coded for the HCCs for kidney failure, stroke, quadriplegia or paraplegia, diabetes, CHF, and chronic obstructive pulmonary disease in 2007 also were coded for those HCCs in 2008. We did this for both FFS enrollees and MA enrollees.

Our results indicate that coding for all of these conditions was not consistent from year to year. The same was true for beneficiaries in both FFS Medicare and MA plans

**TABLE
4-2****Adding number of conditions to
CMS-HCC model improves predictive
accuracy for beneficiaries
who have many conditions**

Category	Predictive ratio	
	Standard model	Conditions model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	0.99
Cancer	0.99	0.99
Mental illness	1.00	1.00
Schizophrenia	1.00	1.00
AMI	1.03	1.03
Unspecified stroke	1.01	1.01
All strokes	1.01	1.00
Number of conditions		
0	0.94	1.00
1	1.02	1.00
2	1.03	1.00
3	1.03	1.00
4	1.02	1.00
5 or more	0.98	0.99
8 or more	0.95	1.00

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. Both models use one year of diagnosis data to determine beneficiaries' conditions.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

(Table 4-3). This lack of consistent coding over time presents two problems for risk adjustment. First, in a given year, many FFS beneficiaries who have a condition will not have that condition appear on a claim. Because CMS uses conditions recorded on claims for FFS beneficiaries to calibrate the CMS-HCC model, the model may not accurately reflect the true additional cost of a particular condition. Second, inconsistent coding of conditions in MA results in greater year-to-year fluctuations in enrollees' risk scores, which leads to less stable payments and revenue streams to MA plans.

These problems related to inconsistent coding of conditions would be mitigated if CMS used two years of beneficiaries' diagnosis data rather than one year to calibrate the CMS-HCC model and determine

beneficiaries' risk scores. The Commission has recommended this position in the past (Medicare Payment Advisory Commission 2000).

We calibrated a version of the CMS-HCC model that is the same as the standard model, but we used two years of diagnosis data to assign beneficiaries to HCCs (two-year model). We found that this model produces risk scores that are more consistent over time than does the standard CMS-HCC model. For example, we found that the correlation coefficient between the 2008 and 2009 risk scores for more than 1 million beneficiaries was 0.62 using the standard model and 0.80 using the two-year model, where the correlation coefficient indicates how strongly one variable is correlated with another. The closer a correlation coefficient is to 1.0, the more closely two variables are correlated.

We also found that for specific conditions, there is little difference in predictive accuracy between the standard model and the two-year model, except for mental illness. However, the two-year model predicts more accurately for beneficiaries who have five or more conditions and for those who have eight or more conditions (Table 4-4). As we mentioned earlier, this means that for most conditions, both models pay accurately, on average, except for AMI, where there is some degree of overprediction of costs. However, for those who have five or more conditions and those who have eight or more conditions, the two-year model underpredicts by a lesser amount than does the

**TABLE
4-3****Beneficiaries who had chronic
condition on claim in 2007
often did not have same
condition on claim in 2008**

**Of those with condition
coded in 2007,
percent who did not have
it coded again in 2008**

Condition category	FFS Medicare	MA program
Diabetes	12.9%	10.9%
COPD	33.8	29.9
CHF	37.9	34.4
Kidney failure	35.4	28.9
Stroke	56.7	59.0
Quadriplegia/paraplegia	58.7	62.3

Note: FFS (fee-for-service), MA (Medicare Advantage), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure).

Source: MedPAC analysis of 2007 and 2008 risk score files from Acumen, LLC, and 2006 and 2007 Medicare denominator files from Acumen, LLC.

**TABLE
4-4****Using two years of diagnoses
in CMS-HCC model improves
predictive accuracy for beneficiaries
who have many conditions**

Category	Predictive ratio	
	Standard model	Two-year model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	1.00
Cancer	0.99	0.99
Mental illness	1.00	0.96
Schizophrenia	1.00	1.00
AMI	1.03	1.02
Unspecified stroke	1.01	1.01
All strokes	1.01	1.01
Number of conditions		
0	0.94	0.92
1	1.02	1.00
2	1.03	1.02
3	1.03	1.03
4	1.02	1.03
5 or more	0.98	1.00
8 or more	0.95	0.97

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. The standard model uses one year of diagnosis data to determine beneficiaries' conditions, the two-year model uses two years of diagnosis data.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

standard model. In summary, the two-year model offers the advantages of smaller year-to-year fluctuations in risk scores and more accurate payments for the sickest beneficiaries.

**Including number of conditions and using
two years of diagnosis data have the
benefits of both**

We also analyzed the effects of a version of the CMS-HCC model that includes indicators for number of conditions and uses two years of diagnosis data to determine beneficiaries' HCCs (combined model). The combined model has the benefits of both the conditions model and the two-year model: It improves the predictive accuracy for beneficiaries who have many conditions and it reduces year-to-year fluctuations in beneficiaries'

risk scores (Table 4-5). However, the combined model underpredicts costliness for mental illness, which also occurs under the two-year model.

**Issues related to financial neutrality
between FFS Medicare and the MA
program**

CMS estimates the CMS-HCC model using cost, demographic, and diagnosis data from FFS beneficiaries. Therefore, the coefficients for each HCC indicate the relative costliness of treating those conditions in FFS Medicare. On several occasions, the Commission has

**TABLE
4-5****Adding measures for number
of conditions and using two years
of diagnoses in CMS-HCC model improves
predictive accuracy for beneficiaries
who have many conditions**

Category	Predictive ratio	
	Standard model	Combined model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	1.00
Cancer	0.99	0.99
Mental illness	1.00	0.95
Schizophrenia	1.00	1.00
AMI	1.03	1.02
Unspecified stroke	1.01	1.01
All strokes	1.01	1.01
Number of conditions		
0	0.94	1.01
1	1.02	1.00
2	1.03	1.00
3	1.03	1.01
4	1.02	0.99
5 or more	0.98	0.99
8 or more	0.95	1.00

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. The standard model uses one year of diagnosis data to determine beneficiaries' conditions, the combined model uses two years of diagnosis data.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

Methods used in regression analysis

For this chapter, we estimated several versions of the CMS–hierarchical condition category (CMS–HCC) risk-adjustment model. We used the same general method to produce all of the regression-based results presented. The only differences between regressions are the explanatory variables. The results in all our regressions are based on a 5 percent sample of fee-for-service (FFS) beneficiaries.

In each regression, we used data from 2007 and 2008. The 2007 data are the HCCs based on diagnoses from hospital inpatient, hospital outpatient, and physician claims that we used to determine each beneficiary’s condition categories for 2008, which are defined by 70 HCCs in the CMS–HCC model. Examples of conditions defined by the HCCs include diabetes with various degrees of severity, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD). The 2008 data include the following for each beneficiary: total costliness to the Medicare program, age, sex, Medicaid status, whether institutionalized for three consecutive months, and whether eligible for Medicare on the basis of age but originally eligible because of disability.

To be included in the analysis, beneficiaries had to meet the following requirements: in both Part A and Part B of Medicare throughout 2007, in both Part A and Part B throughout their Medicare eligibility in 2008, no

Medicare Advantage enrollment at any time in 2007 or 2008, no hospice care in 2008, not classified as having end-stage renal disease in 2008, lived within the United States for all of 2007 and 2008, no Medicare as a secondary payer in 2007 or 2008, and not long-term institutionalized in 2008. In addition, the results in Tables 4-4 and 4-5 include analyses of versions of the CMS–HCC model that use two years of diagnosis data to determine each beneficiary’s HCCs. For this regression, we used diagnoses from 2006 and 2007 claims; when we used data from 2007 to exclude beneficiaries in the other regressions, we used data from 2006 and 2007 to exclude beneficiaries in the two-year regression.

In each regression, the dependent variable was each beneficiary’s 2008 costliness to FFS Medicare that we annualized if the beneficiary was in FFS Medicare for only a fraction of 2008. That is, we divided each beneficiary’s 2008 costliness to FFS Medicare by the fraction of the year the beneficiary was in FFS Medicare in 2008. Each regression included the following explanatory variables:

- 70 HCCs;
- 24 categories indicating age and sex;
- 4 variables indicating Medicaid status;

(continued next page)

stated that payments to MA plans should be equal to what MA enrollees would cost in FFS Medicare (financial neutrality) (Medicare Payment Advisory Commission 2001, Medicare Payment Advisory Commission 2002, Medicare Payment Advisory Commission 2004, Medicare Payment Advisory Commission 2005). The current method of using cost and diagnosis data from FFS Medicare to estimate the CMS–HCC model is consistent with the goal of financial neutrality.⁴

In light of two recently published papers, more discussion about financial neutrality between FFS Medicare and the MA program may be appropriate. One study found that large regional differences in service use among FFS

beneficiaries lead to large regional differences in risk scores (Song et al. 2010). This study indicates that these regional differences in risk scores are due, at least in part, simply to differences in service use rather than differences in health status. It is not known if these regional differences in risk scores also occur in the MA program. If they do, higher risk scores in high-use regions will drive up MA payments not because MA enrollees are less healthy but simply because service use is higher.

A second study found that the relative cost of treating specific conditions differs widely between a large MA plan and FFS Medicare. For some conditions, the relative cost is

Methods used in regression analysis (continued)

- 2 variables indicating beneficiaries who are eligible because of age but were originally eligible because of disability;
- 5 categories indicating that beneficiaries are disabled and have 1 of 5 conditions: opportunistic infections, severe hematologic disorders, drug or alcohol psychosis, drug or alcohol dependence, and cystic fibrosis; and
- 6 disease interaction terms: diabetes and CHF, diabetes and cardiovascular disease, CHF and COPD, CHF with COPD and coronary artery disease, renal failure (RF) and CHF, and RF with CHF and diabetes.

These are the same dependent and explanatory variables that CMS includes in the version of the CMS–HCC model it currently uses.

We ran six weighted regressions to produce the results in Tables 4-1, 4-2, 4-4, and 4-5, where the weight is the fraction of the year each beneficiary was in FFS Medicare in 2008, which is the same fraction we used to annualize each beneficiary’s costs. For Table 4-1, we ran a standard version of the CMS–HCC model, which includes all the variables listed above, and we ran a race/income version that includes the same variables plus indicators for each beneficiary’s race (African American, Hispanic, White, or other) and income,

which we approximated by the per capita income in each beneficiary’s county of residence.

For Tables 4-2, 4-4, and 4-5, we ran the following regressions:

- a conditions version, which includes all the variables in the standard version plus indicators of whether each beneficiary has zero, one, two, three, four, or five or more HCCs (Table 4-2);
- a two-year version, which includes all the variables in the standard version, but HCCs for each beneficiary are based on two years of diagnosis data rather than the single year used in the standard version (Table 4-4); and
- a version that combines the conditions version and the two-year version and includes all the variables in the standard version, whether each beneficiary has zero, one, two, three, four, or five or more HCCs, and HCCs that are based on two years of diagnosis data (Table 4-5).

We developed the analytic samples for each of these regressions from 5 percent samples of all FFS beneficiaries in 2008. It resulted in analytic samples of about 1.2 million beneficiaries for the standard and conditions versions and about 1.1 million beneficiaries for the two-year version and the version that combines the conditions and two-year versions. ■

lower in the MA plan; for other conditions, the relative cost in the MA plan is higher (Newhouse et al. 2011).

Should MA risk scores be adjusted for regional differences in service use?

Risk adjustment affects payments to MA plans through two mechanisms. First, county-level benchmarks depend directly on each county’s per capita FFS spending, divided by the county’s average CMS–HCC risk score among FFS beneficiaries. Second, CMS uses the risk scores to adjust MA payments for each enrollee.

CMS–HCC risk scores depend heavily on beneficiaries’ conditions that providers have coded on claims. Research

indicates that among FFS beneficiaries, per capita service use is higher in some areas of the country than in others. Moreover, average risk scores among FFS beneficiaries are highest in regions where service use is highest and lowest in regions where service use is lowest (Song et al. 2010).

This correlation between regional differences in service use and regional differences in risk scores could occur for two reasons. First, it could occur because those in the high-use regions are sicker. In this case, the relatively high risk scores in the high-use regions accurately reflect regional differences in health status. Second, it could occur because beneficiaries in high-use areas simply use more

medical care without being sicker than beneficiaries in lower use areas. In this case, the relatively high risk scores in high-use areas do not reflect regional differences in health status. Research indicates that at least part of the regional differences in risk scores is due to beneficiaries in high-use regions using more medical care without actually being sicker. That is, beneficiaries in high-use areas would have lower risk scores if they lived in regions where service use was lower (Song et al. 2010).

To the extent that regional differences in service use cause differences in risk scores, there may be little effect on the county-level benchmarks. For example, if a county has a high level of service use, it is likely to be reflected in both high per capita FFS spending and a high average risk score among FFS beneficiaries. The high FFS spending and high average risk score should largely offset each other, so the county benchmark should be unaffected.

Regional differences in service use are more likely to have an effect on MA payments through the risk scores of MA enrollees. In regions with relatively high service use among MA enrollees, it is possible that providers' coding of conditions is more intensive than in other regions, leading to higher risk scores and MA payments in those regions. However, it is not clear whether the regional differences in service use and risk scores that occur in the FFS program also occur in the MA program because data are not available to make that determination. But, CMS has begun collecting beneficiary-level cost and diagnosis data from MA plans; after it has collected multiple years of these data, it may be possible to replicate the analysis by Song and colleagues for the MA population.

Addressing regional differences in risk scores due to differences in service use

The study by Song and colleagues (2010) divided the country into regions and determined per capita service use in FFS Medicare in each region. The regions were sorted into quintiles of per capita service use. The authors found that regional differences in service use led to regional differences in how intensively conditions are coded on claims, which resulted in average risk scores in the highest quintile of service use that were 15 percent higher than they would have been had the beneficiaries lived in a region in the lowest quintile.

If there are similar regional differences in the MA program, adjustments could be made to MA risk scores. Using the results from Song and colleagues as a hypothetical example, these adjustments could work as

follows. Regions that are in the middle (third) quintile of service use could be used as the baseline. MA enrollees residing in a region that is in the third quintile would have no adjustment to their risk scores. Relative to the third quintile, Song and colleagues found that regional differences in service use result in risk scores that are 5.2 percent lower in the first quintile, 1.7 percent lower in the second quintile, 5.7 percent higher in the fourth quintile, and 8.8 percent higher in the fifth quintile. MA risk scores in these four regions could be adjusted by these percentages to account for differences in coding.

Adjusting risk scores for MA enrollees for the effects of regional differences in service use should be considered alongside the Commission's previously stated position on financial neutrality between the MA and FFS programs. On the one hand, making regional adjustments to MA risk scores is somewhat inconsistent with financial neutrality because one sector (FFS or MA) would have a financial advantage over another sector for treating the same patient or condition. On the other hand, to the extent that regional differences in service use that are independent of beneficiaries' health status result in regional differences in risk scores among MA enrollees, plans in high-use regions would have higher payments than plans in lower use regions simply because of regional differences in use rates. It may be appropriate to discuss the merits of each alternative.

Should CMS use FFS or MA data to estimate the CMS-HCC model?

If the large differences found by Newhouse and colleagues between the cost of treating conditions in a large MA plan and FFS Medicare also occur in most or all other MA plans, the CMS-HCC model underpredicts the costs in MA plans for some conditions and overpredicts the costs in MA plans for other conditions. Obviously, it is financially beneficial for plans to have beneficiaries who have conditions for which costs are overpredicted and avoid beneficiaries who have conditions for which costs are underpredicted.

In light of the Commission's stance on financial neutrality and the findings from Newhouse and colleagues, it may be appropriate to have a discussion about whether CMS should continue using data from FFS beneficiaries to calibrate the CMS-HCC model or switch to using data from MA enrollees. An argument for continued use of FFS data is that it is consistent with a policy of financial neutrality, and financial neutrality encourages care to be provided in the sector where it can be provided more

efficiently (MA or FFS). Under financial neutrality, when plans are able to provide care at a lower cost than FFS Medicare, they may be able to offer enhanced benefits that are more attractive to beneficiaries than FFS Medicare. Alternatively, if plans cannot provide care at a lower cost than FFS Medicare, they may not be able to offer benefits that are competitive with FFS Medicare. An argument for use of MA data is that costs incurred by MA plans may differ from costs for FFS Medicare—perhaps because of different risk profiles between sectors or because of different models of care. To the extent these cost deviations occur between sectors, MA payments that reflect the cost of efficient providers require risk adjustment calibrated on data from MA enrollees.

Differences in coding between FFS Medicare and the MA program

MA plans have an incentive for providers to code their enrollees' conditions as completely as possible because MA risk scores and payments strongly depend on each enrollee's conditions. The incentive to code conditions is present but not as strong in FFS Medicare because FFS

payments often depend on the services provided rather than beneficiaries' conditions.

This discrepancy in incentives between the MA program and FFS Medicare may be reflected in analyses by CMS and the Government Accountability Office (GAO), which found differences in diagnostic coding intensity between the two sectors (Centers for Medicare & Medicaid Services 2009, Government Accountability Office 2012). In response to its finding, CMS has reduced risk scores of MA enrollees by 3.4 percent in 2010, 2011, and 2012. However, GAO asserts that CMS has underestimated the magnitude of the greater coding intensity in the MA program by at least 1.4 percentage points and by as much as 3.7 percentage points. Statutory adjustments in the Patient Protection and Affordable Care Act of 2010 (PPACA) are consistent with the findings of the GAO. Starting in 2014, PPACA requires CMS to reduce MA enrollees' risk scores by an amount greater than 3.4 percent in each year, unless CMS begins using diagnosis and cost data from MA enrollees to estimate the CMS–HCC model. ■

Endnotes

- 1 CMS arrived at which HCCs to retain and how many to retain by balancing several competing considerations, including data collection burden, predictive power, whether to retain rare high-cost conditions, and retaining only well-defined, clinically coherent conditions (Pope et al. 2004).
- 2 It is not clear when CMS intends to begin using the data from MA enrollees to estimate the CMS–HCC model.
- 3 When we estimated the model using regression analysis, we used zero conditions as the basis of comparison, so we excluded that variable from the regression.
- 4 Financial neutrality can be obtained only if coding of conditions is the same in FFS Medicare and the MA program. Research by CMS and the Government Accountability Office (GAO) indicates that differences in coding exist between these two sectors (Centers for Medicare & Medicaid Services 2009, Government Accountability Office 2012). CMS has made adjustments to account for these differences, but GAO believes the adjustments are too small.

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EXHIBIT 5



2014: Volume 4, Number 2

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Measuring Coding Intensity in the Medicare Advantage Program

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¹Department of Health and Human Services—Agency for Healthcare Research and Quality

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Secretary for Planning and Evaluation

Background: In 2004, Medicare implemented a system of paying Medicare Advantage (MA) plans that gave them greater incentive than fee-for-service (FFS) providers to report diagnoses.

Data: Risk scores for all Medicare beneficiaries 2004–2013 and Medicare Current Beneficiary Survey (MCBS) data, 2006–2011.

Measures: Change in average risk score for all enrollees and for stayers (beneficiaries who were in either FFS or MA for two consecutive years). Prevalence rates by Hierarchical Condition Category (HCC).

Results: Each year the average MA risk score increased faster than the average FFS score. Using the risk adjustment model in place in 2004, the average MA score as a ratio of the average FFS score would have increased from 90% in 2004 to 109% in 2013. Using the model partially implemented in 2014, the ratio would have increased from 88% to 102%. The increase in relative MA scores appears to largely reflect changes in diagnostic coding, not

real increases in the morbidity of MA enrollees. In survey-based data for 2006–2011, the MA-FFS ratio of risk scores remained roughly constant at 96%. Intensity of coding varies widely by contract, with some contracts coding very similarly to FFS and others coding much more intensely than the MA average. Underpinning this relative growth in scores is particularly rapid relative growth in a subset of HCCs.

Discussion: Medicare has taken significant steps to mitigate the effects of coding intensity in MA, including implementing a 3.4% coding intensity adjustment in 2010 and revising the risk adjustment model in 2013 and 2014. Given the continuous relative increase in the average MA risk score, further policy changes will likely be necessary.

Keywords: Medicare, payment systems, FFS, Capitation, risk adjusted payments, Managed Care Organizations

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Introduction

General

Enrollment in the Medicare Advantage Program has increased dramatically, growing from 9.3 million beneficiaries in March 2008 to 15.4 million in March 2014, an increase of 66% in just six years.

Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout the history of Medicare contracting with health maintenance organizations and other private plans. In the late 1980s, Medicare paid health plans using a system that adjusted for demographic factors such as age and gender, but plan enrollees were healthier than fee-for-service beneficiaries with the same demographic characteristics, and, as a result, health plans were estimated to be overpaid by approximately 11% (Brown, Bergeron, Clement, Hill, & Retchin, 1993).¹

In order to reward health plans for attracting sicker-than-average enrollees, and to discourage plans from constructing business models designed to avoid risk, Medicare and other payers have increasingly turned to diagnosis-based risk-adjusted payment systems in which health plans are paid more for enrollees expected to need more care. While mitigating the incentive to enroll only healthy people, diagnosis-based risk adjustment creates another set of incentives: to find and report as many diagnoses as possible. Risk-adjusted payment using plan-reported diagnostic information creates a dilemma—there are strong policy reasons to pay plans more if they enroll sicker people,

¹ Systems in which payment is based, at least in part, on patient diagnoses create an incentive for providers or plans to report all appropriate diagnoses. Most notably, after the advent of the inpatient prospective payment system, which used diagnosis related groups (DRGs), hospital case-mix increased.

but measuring morbidity using plan-reported diagnostic data provides strong incentives for plans to increase the reported morbidity of enrollees (Government Accountability Office, 2012).

Medicare Risk Adjustment

The first Medicare risk program was established under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. From 1982 to 1999, this program paid health plans (known as TEFRA health maintenance organizations [HMOs]) a monthly amount per enrollee based on 95 percent of the estimated costs of treating an average beneficiary in the traditional fee-for-service (FFS) program. This amount was adjusted for demographic factors such as age and gender (Hellinger & Wong, 2000; Lichtenstein, Thomas, Adams-Watson, Lepkowski, & Simone, 1991).

The Balanced Budget Act of 1997 made significant changes under the Medicare+Choice (M+C) program, including requiring the development of a new risk adjustment system that incorporated morbidity information. Medicare began using diagnoses from inpatient hospitalizations in 2000 to adjust payments to health plans. The Benefits Improvement Protection Act of 2000 required the use of ambulatory diagnoses in Medicare risk-adjustment, and Medicare implemented the CMS-HCC (Centers for Medicare & Medicaid Services-Hierarchical Condition Categories) risk adjustment model in 2004 and fully phased it in by 2007. The CMS-HCC incorporated both inpatient and ambulatory diagnoses that were categorized into 70 HCCs that were determined to be predictive of costs (Pope, *et al.*, 2004). In 2003 the Medicare Modernization Act (MMA) renamed the program “Medicare Advantage (MA).”

The MA payment system uses diagnostic information to assign a risk score to each beneficiary, where the average beneficiary in

fee-for-service has a risk score of 1.0. MA plans are paid the product of their bid multiplied by the enrollee’s risk score—that is, if an MA plan bids \$1,000/month for an enrollee with a risk score of 1.0, and then enrolls a beneficiary with a risk score of 1.2, the plan gets paid \$1,200/month for that enrollee ($1.2 * \$1,000/\text{month}$).

This payment system creates incentives for MA plans to find and report as many diagnoses as can be supported by the medical record. For office-based services, physicians billing FFS are paid based on the procedures performed—for example, one amount for an intermediate office visit, a different amount for a skin biopsy—but are not paid based on the number of diagnoses that are reported (provided there is at least one that supports the need for the service provided). If, for example, a FFS patient with quadriplegia and a urinary tract infection (UTI) has an office visit for treatment of the UTI, the payment to the physician will be no more if both the UTI and quadriplegia are reported on the claim than if only the UTI is reported. Coding guidelines specify that the quadriplegia can legitimately be coded if it contributes to the complexity of care, but unlike the situation for MA plans, in FFS there is no incentive to report more than one diagnosis. In contrast, MA plans have a strong incentive to do so. In addition to the incentives to report more completely, the method of collecting diagnostic information also provides MA plans additional opportunities to increase risk scores. FFS diagnoses are drawn only from health care claims submitted for payment. MA plans may also review medical records and can report all diagnoses that are supported in the record, including those that were not reported by physicians on any health care claim or encounter record. MA plans can also employ nurses to visit enrollees in their homes to conduct health assessments and report diagnoses that are found.

As noted, payment to MA plans is calibrated based on coding patterns in FFS. If, for example, Jane Doe would have a risk score of 1.0 if she were in FFS, the implicit assumption in the design of the MA payment system is that she would have the same risk score of 1.0 if she were enrolled in MA. Alternatively, if the same Jane Doe had a risk score of 1.1 if enrolled in MA, then her plan would be overpaid. As we use the phrase, ‘coding intensity’ is the difference between the scores that a group of beneficiaries would have if enrolled in MA and their scores in FFS.

If we find that MA plans code with high intensity, that does not provide information about whether MA plans are ‘overcoding’ or whether FFS providers are ‘undercoding.’ Similarly, one cannot infer whether MA coding is any more or less accurate than FFS. However, for the purposes of creating an equitable MA payment system, the relevant question is whether MA risk scores are systematically different than those risk scores would be in FFS, and not which set of scores is more accurate. Suppose, for example, that average expenditure per FFS beneficiary is \$10,000/year, and that the average risk score for all FFS beneficiaries is 1.0. The goal of the payment system is to assure that—if all of those beneficiaries were to enroll in MA—the average payment to MA plans would be approximately \$10,000 per beneficiary. If, however, FFS systematically underreports diagnoses and MA reports them more completely, then the average risk score in MA would be greater than 1.0, and MA plans would be paid more than \$10,000 per beneficiary. The goal of the risk adjustment system is to assure that MA plans that enroll sicker-than-average beneficiaries are paid appropriately, but not to increase payment for an average beneficiary.

As a result of concern about the effects of incentives to increase coding intensity on MA plan payment levels, the Deficit Reduction Act

of 2005 directed CMS to measure and adjust for coding intensity (Department of Health and Human Services, 2007), and in the 2010 payment year CMS adjusted risk scores by 3.41% to reflect anticipated differences between MA and FFS coding (Department of Health and Human Services, 2009). The Government Accountability Office (2012) estimated that in 2010 MA beneficiary risk scores were at least 4.8% and perhaps as much as 7.1% higher than they likely would have been if the same beneficiaries had been continuously enrolled in FFS. The Affordable Care Act directs CMS to increase the coding intensity adjustment to at least 4.71% in 2014, and further increase it to at least 5.71% by 2018 (PPACA & HCERA, 2010). The American Taxpayer’s Relief Act of 2012 further increases the minimum coding intensity adjustment to 4.91% in 2014 and 5.91% in 2018.

The risk adjustment model implemented in 2004 was recalibrated in 2007, 2009, and 2013.² These changes slowed the growth in measured MA risk scores somewhat. Further, as described in more detail below, since 2014, CMS has adopted substantial changes to the model, particularly relating to several diagnoses that have been subject to coding intensity efforts by MA plans (Department of Health and Human Services, 2013). In 2014 the risk score is a blend, weighting the risk score calculated using the 2013 model by 25% and the risk score calculated using the 2014 model by 75%.

Concerns about coding intensity in MA plans would be minor if coding in FFS were relatively complete, because in that case there would be little opportunity for MA plans to legitimately increase risk scores through efforts at increasing diagnostic

² HCCs are constrained for a variety of reasons, including methodological and policy reasons. Starting in 2013, the coefficients for the four most severe diabetes HCCs were constrained to the same amount, eliminating the opportunity to increase revenue by increasing the reported severity of diabetes within these four HCCs.

reporting. However, FFS coding is known to be both incomplete and variable. Incomplete coding is evidenced by lack of persistence in coding of chronic conditions. For instance, among Medicare beneficiaries diagnosed with quadriplegia in one year, only 61% had a diagnosis of quadriplegia reported in the subsequent year (Medicare Payment Advisory Commission, 1998). Coding intensity also varies geographically; in the Hospital Referral Regions (HRRs) with the most intense practice patterns, the probability that a beneficiary is diagnosed with three or more chronic conditions is double the probability in low-intensity HRRs, with no evidence of differences in underlying prevalence (Welch, Sharp, Gottlieb, Skinner, & Wennberg, 2011).

Incomplete and variable coding provide ample opportunities for MA plans to increase risk scores of beneficiaries through coding intensity efforts, and a number of vendors actively market services that help plans to do so (Gorman Health Group, 2013; Leprechaun, 2013), often advertising high returns on investment (ROIs) for their services.

This paper uses recent data as well as improved methods to estimate the effects of coding intensity on MA risk scores, with particular attention to variation over time in coding intensity, variation in coding intensity across plans, and variation in the diagnoses most subject to coding intensity efforts. Before describing our methods, we'll review what is known about risk selection in the MA program.

Evidence on Risk Selection

Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout its history of contracting with HMOs and other private plans. For example, Brown *et al.* (1993) found that health plans were overpaid by approximately 11% under the Medicare risk program during the late 1980s

because plans experienced favorable selection; on average, risk plan enrollees were healthier than fee-for-service beneficiaries with the same demographic characteristics, with lower prior reimbursements and fewer indicators of chronic health problems (Brown *et al.*, 1993). Several studies confirmed that the favorable risk selection for early HMOs continued during the early 1990s (Mello, Stearns, Norton, & Ricketts, 2003; Call, Dowd, Feldman, & Maciejewski, 1999; Physician Payment Review Commission, 1996; Riley, Chiang, Ingber, & Tudor, 1996). For example, Mello *et al.* (2003) found that Medicare beneficiaries with a history of cancer or stroke were significantly less likely to be enrolled in HMOs.

Recent analyses suggest that the various policy changes that have been implemented over the past decade—such as the implementation of the CMS-HCC model, the addition of an open enrollment period, and additional refinements of the risk adjustment system—have reduced the degree of selection bias between Medicare Advantage (MA) and the traditional FFS program. For example, Newhouse, Price, Huang, McWilliams, & Hsu (2012) recently found that differences in risk scores for beneficiaries switching from the traditional FFS program to MA and beneficiaries remaining in the traditional program narrowed by a factor of 3 between 2004 and 2008 (with the difference between risk scores for beneficiaries switching into MA and those staying in the traditional FFS program changing from -0.113 to -0.037); and differences in adjusted mortality rates narrowed by a factor of 2 between 1988 and 2008 (with mortality among beneficiaries in MA as a percentage of mortality among beneficiaries in the traditional FFS program increasing from 85 percent to 93 percent) and were almost equal between persons enrolled in MA for five or more years and traditional FFS enrollees (Newhouse *et al.*, 2012). Similarly, McWilliams,

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

- - - - - +

UNITED STATES OF AMERICA,		
ex rel. BENJAMIN POEHLING,		
Plaintiffs,		Case Number:
vs.		CV 16-08697
UNITEDHEALTH GROUP, INC.,		MFW (SSx)
et al.,		
Defendants.		

- - - - - +

(Volume 1)
Videotaped Deposition of Jeffrey Grant
Washington, DC
Tuesday, March 20, 2018
9:07 a.m.

Job No. 139218
Reported by: Laurie Donovan, RPR, CRR, CSR

1 resolution that devolved from the swat team work 9:25AM
2 that was also then assigned into that division, 9:25AM
3 kind of post-reorg, a bunch of people that did 9:26AM
4 that work. 9:26AM

5 And then in a later reorganization, 9:26AM
6 which I don't remember exactly when, that was 9:26AM
7 split off as a separate division, and I was the 9:26AM
8 director of the division of payment 9:26AM
9 reconciliation, and I honestly don't recall the 9:26AM
10 name of the other division that dealt with the 9:26AM
11 payment systems. I was the acting director of 9:26AM
12 that division, and that remained until I left 9:26AM
13 in -- well, really the very end of September of 9:26AM
14 2008. 9:26AM

15 Q And you left the government to join the 9:26AM
16 private sector? 9:26AM

17 A I did. 9:26AM

18 Q You went to work for a company called 9:26AM
19 Health Risk Partners? 9:26AM

20 A That's correct. 9:26AM

21 Q And in -- if we back up for a moment. 9:26AM

22 The payment reconciliation organization 9:26AM
23 for which you were the acting director, was 9:26AM
24 that -- 9:26AM

25 A I was the director. I'm sorry. 9:26AM

1 Q You were the director? 9:26AM

2 A Director of that division. 9:27AM

3 Q Was that only for Part D, or were you 9:27AM

4 also dealing with other payments? 9:27AM

5 A That was the Part D division, so it 9:27AM

6 dealt with the collection of the prescription 9:27AM

7 event, prescription drug event data that collects 9:27AM

8 the cost information necessary to perform the 9:27AM

9 reconciliation, and then the payment 9:27AM

10 reconciliation system. 9:27AM

11 So there's a Drug Data Processing 9:27AM

12 System, DDPS, and the Payment Reconciliation 9:27AM

13 System, PRS, that -- we deployed those and 9:27AM

14 operated the first payment reconciliations for 9:27AM

15 Part D. 9:27AM

16 Q And what, what prompted your decision to 9:27AM

17 join the private sector, sir? 9:27AM

18 MS. KRIEG: Object to form. 9:27AM

19 THE WITNESS: Well, I think a 9:27AM

20 couple of things. So I was approached by an 9:27AM

21 individual that offered me the opportunity to 9:27AM

22 take over a senior position. He was running 9:27AM

23 a business that had been purchased, and he 9:27AM

24 wanted to move up into the corporate 9:27AM

25 hierarchy of the purchaser, and he offered me 9:28AM

1 the chance to come in and run his old 9:28AM
2 business as a division of that company, which 9:28AM
3 sounded intriguing. 9:28AM

4 It fit -- it was a risk adjustment 9:28AM
5 support company. It fit kind of my, my skill 9:28AM
6 set, at which point I entered into a more 9:28AM
7 large job search to talk to other folks, and 9:28AM
8 I actually joined Health Risk Partners, which 9:28AM
9 was a competing firm in the same area. 9:28AM

10 BY MR. QURESHI: 9:28AM

11 Q And the individual who approached you, 9:28AM
12 what was his name? 9:28AM

13 A Oh, God. I know him, too. I can 9:28AM
14 picture him. Oh, God, I can't remember his name. 9:28AM

15 Q That's fine. If it comes to you 9:28AM
16 throughout the day, please let me know. 9:28AM

17 Do you recall the name of the, the 9:28AM
18 company? 9:28AM

19 A It was a subsidiary of Trizetto, and I 9:28AM
20 want to say it was Planned Data Management, I 9:29AM
21 believe. 9:29AM

22 Q And when you joined Health Risk 9:29AM
23 Partners, what was your position upon joining? 9:29AM

24 A Oh, and I'm sorry, it's Stephen Jackson. 9:29AM

25 Q Okay. Thank you, sir. 9:29AM

1 A S-T-E-P-H-E-N Jackson. Pardon me? 9:29AM

2 Q When you joined Health Risk Partners, 9:29AM

3 what was your, your position? 9:29AM

4 A It was senior vice president for client 9:29AM

5 services. 9:29AM

6 Q Did you report to the CEO? 9:29AM

7 A I reported to the president. 9:29AM

8 Q Okay, and was that Ms. Susan Cimbalo at 9:29AM

9 the time? 9:29AM

10 A Correct. 9:29AM

11 Q And that's C-I-M-B-A-L-O? 9:29AM

12 A That is. 9:29AM

13 Q And at this time, 2008 through 2010, was 9:29AM

14 Health Risk Partners an independent company, or 9:29AM

15 was it owned by a larger entity? 9:29AM

16 A It was independent. 9:29AM

17 Q Okay. At some point during your tenure 9:29AM

18 with Health Risk Partners, was it acquired by a 9:30AM

19 larger company? 9:30AM

20 A It was not. 9:30AM

21 Q Sir, I'd like to now focus on your 9:30AM

22 tenure at CMS before you joined Health Risk 9:30AM

23 Partners, and in particular I'd like to review a 9:30AM

24 series of names and understand whether you have 9:30AM

25 ever met these individuals, interacted with them, 9:30AM

Page 87

1	sir, to --	10:57AM
2	A For calibration?	10:57AM
3	Q Yes, sir, the risk adjustment model	10:57AM
4	calibration.	10:57AM
5	A It would have no impact.	10:57AM
6	Q Why is that?	10:57AM
7	MS. KRIEG: Object to form.	10:57AM
8	THE WITNESS: Because a sample	10:57AM
9	would be very small, and you could adjust the	10:57AM
10	diagnoses in that sample, and you could not	10:57AM
11	adjust any diagnoses on anything outside the	10:57AM
12	sample, because you are doing a linear	10:57AM
13	regression model that is comparing each	10:58AM
14	person's diagnoses to costs.	10:58AM
15	BY MR. QURESHI:	10:58AM
16	Q The, the model calibration for risk	10:58AM
17	adjustment, what -- did that use sampling at all?	10:58AM
18	MS. KRIEG: Object to form.	10:58AM
19	THE WITNESS: I'm not sure.	10:58AM
20	BY MR. QURESHI:	10:58AM
21	Q We were talking earlier about	10:58AM
22	Mr. Gorman's comments regarding how doctors code.	10:58AM
23	Other than Mr. Gorman, did you hear anything from	10:58AM
24	anyone else?	10:58AM
25	MS. KRIEG: Object to form.	10:58AM

1 BY MR. QURESHI: 10:58AM

2 Q On this topic? 10:58AM

3 A At what point in time? 10:58AM

4 Q If I recall, you didn't remember the, 10:58AM

5 the precise point in time Mr. Gorman made his 10:59AM

6 comments, so you were just surveying your 10:59AM

7 recollection generally. 10:59AM

8 A Moving forward from that point in time, 10:59AM

9 certainly I have heard many people say the same 10:59AM

10 thing. 10:59AM

11 Q Okay, and have you formed your own 10:59AM

12 opinion? 10:59AM

13 A I have. 10:59AM

14 Q And what is that opinion? 10:59AM

15 MS. KRIEG: Object to form. 10:59AM

16 THE WITNESS: That there is a 10:59AM

17 degree of error in doctors' coding, that the 10:59AM

18 codes on claims are not perfect. 10:59AM

19 BY MR. QURESHI: 10:59AM

20 Q In the sense that the codes on claims do 10:59AM

21 not capture everything in the medical chart? 10:59AM

22 MS. KRIEG: Object to form. 10:59AM

23 THE WITNESS: That is one potential 10:59AM

24 problem. 10:59AM

25

1 BY MR. QURESHI: 12:03PM

2 Q Okay. I believe your testimony was that 12:03PM

3 you do agree with the statement as expressed. 12:03PM

4 MS. KRIEG: Object to form. 12:04PM

5 THE WITNESS: In my opinion, yes, 12:04PM

6 that is a correct statement. 12:04PM

7 BY MR. QURESHI: 12:04PM

8 Q Okay. Now let's put this aside and 12:04PM

9 focus on your opinion. 12:04PM

10 Is there a time frame you can assign to 12:04PM

11 when you held that opinion? 12:04PM

12 MS. KRIEG: Object to form. 12:04PM

13 THE WITNESS: Again, I think -- no, 12:04PM

14 I can't really assign a time frame to it. 12:04PM

15 BY MR. QURESHI: 12:04PM

16 Q You're unable to even approximate, sir? 12:04PM

17 MS. KRIEG: Object to form. 12:04PM

18 THE WITNESS: I'm unable to 12:04PM

19 approximate. 12:04PM

20 MR. QURESHI: Okay. Let's flip 12:05PM

21 these over, and you can refer to them anytime 12:05PM

22 you like. Let's go through another document 12:05PM

23 now that we will mark as Exhibit 1010. 12:05PM

24 (Exhibit 1010 was marked for 12:05PM

25 identification.) 12:05PM

1 BY MR. QURESHI: 12:05PM

2 Q Again, sir, please take a moment to 12:05PM

3 review this as much as you like, but I'm only 12:06PM

4 going to focus on a particular statement on page 1 12:06PM

5 of the document. 12:06PM

6 A All right. 12:06PM

7 Q Let's start with whether you've ever 12:06PM

8 seen the document marked Exhibit 1010 before. 12:06PM

9 A Not to my knowledge. 12:06PM

10 Q Okay. Well, I'll represent to you it's 12:06PM

11 a GAO report entitled "Medicare Advantage -- 12:06PM

12 Substantial Excess Payments Underscore Need for 12:06PM

13 CMS to Improve Accuracy of Risk Score 12:06PM

14 Adjustments." 12:06PM

15 Did I read that correctly, sir? 12:06PM

16 A Yes. 12:06PM

17 Q On page 1 in the second paragraph, 12:06PM

18 there's a statement that reads, quote, "Risk 12:06PM

19 scores for beneficiaries with the same diagnoses 12:06PM

20 and characteristics should be identical, 12:06PM

21 regardless of whether the beneficiaries are in an 12:06PM

22 MA plan or Medicare FFS," end quote. 12:06PM

23 Did I read that correctly, sir? 12:07PM

24 A I'm sorry. Where are you? 12:07PM

25 Q I'm on page 1. It's a letter. The 12:07PM

1 bottom of the page is marked page 1. 12:07PM

2 A Oh, I was on the first page. I'm sorry. 12:07PM

3 Got it. 12:07PM

4 Q Okay. Sorry for not -- 12:07PM

5 A No, that's okay. 12:07PM

6 Q Allow me to read it again, please. 12:07PM

7 In the second paragraph, the first 12:07PM

8 sentence states, quote, "Risk scores for 12:07PM

9 beneficiaries with the same diagnoses and 12:07PM

10 characteristics should be identical, regardless of 12:07PM

11 whether the beneficiaries are in an MA plan or 12:07PM

12 Medicare FFS," end quote. 12:07PM

13 Did I read that correctly? 12:07PM

14 A Yes. 12:07PM

15 Q Okay. Do you agree with that statement, 12:07PM

16 sir? 12:07PM

17 MS. KRIEG: Object to form. 12:07PM

18 THE WITNESS: Yes. 12:07PM

19 BY MR. QURESHI: 12:07PM

20 Q What do you understand the phrase "risk 12:07PM

21 scores" to refer to? 12:08PM

22 MS. KRIEG: Object to form. 12:08PM

23 THE WITNESS: The end result of a 12:08PM

24 risk adjustment calculation using the CMS-HCC 12:08PM

25 model in this case for -- which is basically 12:08PM

1 a sum of the risk adjustment factors. 12:08PM

2 BY MR. QURESHI: 12:08PM

3 Q And is that the model you were referring 12:08PM

4 to earlier today? 12:08PM

5 A Correct. 12:08PM

6 MS. KRIEG: Object to form. 12:08PM

7 THE WITNESS: Yes. 12:08PM

8 BY MR. QURESHI: 12:08PM

9 Q The statement also uses the words or the 12:08PM

10 word "FFS." Do you have an understanding as to 12:08PM

11 what that refers to? 12:08PM

12 MS. KRIEG: Object to form. 12:08PM

13 THE WITNESS: "Fee-for-service" is 12:08PM

14 what I would assume it refers to. 12:08PM

15 BY MR. QURESHI: 12:08PM

16 Q Yeah, and in fact, if you look to the 12:08PM

17 page marked romanette ii, it provides a glossary. 12:08PM

18 MS. KRIEG: Object to form. 12:08PM

19 MR. QURESHI: Mr. Grant, we're now 12:09PM

20 going to mark a document as Exhibit 1011. 12:09PM

21 (Exhibit 1011 was marked for 12:09PM

22 identification.) 12:09PM

23 BY MR. QURESHI: 12:09PM

24 Q Please take a moment to review it. I'm 12:09PM

25 going to focus on pages E3 and E4. 12:09PM

1 A E3 and E4? 12:10PM

2 Q Yes, sir. 12:10PM

3 (Witness peruses document.) 12:11PM

4 BY MR. QURESHI: 12:11PM

5 Q Sir, have you had an opportunity to 12:11PM

6 review the document marked as Exhibit 1011? 12:11PM

7 A I have. 12:11PM

8 Q Okay. Have you seen this document 12:11PM

9 before? 12:11PM

10 A Not to my knowledge. 12:12PM

11 Q I'll represent to you that Exhibit 1011 12:12PM

12 is an article from the periodical Medicare & 12:12PM

13 Medicaid Research Review, entitled "Measuring 12:12PM

14 Coding Intensity in the Medicare Advantage 12:12PM

15 Program." The authors are Richard Kronick and 12:12PM

16 W. Pete Welch. 12:12PM

17 Do you know either Mr. Kronick or 12:12PM

18 Mr. Welch? 12:12PM

19 A I know Mr. Kronick. 12:12PM

20 Q And how do you know Mr. Kronick? 12:12PM

21 A Do you mean when did I first know him? 12:12PM

22 Q I certainly will ask you that, but I'm 12:12PM

23 trying to understand the nature of your knowledge 12:12PM

24 about who he is. 12:12PM

25 A That's a fairly -- 12:12PM

1 Q All I'm trying to ask, Mr. Grant, is did 12:12PM
2 you play golf with him? Did you -- 12:12PM

3 A Oh, oh. 12:13PM

4 Q -- hear him speak at a conference? Who 12:13PM
5 is he? 12:13PM

6 A Okay. I wasn't clear what you were -- 12:13PM
7 he, he works in risk adjustment. He, he's the 12:13PM
8 developer of a risk adjustment model. 12:13PM

9 Q And is it in that capacity that you have 12:13PM
10 come to know him? 12:13PM

11 A That is the first capacity in which I 12:13PM
12 came to know him. 12:13PM

13 Q In what other capacities have you come 12:13PM
14 to know Mr. Kronick? 12:13PM

15 A He worked as the deputy assistant 12:13PM
16 secretary for planning and evaluation, the 12:13PM
17 Department of Health and Human Services. 12:13PM

18 Q Did you ever supervise him? 12:13PM

19 A No. 12:13PM

20 Q Okay. Did he ever supervise you? 12:13PM

21 A No. 12:13PM

22 Q And approximately when did you come to 12:13PM
23 know Mr. Kronick? 12:13PM

24 A I guess I -- when you say "know," do you 12:13PM
25 mean "know of" or "be acquainted with"? 12:13PM

1 Q Let's start with "know of," and then 12:13PM

2 we'll move to "become acquainted with." 12:13PM

3 A Okay. "Know of" would have been 12:14PM

4 somewhere in the early 2000s when we were 12:14PM

5 evaluating risk adjustment models. 12:14PM

6 Q And when did you become acquainted with 12:14PM

7 him? 12:14PM

8 A When he came to HHS, and I guess he was 12:14PM

9 probably in HHS when I got here, so when I 12:14PM

10 returned to Health and Human Services in July of 12:14PM

11 2010. 12:14PM

12 Q So when you left Health Risk Partners 12:14PM

13 and came back to CMS, that's when you became 12:14PM

14 acquainted with him? 12:14PM

15 A Yes. 12:14PM

16 Q And, sir, do you have an opinion on his 12:14PM

17 competence or expertise? 12:14PM

18 MS. KRIEG: Object to form. 12:14PM

19 THE WITNESS: I do. 12:14PM

20 BY MR. QURESHI: 12:14PM

21 Q And what is that opinion? 12:14PM

22 MS. KRIEG: Object to form. 12:14PM

23 THE WITNESS: He's an expert on 12:14PM

24 risk adjustment. 12:14PM

25

1 BY MR. QURESHI: 12:14PM

2 Q Sir, if you might turn to page E4 and 12:14PM

3 follow along with respect to the first paragraph 12:15PM

4 on E4. 12:15PM

5 Quote, "As noted, payment to MA plans is 12:15PM

6 calibrated based on coding patterns in FFS. If, 12:15PM

7 for example, Jane Doe would have a risk score of 12:15PM

8 1.0 if she were an FFS, the implicit assumption in 12:15PM

9 the design of the MA payment system is that she 12:15PM

10 would have the same risk score of 1.0 if she were 12:15PM

11 enrolled in MA. Alternatively, if the same Jane 12:15PM

12 Doe had a risk score of 1.1 if enrolled in MA, 12:15PM

13 then her plan would be overpaid. As we use the 12:15PM

14 phrase, 'coding intensity' is the difference 12:15PM

15 between the scores that a group of beneficiaries 12:15PM

16 would have if enrolled in MA and their scores in 12:15PM

17 FFS." 12:15PM

18 Did I read that correctly, sir? 12:15PM

19 A You did. 12:15PM

20 Q Okay. Do you agree with the statements 12:15PM

21 in that paragraph I read? 12:15PM

22 MS. KRIEG: Object to form. 12:16PM

23 THE WITNESS: I do. 12:16PM

24 BY MR. QURESHI: 12:16PM

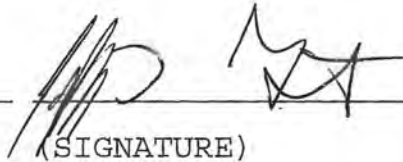
25 Q If you would please follow along as I 12:16PM

ACKNOWLEDGEMENT OF WITNESS

I, Jeffrey Grant, do hereby
acknowledge that I have read and examined the
foregoing testimony, and the same is a true,
correct and complete transcription of the
testimony given by me, and any corrections
appear on the attached Errata sheet signed by
me.

June 18, 2018

(DATE)


(SIGNATURE)

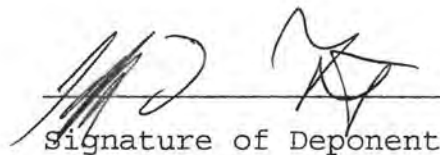
ERRATA SHEET

Case Name:

Deposition Date:

Deponent:

Pg.	No.	Now Reads	Should Read	Reason
18	25	Balance	Balanced	Title of the Act
57	21	Balanced	Balanced	Title of the ACT
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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS ____ DAY OF _____, 2018.

(Notary Public) MY COMMISSION EXPIRES: _____

EXHIBIT 7

1 IN THE UNITED STATES DISTRICT COURT

2 CENTRAL DISTRICT OF CALIFORNIA

3 Case No. CV 16 08697 MFW (SSx)

4
5 UNITED STATES OF AMERICA,)

6 ex rel. BENJAMIN POEHLING,)

7 Plaintiffs,)

8 v.)

9 UNITEDHEALTH GROUP, INC., et al.,)

10 Defendants.)

11)

12
13
14
15 (Volume 2)

16 DEPOSITION OF JEFFREY GRANT

17 Washington, D.C.

18 May 16, 2018

19
20
21
22
23
24 Reported by: Mary Ann Payonk

25 Job No. 140253

1

2

3

4

May 16, 2018

5

10:00 a.m.

6

7

Deposition of JEFFREY GRANT, Volume 2,

8

held at the law offices of Latham & Watkins

9

LLP, 555 Eleventh Street, N.W., Suite 1000,

10

Washington, D.C., pursuant to Notice before

11

Mary Ann Payonk, Shorthand Reporter and Notary

12

Public of the District of Columbia,

13

Commonwealth of Virginia, and State of New

14

York.

15

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25

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8 ALSO PRESENT:

9 Glen Fortner, Legal Video Specialist

10 Johanna Kriesel, HHS

11 Matthew Shors, Senior Deputy

12 General Counsel, UnitedHealth Group,

13 Inc., Minnetonka, MN

14

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1	THE VIDEOGRAPHER: This is the	10:02
2	start of tape labeled number 1 of the	10:02
3	videotaped deposition of Jeffrey Grant	10:02
4	in the matter of United States of	10:02
5	America v. UnitedHealth Group, Inc.	10:02
6	et al., in the United States District	10:02
7	Court, District of -- Central District	10:02
8	of California, Case Number	10:02
9	CV-16-08697(MFW). This deposition is	10:02
10	being held at 555 11th Street Northwest,	10:03
11	Washington, D.C. on May 16, 2018, at	10:03
12	approximately 10:03.	10:03
13	My name is Glen Fortner from	10:03
14	TSG Reporting, Inc., and I am the legal	10:03
15	video specialist. The court reporter is	10:03
16	Mary Ann Payonk, in association with	10:03
17	TSG Reporting.	10:03
18	Will counsel please introduce	10:03
19	yourselves?	10:03
20	(Whereupon, counsel placed their	10:03
21	appearances on the video record.)	10:03
22	THE VIDEOGRAPHER: The court	10:03
23	reporter may swear the witness and we	10:03
24	will begin.	10:03
25		

1 JEFFREY GRANT, 10:04

2 called as a witness, having been duly 10:04

3 sworn, was examined and testified as 10:04

4 follows: 10:04

5 EXAMINATION 10:04

6 BY MR. QURESHI: 10:04

7 Q. Good morning, Mr. Grant. 10:04

8 A. Good morning. 10:04

9 Q. You understand that we are today 10:04

10 continuing the deposition that was commenced on 10:04

11 March 20? 10:04

12 A. Yes. 10:04

13 Q. Do you recall generally the 10:04

14 instructions that we reviewed at the beginning 10:04

15 of that deposition? 10:04

16 A. I do. 10:04

17 Q. I'm not going to repeat all of them, 10:04

18 but I will ask you to, or remind you to listen 10:04

19 carefully to my questions. If you do not 10:04

20 understand a question, please ask me to clarify 10:04

21 it. And I may ask you what you don't 10:04

22 understand so I can learn how to clarify my 10:04

23 question. Is that fair? 10:04

24 A. Yes. 10:04

25 Q. If you answer my question, I'll 10:04

1 assume that you've understood it. Okay? 10:04

2 If you need to take a break at any 10:04

3 time to get some coffee, water, use the 10:04

4 restroom, just let me know and we will go off 10:04

5 the record. I would ask, however, that we not 10:04

6 take a break while a question is pending unless 10:05

7 you need to confer with your counsel about 10:05

8 questions of privilege. 10:05

9 A. I understand. 10:05

10 Q. Are you aware of any reason your 10:05

11 deposition should not go forward today? 10:05

12 A. No. 10:05

13 Q. Okay. Are you on any medication or 10:05

14 substance that might impact your ability to 10:05

15 recall information truthfully? 10:05

16 A. No. 10:05

17 MR. HASEGAWA: Can we have the same 10:05

18 agreement that we had last time, that 10:05

19 relator joins in any objection to form? 10:05

20 MR. QURESHI: Yes. 10:05

21 MR. HASEGAWA: Thank you. 10:05

22 BY MR. QURESHI: 10:05

23 Q. Mr. Grant, are you familiar with the 10:05

24 phrase "coding intensity adjuster? 10:05

25 A. Yes. 10:05

1 Q. Okay. What is it? 10:05

2 A. I have a general understanding of it. 10:05

3 I have never worked on the coding intensity 10:05

4 adjuster. It's something that Medicare does, 10:05

5 and they did it after I stopped working on 10:05

6 Medicare. 10:05

7 Q. And what is your general 10:05

8 understanding of a coding intensity adjuster? 10:05

9 MS. KRIEG: Object to the question. 10:05

10 A. My general understanding is that it's 10:06

11 an adjuster for differences in the intensity of 10:06

12 coding that occur, regardless of reason, 10:06

13 between like one -- a base group like, for 10:06

14 instance, in risk adjustment, a base group that 10:06

15 is used to calibrate the model, fee-for-service 10:06

16 base group, and a Medicare Advantage group that 10:06

17 is actually being paid based on the codes 10:06

18 submitted. 10:06

19 Q. Do you have an understanding that 10:06

20 Medicare Advantage groups or plans engage in 10:06

21 activities to gather more complete diagnostic 10:06

22 codes than does CMS? 10:06

23 MS. KRIEG: Object to the question. 10:06

24 A. Definitionally, when you say CMS, you 10:06

25 mean CMS fee-for-service Medicare? 10:07

1 Q. Correct. 10:07

2 A. That was -- yeah, that has been my 10:07

3 understanding is that by paying for something, 10:07

4 it causes folks to wish to code more completely 10:07

5 than those who are not paid for. 10:07

6 Q. And are you able to identify any of 10:07

7 those activities that MA plans might engage in 10:07

8 to code more completely, using your words? 10:07

9 A. Yes. 10:07

10 Q. Okay. Can you please provide 10:07

11 examples? 10:07

12 A. It would start with provider outreach 10:07

13 to try to educate providers, physicians who do 10:07

14 not get paid for diagnosis codes, of the 10:07

15 portion of diagnosis codes in an MA setting. 10:07

16 It would then also go to pulling charts, 10:07

17 medical records for review, and then in kind of 10:07

18 the 2008-2009 period, it extended to doing home 10:08

19 visits to folks that had not been to the doctor 10:08

20 to do medical assessments and using those 10:08

21 health assessments to then develop diagnosis 10:08

22 codes off the health assessments and submit 10:08

23 those. 10:08

24 Q. Sir, do you have a view as to whether 10:08

25 any of the three activities you mentioned are 10:08

1 improper? 10:08

2 MS. KRIEG: Object. 10:08

3 A. Yes. 10:08

4 Q. Okay. I'd like to go through each 10:08

5 one of them and then ask whether you believe 10:08

6 it's appropriate or not. 10:08

7 Provider outreach. 10:08

8 MS. KRIEG: Object to the question. 10:08

9 Q. Do you believe that that's an 10:08

10 appropriate activity for MA plans to engage in? 10:08

11 A. Yes. 10:08

12 MS. KRIEG: Object to form. 10:08

13 A. Yes. 10:08

14 Q. Okay. The same question with respect 10:08

15 to pulling charts for review. Is that an 10:08

16 appropriate activity for MA plans to engage in? 10:09

17 MS. KRIEG: Object to the question. 10:09

18 A. Yes. 10:09

19 Q. And the last one was home visits. Do 10:09

20 you believe that home visits are an appropriate 10:09

21 activity for MA plans to engage in? 10:09

22 MS. KRIEG: Object to the question. 10:09

23 A. I think they can be. 10:09

24 Q. Okay. In what instances might they 10:09

25 not be appropriate? 10:09

1 MS. KRIEG: Object to the question. 10:09

2 A. I think a home visit that is not part 10:09

3 of kind of what I would characterize as a 10:09

4 continuity of care, so home visit that is done 10:09

5 strictly for the purpose of generating 10:09

6 diagnosis codes with no intent of actually 10:09

7 caring for the individual would not be 10:09

8 consistent with the goals of the Medicare 10:09

9 Advantage program. 10:09

10 Q. Other than home visits that are done 10:09

11 strictly to generate diagnoses codes with no 10:09

12 intent of actually caring for the individual, 10:10

13 are there other instances in which you believe 10:10

14 home visits are inappropriate? 10:10

15 MS. KRIEG: Object to the question. 10:10

16 A. I think -- I think the homes visits 10:10

17 subject is very complicated is what I would 10:10

18 say, so I think it all depends -- you would 10:10

19 have to be very specific about how a home visit 10:10

20 was conducted, the terms under which it was 10:10

21 done. There are many ways to do it 10:10

22 appropriately and inappropriate. I think you 10:10

23 would have to be very specific about how a home 10:10

24 visit was done to judge it appropriate or 10:10

25 inappropriate. 10:10

1 Q. Sir, do you have an understanding as 10:11
2 to why a coding intensity adjuster is used by 10:11
3 the Medicare program? 10:11

4 MS. KRIEG: Object to the question. 10:11

5 And to the extent it calls for 10:11
6 deliberative process, I instruct you not 10:11
7 to answer. 10:11

8 A. Well, the simplest thing is I was not 10:11
9 involved in the deliberative process so any 10:11
10 understanding I would have would be just my 10:11
11 opinion as to why they did it. 10:11

12 Q. And that's all I'm interested in, 10:11
13 sir. 10:11

14 A. Okay. My understanding is -- well, 10:11
15 first of all, it goes to a statute that 10:11
16 required it. I think Medicare probably could 10:11
17 have done it within the statute but instead, 10:11
18 they were required to do it. So it was 10:11
19 something that would have been optional, 10:11
20 something that became required by statute, so 10:11
21 that is the simplest answer. 10:11

22 I think the reason that Medicare 10:11
23 would look at doing such a thing would be that 10:12
24 they would see a different pattern of coding 10:12
25 going on in Medicare Advantage than they 10:12

1 observe in fee-for-service. 10:12

2 Q. And how would the coding intensity 10:12

3 adjuster relate to this different pattern of 10:12

4 coding? 10:12

5 MS. KRIEG: Object to the question. 10:12

6 A. That would entirely depend on how it 10:12

7 is calculated, so it's hard to say. 10:12

8 Q. You referenced a statute, sir. Do 10:12

9 you know which statute? 10:12

10 A. It would fall within the Social 10:12

11 Security Act, but I have no idea what section. 10:12

12 Q. Mr. Grant, you mentioned that the 10:13

13 coding intensity adjuster would address a 10:13

14 different pattern of coding going on in 10:13

15 Medicare Advantage than what was observed in 10:13

16 fee-for-service? 10:13

17 A. That's correct. 10:13

18 Q. Why would that difference need 10:13

19 addressing? 10:13

20 MS. KRIEG: Object to the question. 10:13

21 A. You've calibrated an actuarial model 10:13

22 to predict a pattern of expenditures based on 10:13

23 people's characteristics. When you define a 10:13

24 similar group of people but give them different 10:13

25 characteristics that indicate that they are 10:13

1 sicker than or more expensive, they have more 10:13
2 expensive conditions than what would be 10:13
3 predicted under the calibration of the model, 10:13
4 then you're going to pay more than the model 10:13
5 calibration would anticipate that you would 10:14
6 pay. 10:14

7 Q. And it is to address that issue that 10:14
8 the coding intensity adjuster is focused? 10:14

9 MS. KRIEG: Object to the question. 10:14

10 A. Again, not having been in that, that 10:14
11 would be my understanding. Again, I did not 10:14
12 work on the coding intensity adjuster, but that 10:14
13 theoretically would be what it would be for. 10:14

14 MR. QURESHI: I'm going to begin by 10:14
15 marking a document that I'd ask you to 10:14
16 review. 10:14

17 (Exhibit No. 1014 was marked for 10:14
18 identification.) 10:14

19 BY MR. QURESHI: 10:15

20 Q. Mr. Grant, you've been handed a 10:15
21 document that's marked Exhibit 1014, and you're 10:15
22 welcome to review the entirety of it. I'm 10:15
23 going to be focusing on portions on page 12. 10:15
24 Please take as much time as you need to flip 10:15
25 through it. 10:15

1 On page 12, the section that I would 10:16
2 be interested in is the one that begins with 10:16
3 the italicized "More complete coding." It's 10:16
4 near the bottom of the page. 10:16

5 A. On page 12? 10:16

6 Q. I'm sorry, it's page 20. 10:16

7 MR. HASEGAWA: What page? 10:16

8 MR. QURESHI: 20. 10:16

9 MR. HASEGAWA: Just to make sure, 10:16
10 you're looking at the April 7, 2008 10:16
11 announcement of 2009 rates? 10:17

12 MR. QURESHI: I believe we're 10:17
13 looking at the April 7, 2008. 10:17

14 MR. HASEGAWA: And on page 20, 10:17
15 we're looking at something that begins 10:17
16 with an Italicized -- 10:17

17 MR. QURESHI: No, we're just 10:17
18 looking at the top of the page. 10:17

19 MR. HASEGAWA: Okay. 10:17

20 MR. QURESHI: It begins with "Given 10:17
21 the fact that." 10:17

22 MR. HASEGAWA: Okay. 10:17

23 THE WITNESS: So I've read the 10:19
24 section in question. 10:19

25 BY MR. QURESHI: 10:19

1 Q. Okay. Sir, I'm going to go through 10:19
2 the first sentence on page 20, different 10:19
3 components, and then ask you whether or not you 10:19
4 agree with them or not. 10:19

5 Do you agree that the MA payment 10:19
6 methodology is based on fee-for-service 10:19
7 payments? 10:19

8 MS. KRIEG: Object to that 10:19
9 question. 10:19

10 A. I would agree that aspects of the MA 10:19
11 payment methodology are related to the MA 10:19
12 payments. The risk adjustment model 10:19
13 calibration, I mean, is based on 10:19
14 fee-for-service payments, specifically the risk 10:19
15 adjustment model calibration. 10:19

16 Q. Okay. So the risk adjustment model 10:19
17 calibration is based on fee-for-service 10:19
18 payments? 10:19

19 A. Yes. 10:19

20 Q. And would you agree further that the 10:19
21 risk adjustment methodology is designed to 10:19
22 compare the risk scores of MA plan enrollees to 10:19
23 other plan enrollees and beneficiaries not 10:20
24 enrolled in MA plans? 10:20

25 MS. KRIEG: Object to the question. 10:20

1 A. I think that's an odd way of wording 10:20
2 it is what I would say, but I think -- I'm not 10:20
3 sure that design to compare beneficiaries not 10:20
4 enrolled in MA plans is true. I mean, I think 10:20
5 you can do it. I think the design is to pay MA 10:20
6 plans. The method by which that is done is to 10:20
7 calibrate expected cost patterns using 10:20
8 fee-for-service data. 10:20

9 So I think I would restate that 10:20
10 there -- you would want there to be a 10:20
11 comparability between the data that was being 10:20
12 used to pay the plans and the data on which it 10:21
13 was calibrated, which is a little bit different 10:21
14 than saying it was designed to be that way. 10:21

15 Q. Okay. And why would you want that 10:21
16 comparability? 10:21

17 A. Because you're calibrating a model 10:21
18 using a certain data set you would like the 10:21
19 data set that you pay on to be comparable to 10:21
20 the data set that you used to calibrate the 10:21
21 expected costs; otherwise, you have a 10:21
22 misalignment between risk adjustment in 10:21
23 practice and risk adjustment as you develop the 10:21
24 model. 10:21

25 Q. In your view, what are the 10:21

1 consequences of misalignment? 10:21

2 MS. KRIEG: Object to the question. 10:21

3 A. The specific consequences that were 10:21

4 being addressed here were that the coding 10:21

5 intensity was greater in Medicare Advantage. I 10:21

6 mean, if you have -- in any case, you could 10:21

7 have somebody that undercoded, theoretically. 10:21

8 If they were bad at submitting risk adjustment 10:22

9 data, they would be underpaid. If they good at 10:22

10 submitting risk adjustment data and got more 10:22

11 data in, they would be overpaid according to 10:22

12 the design of the methodology, which would 10:22

13 anticipate that they would submit data exactly 10:22

14 the same as fee for service. 10:22

15 Q. And in connection with that last 10:22

16 point, would you agree with this clause that 10:22

17 states for the comparison, comparability, to 10:22

18 use your words, to be valid, MA plans must code 10:22

19 the way Medicare Part A and B does? 10:22

20 MS. KRIEG: Object to the question. 10:22

21 A. As a theoretical construct, I think 10:22

22 yes. But as a practical matter, it's kind of 10:22

23 impossible once you've started all of these 10:22

24 other things oriented around focusing on 10:22

25 diagnosis codes, I think it is practical -- it 10:22

1 is not a practical construct. It is a 10:22
2 theoretical statement. But I think it is 10:23
3 impossible once people start focusing on 10:23
4 diagnosis codes to say that Medicare plans 10:23
5 would code exactly the way fee for service 10:23
6 does. 10:23

7 Q. But in your view, they should? 10:23

8 MS. KRIEG: Object to the question. 10:23

9 A. I think the whole point of the 10:23
10 adjuster is that they don't and won't so I 10:23
11 don't know that they should. I think -- I 10:23
12 would never expect that they would, so -- and 10:23
13 we were running -- I mean, from the time we ran 10:23
14 the payment system, we realized, as with every 10:23
15 payment system Medicare has ever implemented, 10:23
16 that once you start paying for A, A becomes 10:23
17 focused on and A is no longer equivalent to A. 10:23
18 It becomes A prime. It becomes something 10:23
19 different by virtue of paying for it. 10:23

20 So as an ideal, like, way the world 10:23
21 would be nice if it existed, yes, but that's 10:24
22 not really economically how a world works. 10:24
23 When you focus on something, it changes it. 10:24

24 Q. And in order to address that issue 10:24
25 that you've just described, the coding 10:24

1 intensity adjuster was introduced? 10:24

2 MS. KRIEG: Object to the question. 10:24

3 A. Again, if you read this, that would 10:24

4 be what this would indicate, and that would be 10:24

5 my understanding of it. But again, I didn't 10:24

6 introduce the coding intensity adjuster, so -- 10:24

7 Q. I understand, Mr. Grant. 10:24

8 A. But reading -- you know, that's what 10:24

9 this record would indicate, and it makes sense. 10:24

10 Q. Okay. I'm just interested in your 10:24

11 understanding. 10:24

12 A. That is my understanding of it, yes. 10:24

13 Q. The paragraph goes on to state: 10:24

14 "This would result in the MA plan's coding 10:24

15 accurately reflecting the fee-for-service 10:24

16 coding used on the beneficiaries to whom MA 10:24

17 plan enrollees are being compared." 10:24

18 Did I read that correctly? 10:25

19 A. Yes. 10:25

20 Q. And do you agree with that statement? 10:25

21 MS. KRIEG: Object to the question. 10:25

22 A. I agree if you had an ideal world 10:25

23 where you could just magically have MA data 10:25

24 come in the same way fee-for-service data, not 10:25

25 influenced by the fact that you paid on it, 10:25

1 then you would end up with data that was 10:25
2 accurate from the standpoint of being kind of 10:25
3 comparable data, which is what that is saying. 10:25
4 It's predicated on the idea that plans would 10:25
5 code exactly the same way, which I've already 10:25
6 said I don't believe is true. But if you could 10:25
7 create a magical world where that would happen, 10:25
8 that would be true. 10:25

9 Q. And in your response, you indicated 10:25
10 accurate with -- the word "accurate" relates to 10:25
11 comparability to fee-for-service data? 10:25

12 A. Right. 10:25

13 MS. KRIEG: Object to the question. 10:25

14 THE WITNESS: Oh, sorry. 10:25

15 A. Yes, and that's what the next 10:25
16 sentence is referring -- I mean, the -- if you 10:25
17 look at this in the context of the overall 10:26
18 paragraph here, and the statements below by the 10:26
19 Senators and by -- by Senator Grassley, I mean, 10:26
20 you have to look at this in the whole context 10:26
21 of this. And they are using accuracy not to 10:26
22 talk about whether any specific diagnosis code 10:26
23 in fee-for-service or managed care is accurate. 10:26
24 It is to compare -- to have comparable 10:26
25 diagnoses. So it is accuracy of risk 10:26

1 adjustment, really, not accuracy of coding. 10:26

2 That's what they're talking about here. 10:26

3 So they are -- when they say 10:26

4 "inaccurate," they are not referring to the 10:26

5 accuracy or inaccuracy of any specific code on 10:26

6 any specific claim or any specific RAP 10:26

7 submission. They're talking about comparable 10:26

8 types of data. 10:26

9 Q. Mr. Grant, if you focus in on the 10:27

10 excerpt attributed to Senator Grassley on page 10:27

11 20, there's a reference to paying plans 10:27

12 accurately. 10:27

13 Do you see that in the last sentence 10:27

14 of the excerpt? 10:28

15 A. Yes. 10:28

16 Q. Okay. What is your understanding of 10:28

17 the relationship between paying plans 10:28

18 accurately and ensuring this comparability 10:28

19 between the fee-for-service data and Medicare 10:28

20 Advantage plan data? 10:28

21 MS. KRIEG: Object to the question. 10:28

22 A. So again, what this is saying in its 10:28

23 entirety is that there is not comparability. 10:28

24 So given that there is not comparability, some 10:28

25 external adjustment must be made to make 10:28

1 payment comparable or risk adjustment 10:28

2 comparable to what risk adjustment would be if 10:28

3 plans coded just like fee for service. 10:28

4 Q. So in your response, I take it that 10:28

5 the accuracy of payment depends on the 10:28

6 comparability between fee-for-service data and 10:28

7 Medicare Advantage plan data. 10:29

8 A. No, because it's not comparable. So 10:29

9 what you do is you take data, fee-for-service 10:29

10 data, managed care data. You run it through a 10:29

11 model. You will get different results. 10:29

12 So if we put all of us in the room in 10:29

13 fee for service and then magically put us in 10:29

14 managed care and had all the same visits coded 10:29

15 by managed care, we'd all end up with higher 10:29

16 risk scores, the theory here. Or like overall, 10:29

17 the overall average risk score of this room 10:29

18 would rise. 10:29

19 We're not changing the data. That 10:29

20 data is what it is. But because of those data 10:29

21 differences, we are imposing an external 10:29

22 adjustment to bring the risk score down. So it 10:29

23 is not an adjustment to the data, it is an 10:29

24 adjustment to the risk score that results from 10:29

25 noncomparable data. So you don't achieve 10:29

1 comparable data; you achieve comparable risk 10:29
2 scores. 10:29

3 Q. Understood. Thank you. And what's 10:29
4 the impact of the comparability of risk scores 10:29
5 on payment? 10:29

6 MS. KRIEG: Object to the question. 10:30

7 A. The goal of establishing comparable 10:30
8 risk scores, if you could perfectly establish 10:30
9 comparable risk scores, is have the payment 10:30
10 that's going out to the plans or the risk 10:30
11 adjustment component of the payment that goes 10:30
12 out to the plans be reflective of how the model 10:30
13 was calibrated. 10:30

14 Q. The goal that you mentioned of 10:30
15 establishing comparable risk scores, in your 10:30
16 view, that is the goal of the risk advantage -- 10:30
17 the risk adjustment system? 10:30

18 MS. KRIEG: Object to the question. 10:30

19 A. I think the principal goal of the 10:31
20 risk adjustment system is to pay plans relative 10:31
21 to each other and relative to fee for service 10:31
22 an amount that reflects the actuarial risk 10:31
23 they've assumed. 10:31

24 So that is -- the overall goal is -- 10:31
25 this is like within that goal then you have 10:31

1 kind of necessary things that must occur to 10:31
2 achieve that goal. So I would characterize 10:31
3 this as something that helps you achieve that 10:31
4 goal. It's not the goal itself. 10:31

5 Q. And the "this" that you referred to 10:31
6 in your response, what is that? 10:31

7 A. Oh, having comparability in the risk 10:31
8 scores between the two systems. That is a 10:31
9 building block toward achieving the goal. So 10:31
10 you -- I can't remember the phraseology you 10:31
11 used, if you want to restate your question. 10:31

12 Q. And when you say that it's a building 10:31
13 block towards achieving the goal, do you 10:32
14 believe that it's a necessary component in 10:32
15 order to get to the goal? 10:32

16 MS. KRIEG: Object to the question. 10:32

17 A. I think that varies through time. So 10:32
18 early on, we had a budget neutrality component 10:32
19 built into risk adjustment that intentionally 10:32
20 kept payments where they had been traditionally 10:32
21 without risk adjustment. So there was no goal 10:32
22 of paying comparably. So I think goals change 10:32
23 through time. 10:32

24 Q. And in the 2008-2009 time frame, do 10:32
25 you know what the goal was? 10:32

1 MS. KRIEG: Object to the question. 10:32

2 A. I don't know what the specific goal 10:32

3 was in 2008-2009. 10:32

4 Q. Okay. You mentioned the goal at the 10:32

5 outset. Did it change at some time? 10:33

6 MS. KRIEG: Object to the question. 10:33

7 A. I honestly don't know. Processes 10:33

8 definitely changed, as evidenced by the record 10:33

9 here. Whether that is a change of goal, I 10:33

10 don't know. 10:33

11 Q. Okay. Mr. Grant, had you seen -- 10:33

12 other than in meetings with your lawyers, had 10:33

13 you seen the exhibit that's been marked 1014 10:33

14 previously? 10:33

15 A. I am sure I must have seen aspects of 10:33

16 this. I'm sure it went through my "In" box 10:33

17 when I was, you know, part of the overall 10:34

18 clearance process. But I'd have to look 10:34

19 through it and see if there was anything that 10:34

20 related to what I worked on. I'd have to flip 10:34

21 through this and refresh my memory on what 10:34

22 would have been in here. 10:34

23 But again, this was outside of the 10:34

24 period when I was doing Medicare Advantage 10:34

25 payment. I was strictly focused on Part D at 10:34

1 this point in time. And at this point in time, 10:34
2 in April of 2008, we were very focused on our 10:34
3 first reopening of the Part D payment 10:34
4 reconciliation. So the very first year payment 10:34
5 reconciliation, we were doing our very first 10:34
6 reopening, which was very complex, so I was not 10:34
7 paying a whole a lot of attention to anything 10:34
8 that was not directly related to Part D. 10:34

9 Q. Okay. In this time, were you still 10:34
10 part of the approval process for something akin 10:34
11 to Exhibit 1014? 10:34

12 A. I would say review, not necessarily 10:34
13 approval. It would not have had -- like, they 10:34
14 would not have required a sign-off from me for 10:34
15 this to go out the door. They would have sent 10:34
16 it to me and asked me if I had any comments. 10:34
17 If I didn't say anything, there were people far 10:35
18 senior to me that would be approving it. 10:35

19 MR. QURESHI: We're going to mark 10:35
20 another document and perform a similar 10:35
21 exercise. 10:35

22 (Exhibit No. 1015 was marked for 10:35
23 identification.) 10:35

24 BY MR. QURESHI: 10:35

25 Q. Mr. Grant, you've been handed a 10:35

1 document that's marked Exhibit 1015. Please 10:35
2 take a moment to review it. My questions are 10:35
3 going to be focused on a specific page, 10:35
4 actually, two pages, 20 and 21, but please do 10:35
5 flip through it as much as you like. 10:36

6 And on page 20 I will be focused on 10:36
7 the section at the bottom of the page that 10:36
8 starts with the word "Response" that's 10:36
9 underlined. 10:36

10 A. All right. 10:39

11 Q. Have you had a chance to review that 10:39
12 section? 10:39

13 A. I did. 10:39

14 Q. Okay. In that section, there's a 10:39
15 sentence that states on page 20, the last 10:39
16 paragraph: "This means that MA organizations 10:39
17 are coding accurately when they're coding in a 10:39
18 manner similar to fee-for-service coding used 10:39
19 on the beneficiaries to whom MA plan enrollees 10:39
20 are being compared." 10:39

21 Did I read that correctly, sir? 10:39

22 A. You did. 10:39

23 Q. Do you agree with this assertion? 10:39

24 MS. KRIEG: Object to the question. 10:39

25 A. I think similar to in the previous 10:39

1 document, I agree that if theoretically that 10:39
2 were possible to occur, which I do not believe 10:39
3 it is possible for that to occur, if it were 10:39
4 theoretically possible for that to occur, MA 10:39
5 plans would precisely represent fee-for-service 10:39
6 coding. They would be paid consistently with 10:39
7 how the model is calibrated, which is the 10:40
8 definition of accuracy here. 10:40

9 Q. And because it's not, according to 10:40
10 your view, theoretically possible, what occurs 10:40
11 in practice to ensure that MA plans are paid 10:40
12 consistent with how the model is calibrated? 10:40

13 MS. KRIEG: Object to the question. 10:40

14 A. Well, I think that question has a 10:40
15 buried assumption that something is done in 10:40
16 practice to make sure that has occurred. 10:40

17 Q. Is it? 10:40

18 MS. KRIEG: Object to the question. 10:40

19 A. I don't know now. I would say a 10:40
20 plain language reading of this entire section 10:40
21 would indicate absolutely not. 10:40

22 Q. What about the coding intensity 10:40
23 adjuster? What role does that play? 10:40

24 A. If you go back -- 10:40

25 MR. HASEGAWA: Object to form. 10:40

1 MS. KRIEG: Yeah, object to the 10:40
2 question. 10:40

3 THE WITNESS: Sorry. 10:40

4 A. There's a whole discussion of coding 10:41
5 intensity adjustment here and what the value is 10:41
6 and very -- making the point that the degree to 10:41
7 which coding intensity varies is changing 10:41
8 through time and accelerating. And as we 10:41
9 discussed before, the home visit thing is 10:41
10 starting right in this time period, which will 10:41
11 continue to accelerate coding intensity. 10:41

12 So what you have is coding intensity 10:41
13 exceeding the rate at which CMS could keep up 10:41
14 with it through any study. They're doing a 10:41
15 three-year longitudinal study and averaging the 10:41
16 results, knowing that the third year is likely 10:41
17 to underpredict the year for which they're 10:41
18 paying and they're not using the third year, 10:41
19 they're using a three-year average. 10:41

20 So they are in writing here saying 10:41
21 that they are underpredicting the effect of 10:41
22 coding intensity. To what degree, we don't 10:41
23 know, because again, this is a payment notice 10:41
24 for a future year in which the coding intensity 10:42
25 is not even known. It is an expectation that 10:42

1 this is underpredicting coding intensity. 10:42

2 Now, where they've gone after this, 10:42

3 we'd have to see other payment notices to see 10:42

4 if they have ever tried to do an anticipatory 10:42

5 adjustment to actually make it equal. But they 10:42

6 are saying here they are take a very 10:42

7 conservative approach, which is another way of 10:42

8 saying not trying to make it exactly equal. 10:42

9 Q. And what impact would this have on 10:42

10 payments to MA plans if they're 10:42

11 underpredicting? 10:42

12 MS. KRIEG: Object to form. 10:42

13 A. MA plans' risk adjustment scores 10:42

14 would be higher than they would -- than those 10:42

15 same people coded and fee for service and run 10:42

16 through the risk adjustment model so even -- 10:42

17 and then -- and not adjusted. So you have a 10:42

18 zero adjustment to fee for service, you have 10:42

19 some adjustment to the MA risk scores. And 10:42

20 again, if you could theoretically put these two 10:42

21 people -- these same group of people through 10:43

22 two different claim submission methods, the 10:43

23 scores would always come out higher in MA. By 10:43

24 what degree, it's impossible to say. 10:43

25 Q. And is that consistent with your 10:43

1 understanding of the goal of the risk 10:43

2 adjustment program? 10:43

3 MS. KRIEG: Object to the form. 10:43

4 A. Again, I think the goal of the risk 10:43

5 adjustment form -- program is to pay on 10:43

6 relative risk. How much you want to pay is 10:43

7 determined every year through regulatory 10:43

8 policymaking. 10:43

9 So if you again look in other places 10:43

10 here, they talk about the budget neutrality 10:43

11 factor, which we've talked about earlier. They 10:43

12 talk about rate book issues and indicate that 10:43

13 the rate books are already -- and I think maybe 10:43

14 the combination of the rate books and the 10:43

15 budget neutrality are 14 percent higher, just 10:43

16 the base that you're paying on. So already 10:43

17 you're paying more than a fee-for-service basis 10:43

18 by 14 percent. 10:43

19 Now you have some other thing added 10:43

20 in here, and the degree to which that varies 10:43

21 depends on what rate book you're in. So it's 10:44

22 not even evenly distributed variance from fee 10:44

23 for service. So I would not say that 10:44

24 there's -- you know, again, it's not a goal of 10:44

25 paying exactly the same as fee for service. 10:44

1 The goal is to appropriately pay plans under 10:44
2 whatever policy they've set, which I -- is 10:44
3 somewhat different, because they've never 10:44
4 really in any of these payment notices here 10:44
5 said they're trying to pay exactly as fee for 10:44
6 service. 10:44

7 Q. Is it an objective of the plan to 10:44
8 have comparability between the risk scores on 10:44
9 the fee-for-service side and the MA side? 10:44

10 MS. KRIEG: Object to form. 10:44

11 A. Is it a goal of an MA plan to do 10:44
12 that? 10:44

13 Q. No, is it a goal of the program. 10:44

14 A. To have comparability? 10:44

15 Q. Yes, sir. 10:44

16 MS. KRIEG: Object to form. 10:44

17 A. To have exact comparability might be 10:44
18 a theoretical goal. I don't know. But clearly 10:45
19 here, it is not an objective that they are 10:45
20 striving toward in this payment notice. They 10:45
21 are very specifically not achieving exact 10:45
22 comparability on the risk adjustment side. 10:45

23 Q. What makes you say that it is a 10:45
24 theoretical goal? 10:45

25 MS. KRIEG: Object to form. 10:45

1 Q. What's your basis for saying that? 10:45

2 MS. KRIEG: Object. 10:45

3 A. I said it might be. It could be an 10:45

4 underlying goal for this, but it is clearly not 10:45

5 the objective that they are trying to achieve 10:45

6 with this payment notice. Whether somebody has 10:45

7 that overall goal, I don't know. 10:45

8 Q. Okay. And during the period of time 10:45

9 in which you were involved in the Medicare 10:45

10 Advantage program, did you understand what the 10:45

11 objective of the program was? 10:45

12 A. The objective of Medicare Advantage? 10:45

13 Q. Yes, sir. 10:45

14 MS. KRIEG: Object to the form. 10:45

15 A. Just Medicare Advantage, or the 10:45

16 Medicare Advantage payment? 10:45

17 Q. The -- let's start with the program. 10:46

18 MS. KRIEG: Object to form. 10:46

19 A. It is to provide alternate ways for 10:46

20 members to receive care, so you could go into 10:46

21 fee for service, but it's a model that, lacking 10:46

22 any, you know, any, like, coordinated physician 10:46

23 practice or, you know, being in a health -- you 10:46

24 know, happening to fall into a health system on 10:46

25 the fee-for-service side that has independent 10:46

1 coordination of care activity, the goal of this 10:46
2 is to provide opportunities for folks that 10:46
3 would like different options for care, 10:46
4 including possibly care management programs and 10:46
5 stuff that allows the flexibility that private 10:46
6 sector entities can provide. 10:46

7 So they have to provide a minimum 10:46
8 benefit, but the way in which they provide it 10:46
9 can vary from the way that minimum benefit is 10:46
10 provided is just a claims payment model, which 10:46
11 is fee for service. And so it's providing 10:46
12 options to members. 10:47

13 Q. As part of the program, I believe you 10:47
14 talked about the model calibration. 10:47

15 Do you recall that? 10:47

16 A. Yes. 10:47

17 Q. Okay. What is the purpose of 10:47
18 calibrating the model? 10:47

19 MS. KRIEG: Object to form. 10:47

20 A. It's a necessary condition of -- you 10:47
21 have to create a risk adjustment factor, so you 10:47
22 have to create risk adjustment factors so that 10:47
23 you can pay under health status risk 10:47
24 adjustment. 10:47

25 Q. And what data is used to calibrate 10:47

1 that model? 10:47

2 A. Fee-for-service claims data. 10:47

3 Q. Okay. If you look at the last 10:47

4 sentence on page 20 -- 10:47

5 A. Yes. 10:48

6 Q. -- it states: "In this sense, 10:48

7 differences in coding patterns, regardless of 10:48

8 the source, would make the MA plan coding 10:48

9 inaccurate for purposes of implementing risk 10:48

10 adjustment." 10:48

11 Did I read that correctly? 10:48

12 A. Yes. 10:48

13 Q. Okay. Do you agree with that? 10:48

14 MS. KRIEG: Object form. 10:48

15 A. Again, if you think that the purpose 10:48

16 of implementing risk adjustment is to have some 10:48

17 comparability between the cost structures in 10:48

18 the calibration and the theoretical cost 10:48

19 structures of the plan is the risk that a plan 10:48

20 is taking on by picking up these members, yes. 10:48

21 Q. And is that, in your view, a 10:48

22 reasonable reading? 10:48

23 MS. KRIEG: Object to form. 10:48

24 A. Again, as not the writer of it, if 10:48

25 you're asking my opinion, yes, it's a 10:48

1	reasonable reading.	10:48
2	MR. QURESHI: Can we take a short	10:50
3	break?	10:50
4	MS. KRIEG: Sure.	10:50
5	THE VIDEOGRAPHER: Going off the	10:50
6	record. The time is 10:50.	10:50
7	(Recess taken.)	10:50
8	THE VIDEOGRAPHER: We are going	11:06
9	back on the record. The time is 11:06.	11:06
10	BY MR. QURESHI:	11:06
11	Q. Mr. Grant, are you familiar with the	11:06
12	phrase "RADV audit"?	11:06
13	A. Yes.	11:06
14	Q. What is a RADV audit?	11:06
15	MS. KRIEG: Object to the form.	11:06
16	A. RADV stand for risk adjustment data	11:06
17	validation.	11:07
18	Q. And do you have expertise in RADV	11:07
19	audits?	11:07
20	MS. KRIEG: Object to the form.	11:07
21	A. I have overseen them. I have	11:07
22	expertise in overseeing RADV audits. There are	11:07
23	many different components to a RADV audit, some	11:07
24	of which I know well and some of which I do	11:07
25	not.	11:07

1 Q. You were at the healthcare consulting 11:07
2 firm Health Risk Partners for a period of time, 11:07
3 2008 to 2010, sir? 11:07

4 A. Yes. 11:07

5 Q. Okay. And when you were at Health 11:07
6 Risk Partners, did you offer consulting 11:07
7 guidance on RADV audits? 11:07

8 MS. KRIEG: Object to the form. 11:07

9 A. We supported clients that were 11:07
10 undergoing RADV audits. 11:07

11 Q. And you used the word "we." Were you 11:07
12 personally involved in those efforts? 11:07

13 A. I was the client services manager, so 11:07
14 on certain engagements, I was in charge of kind 11:08
15 of coordinating the engagement along with 11:08
16 others. 11:08

17 Q. And in August 2009, you were with -- 11:08
18 the spring-summer of 2009, you were with Health 11:08
19 Risk Partners? 11:08

20 A. Yes. 11:08

21 (Exhibit No. 1016 was marked for 11:08
22 identification.) 11:08

23 BY MR. QURESHI: 11:08

24 Q. Mr. Grant, I'm going to hand you a 11:08
25 document that's marked Exhibit 1016. I'll ask 11:08

1 you to please take a moment to review it. Sir, 11:08

2 have you had an opportunity to review 11:10

3 Exhibit 1016? 11:10

4 A. I have. 11:10

5 Q. What is it? 11:11

6 MS. KRIEG: Object to form. 11:11

7 A. It is an email forwarded among CMS 11:11

8 employees of an email that I sent to Tom 11:11

9 Hutchinson. 11:11

10 Q. And the email that you sent to 11:11

11 Mr. Tom Hutchinson is dated on or about Friday, 11:11

12 May 29, 2009? 11:11

13 A. Yes. 11:11

14 Q. And at this period of time, you were 11:11

15 with Health Risk Partners; correct? 11:11

16 A. I was. 11:11

17 Q. And Mr. Tom Hutchinson was with CMS? 11:11

18 A. He was. 11:11

19 Q. Do you recall his position with CMS 11:11

20 at this point in time? 11:11

21 A. Yes. 11:11

22 Q. And what was that position? 11:11

23 A. The director of the Medicare plan 11:11

24 payment group. 11:11

25 Q. And why were you writing to 11:11

1 Mr. Hutchinson in May of 2009? 11:11

2 MS. KRIEG: Object to form. 11:11

3 A. It was part of an ongoing discussion 11:12

4 related to RADV that was precipitated by the 11:12

5 RADV pilot of extrapolated RADV methodology. 11:12

6 Q. Do you recall when this discussion 11:12

7 commenced? 11:12

8 A. It would have been in the fall of 11:12

9 2008, sometime after I found out that one of 11:12

10 our clients was part of this, and I was working 11:12

11 through how it worked. 11:12

12 Q. So the purpose of your correspondence 11:12

13 with Mr. Hutchinson was to understand how the 11:12

14 RADV methodology worked? 11:12

15 MS. KRIEG: Object to form. 11:12

16 A. Not this particular correspondence. 11:12

17 This was later in the conversation. 11:12

18 Q. Okay. What was the purpose of this 11:13

19 conversation, exhibit -- that's reflected in 11:13

20 Exhibit 1016? 11:13

21 MS. KRIEG: Object to form. 11:13

22 A. It was to point out potential 11:13

23 problems that I was observing with the proposed 11:13

24 method of extrapolating RADV findings to 11:13

25 Medicare Advantage plans. 11:13

1 Q. And in this correspondence that's 11:13
2 reflected in Exhibit 1016, were you being 11:13
3 truthful with Mr. Hutchinson? 11:13

4 MS. KRIEG: Object to form. 11:13

5 A. Yes. 11:13

6 Q. Did you correspond with any other 11:13
7 government person about this issue during this 11:13
8 time? 11:13

9 MS. KRIEG: Object to form. 11:13

10 A. I -- you know, I don't remember 11:13
11 specific conversations. I would say that 11:13
12 during the entire period of time, I mean, if 11:14
13 you -- are you -- if you're focusing on May, I 11:14
14 have no idea who I was talking to in May. If 11:14
15 you want to talk about the entire span of my 11:14
16 engagement, that's a different question. So I 11:14
17 guess I want to just be clear about what time 11:14
18 frame you're talking about. 11:14

19 Q. Sure. Let's talk about the wider 11:14
20 span. And it would be helpful before you 11:14
21 answered the question to define for us what the 11:14
22 wider span is. 11:14

23 A. These would still be approximate 11:14
24 dates, but sometime after I first discovered, 11:14
25 you know, what was going on with RADV and one 11:14

1 of our clients in mid-late October, 2008. And 11:14
2 then for a period of time, I don't know if it 11:14
3 extended throughout my time at Health Risk 11:14
4 Partners, but it was certainly for an extended 11:14
5 period of time. I would say upwards of a year, 11:14
6 at least. 11:15

7 Q. And were these discussions during 11:15
8 this wider span all on behalf of a particular 11:15
9 client -- 11:15

10 MS. KRIEG: Object to form. 11:15

11 Q. -- or a group of clients? 11:15

12 MS. KRIEG: Object to form. 11:15

13 A. I would characterize it as not on -- 11:15
14 specifically on behalf of a client. I was not 11:15
15 there to represent. I was not a representative 11:15
16 of -- official representative of a client. It 11:15
17 was spurred by concerns my clients had and then 11:15
18 I had. 11:15

19 Q. So the concerns that are expressed 11:15
20 during this wider span, are they your personal 11:15
21 concerns or are they the concerns of your 11:15
22 clients, or both? 11:15

23 MS. KRIEG: Object to form. 11:15

24 A. Certainly, any concern that I would 11:16
25 express in writing -- again, you asked about 11:16

1 truth. These are true expressions of my 11:16
2 personal opinions. So I did not go take 11:16
3 something somebody else said that I did not 11:16
4 believe and then push that in front of CMS. 11:16
5 Whether or not my client -- client came up with 11:16
6 some of this or I did, at this point, it would 11:16
7 be hard to say. I had many discussions with 11:16
8 clients and, you know, I would say that was 11:16
9 just a starting point. Others in the industry. 11:16
10 It's hard to say where a specific idea may have 11:16
11 originated. 11:16
12 Q. Is it fair to say that you wouldn't 11:16
13 have pushed it forward to CMS unless you 11:16
14 believed it to be true? 11:16
15 MS. KRIEG: Object to form. 11:16
16 A. That is fair to say. 11:16
17 Q. Let's focus on your email to 11:16
18 Mr. Hutchinson on May 29 there. It appears 11:17
19 that you are sending him, quote, "select pieces 11:17
20 of my RA For Dummies presentation." Is that 11:17
21 correct? 11:17
22 A. Yes. 11:17
23 Q. RA in your email refers to risk 11:17
24 adjustment? 11:17
25 A. That's correct. 11:17

1 Q. And do you recall when you created a 11:17
2 presentation entitled RA For Dummies? 11:17

3 MS. KRIEG: Object to form. 11:17

4 A. First of all, I'm not sure that I had 11:17
5 a presentation that was titled RA For Dummies. 11:17
6 I think that is how I am characterizing a 11:17
7 presentation that I produced of simplified RA 11:17
8 concepts so that you didn't have to be -- have 11:17
9 a -- you know, advanced actuarial science 11:17
10 skills to be able to understand the principles 11:17
11 of how risk adjustment worked. 11:17

12 So it was a simplification of risk 11:17
13 adjustment. It was used for many different 11:17
14 purposes, so it was used to educate clients, it 11:18
15 was used to educate Health Risk Partners staff, 11:18
16 and I -- I don't remember when I would have 11:18
17 created that. 11:18

18 Q. And the particular principles that 11:18
19 you are highlighting for Mr. Hutchinson in this 11:18
20 email are based, according to your email, on a 11:18
21 simple world with one demographic factor and 11:18
22 one disease factor; is that correct? 11:18

23 MS. KRIEG: Object to form. 11:18

24 A. That is correct. 11:18

25 Q. But then you go on to say "Same 11:18

1 principles apply to more complex models, 11:18

2 obviously." Is that correct? 11:18

3 MS. KRIEG: Object to form. 11:18

4 A. That is correct. 11:18

5 Q. You go on to write: "I walk through 11:18

6 the calibration and then how it pays wrong when 11:18

7 the calibration has flaws." Did I read that 11:18

8 correctly? 11:19

9 A. You did. 11:19

10 Q. What does that mean? 11:19

11 A. It's probably very loose terminology. 11:19

12 I would probably restate that, if that's okay. 11:19

13 Q. Please. 11:19

14 A. So I think it's basically saying that 11:19

15 if you wanted the calibration to perfectly 11:19

16 reflect expected costs of a disease condition 11:19

17 that an individual had, the model has flaws in 11:19

18 that it will have people in there that don't 11:19

19 have the condition included in with people that 11:19

20 do have the condition. It will have people 11:19

21 that have a condition not labeled as having the 11:19

22 condition. And so you end up with some levels 11:19

23 of inaccuracy in the model that are due 11:19

24 strictly to the codes not accurately reflecting 11:19

25 what somebody's health status is. 11:19

1 So if you really want to know what 11:19
2 diabetes costs, you're getting somewhat of an 11:20
3 inaccuracy on the expected costs of diabetes 11:20
4 relative to being healthy or relative to CHF or 11:20
5 something else. 11:20

6 Q. And when you write "how it pays 11:20
7 wrong," what payment are you referring to? 11:20

8 MS. KRIEG: Object to form. 11:20

9 A. Again, I think focusing on the term 11:20
10 "pays wrong" is probably not appropriate. It's 11:20
11 leading to an inaccurate prediction is a better 11:20
12 way to state it. 11:20

13 Q. Okay. And did you have a 11:20
14 conversation with Mr. Hutchinson in which you 11:20
15 explained to him that the use of the phrase 11:20
16 "pays wrong" really reflects inaccurate 11:20
17 prediction? 11:20

18 A. I don't know if I used those terms 11:20
19 precisely. I mean, I think we understood that 11:20
20 we were dealing with a predictive model. I 11:20
21 don't know precisely what words I would have 11:20
22 used in the conversation. This is now, what, 11:20
23 nine years ago? 11:20

24 Q. Okay. And the email is one that you 11:20
25 wrote, or did someone write it for you? 11:20

1 A. I wrote it. 11:20

2 Q. Okay. So you chose to use those 11:21

3 words? 11:21

4 MS. KRIEG: Object to form. 11:21

5 A. I did. 11:21

6 Q. If you read the -- that entire 11:21

7 paragraph, the last sentence states: "Again, 11:21

8 that requires the study of FFS coding and 11:21

9 documentation that we have previously discussed 11:21

10 and will not be able to inform your immediate 11:21

11 issue." 11:21

12 Did I read that correctly? 11:21

13 A. You did. 11:21

14 Q. What do you recall about the 11:21

15 immediate issue referenced in that sentence? 11:21

16 MS. KRIEG: Object to form. 11:21

17 A. The immediate issue that we were 11:21

18 concerned about was a straight extrapolation of 11:21

19 risk adjustment data validation findings on a 11:21

20 small sample to the entire population of a 11:21

21 plan. 11:21

22 Q. And what's the issue related to that 11:21

23 topic? 11:21

24 MS. KRIEG: Object to form. 11:21

25 A. It -- there are a series of issues 11:21

1 that are laid out in the email. 11:22

2 Q. Okay. Let's go over -- 11:22

3 A. Okay. 11:22

4 Q. -- those particular issues, starting 11:22

5 with the one numbered 2. 11:22

6 A. Number 2? 11:22

7 Q. Yes, sir. 11:22

8 A. Okay. 11:22

9 Q. What issue were you referring to 11:22
10 there? 11:22

11 MS. KRIEG: Object to form. 11:22

12 A. So this goes back to statements that 11:22
13 we made early on in risk adjustment about the 11:22
14 data submission policies and how they related 11:22
15 to diagnosis codings. And plans were worried 11:22
16 about how diagnosis codings were reflecting 11:23
17 and -- and, you know, accuracy of diagnosis 11:23
18 codings might impact them. 11:23

19 And kind of the consistent CMS 11:23
20 statement at the time was if you just submit 11:23
21 claims like fee for service and don't do all 11:23
22 those other things, they were -- this is a 11:23
23 whole alternate data sources discussion where 11:23
24 they wanted to use things other than claims. 11:23
25 We were saying you don't need to use things 11:23

1 other than claims. Use claims. The model's 11:23

2 calibrated on claims. Use claims. 11:23

3 Q. You referred to a consistent CMS 11:23

4 statement at the time. Where could I find this 11:23

5 consistent CMS statement? 11:23

6 A. I'm not sure if it's in writing or if 11:23

7 it was verbal. I think there are discussions 11:23

8 in the original risk adjustment documents about 11:23

9 alternate data sources and how they would be 11:24

10 used or how they could or could not be used. 11:24

11 Q. That first sentence in section 2 11:24

12 states in part that CMS consistently responded 11:24

13 that FFS coding represented then you have 11:24

14 quotes, perfect payment, i.e., replication of 11:24

15 the model calibration, end quote. Did I read 11:24

16 that correctly? 11:24

17 A. Yes. 11:24

18 Q. Okay. And was that information 11:24

19 communicated to plans? 11:24

20 MS. KRIEG: Object to form. 11:24

21 A. Again, now you're going back to, you 11:24

22 know, 2001, 2002, 2003. Whether it was phrased 11:24

23 that way, I don't know. This -- again, an 11:24

24 email conversation I'm having with Tom, but 11:24

25 the -- this is a statement that is basically 11:24

1 consistent with the statements made in the 11:24
2 other documents, that it -- it is -- that this 11:25
3 theoretical perfection is that data looks 11:25
4 exactly like it looks in calibration and when 11:25
5 it varies from that, it doesn't look like that. 11:25

6 Q. And when it varies, it requires some 11:25
7 adjustment? 11:25

8 MS. KRIEG: Object to form. 11:25

9 A. It depends on what the policy is. 11:25

10 Q. And when you were writing to 11:25
11 Mr. Hutchinson, what policy were you referring 11:25
12 to? 11:25

13 A. My note was not about how payment was 11:25
14 calculated, it was dealing with RADV 11:25
15 extrapolation. 11:26

16 Q. Okay. But, sir, in the first 11:26
17 paragraph of your email you write: "I walked 11:26
18 through calibration and then how it pays wrong 11:26
19 when the calibration has flaws." Is that 11:26
20 right? 11:26

21 A. Right. 11:26

22 Q. Did that refer to payment to MA 11:26
23 plans? 11:26

24 MS. KRIEG: Object to form. 11:26

25 A. So if you go back to how I answered 11:26

1 that, that is sloppy terminology that is 11:26
2 actually referring to that the -- the 11:26
3 calibration is inaccurately predicting -- 11:26
4 within the fee-for-service population 11:26
5 inaccurately predicting the attribution of 11:26
6 specific costs to any disease condition or any 11:26
7 demographic category that results from 11:26
8 inaccurate coding. 11:26

9 So not having an accurate description 11:26
10 of who has what disease leads to some level of 11:26
11 inaccuracy in the calibration. I used the word 11:26
12 "payment," but I would say now that that is 11:26
13 kind of an inaccurate way of stating it and it 11:26
14 would be better to say, you know, that the 11:27
15 predictions of the model are affected by it. 11:27

16 Q. Sir, when we were talking about 11:27
17 number 2 on your itemized email, I want to go 11:27
18 back to your testimony that there were some 11:27
19 oral statements in which CMS may have 11:27
20 represented that fee-for-service coding 11:27
21 represented perfect payment. And the question 11:27
22 is, did you ever have any conversations with 11:27
23 anyone while you were at CMS before writing 11:27
24 this email in which you informed plans that 11:27
25 fee-for-service coding represented perfect 11:27

1 payment? 11:27

2 MS. KRIEG: Object to form. 11:27

3 A. Again, I -- 11:28

4 MS. KRIEG: Can I also object? 11:28

5 You're asking conversations with people 11:28

6 outside of CMS? 11:28

7 MR. QURESHI: Yes. 11:28

8 MS. KRIEG: Okay. 11:28

9 A. Again, we are going back to 2001, 11:28

10 2002, 2003. We would have user group calls 11:28

11 with like a bunch of us sitting around the 11:28

12 table. So I don't know who would have said 11:28

13 what in what precise terminology. 11:28

14 I'm now summarizing my understanding 11:28

15 of what we communicated to plans in an email to 11:28

16 Tom Hutchinson. So whether we used this 11:28

17 precise word, because I believe that's not like 11:28

18 a quote like we said, and that's a, quote, 11:28

19 perfect payment. It's like air quotes, perfect 11:28

20 payment. And it is explained what I mean much 11:28

21 clearer by not saying perfect payment but 11:28

22 replication of the model calibration, which we 11:28

23 always did talk about with -- this with plans 11:28

24 who were concerned about needing to get all 11:29

25 this extra data in. 11:29

1 I mean, the main point of contention 11:29
2 between us and the industry implementing risk 11:29
3 adjustment is they said you're not going to get 11:29
4 all the diagnosis codes. That was the whole 11:29
5 alternate data sources, and this is what this 11:29
6 is -- this goes back to alternate data sources 11:29
7 and the pressure for alternate data sources to 11:29
8 supplement what comes in on the claim because 11:29
9 they say you're not going to get all the 11:29
10 diabetics but we can get them by, like, if we 11:29
11 have an insulin claim, for instance. We're 11:29
12 like, that's how the model's calibrated. You 11:29
13 cannot submit insulin and get credit for 11:29
14 diabetes. And then we came out with alternate 11:29
15 data source instructions. But then we would 11:29
16 always say we don't believe this is necessary. 11:29
17 We believe that if you just rely on the claims 11:29
18 data, you don't need to supplement the claims 11:29
19 data. And those were the kind of statements we 11:29
20 were making. 11:29
21 Q. And I certainly understand that you 11:29
22 don't remember who in particular may have made 11:29
23 misstatements, but when you're writing to 11:29
24 Mr. Hutchinson in 2009, you're not making stuff 11:30
25 up; right? This is based on your recollection 11:30

1 and facts that you understood at the time. 11:30

2 MS. KRIEG: Object to the form. 11:30

3 A. So I am not making stuff up, but I 11:30

4 may not be perfectly quoting it either. I am 11:30

5 saying a general understanding, which I think 11:30

6 this paragraph gives a general understanding, 11:30

7 and it is getting back to the same discussions 11:30

8 we have had over differences between MA data 11:30

9 and fee-for-service data and trying to convince 11:30

10 plans that if they could end up in this 11:30

11 theoretically perfect world where they looked 11:30

12 like fee-for-service data, they would be 11:30

13 matching the model calibration, and that's the 11:30

14 point of this paragraph. 11:30

15 Q. And they would be paid correctly? 11:30

16 MS. KRIEG: Object to form. 11:30

17 A. They would be paid commensurate with 11:30

18 the model calibration. I think "correctly" is 11:30

19 eye of the beholder. 11:30

20 Q. Sir, let's go back to your email. In 11:30

21 the same section, you write: "Plans were told 11:31

22 that if they stuck to how the data comes into 11:31

23 FFS, they would be paid correctly." Did I read 11:31

24 that correctly? 11:31

25 A. Yes. 11:31

1 Q. And was that a true statement when 11:31
2 you wrote it? 11:31

3 MS. KRIEG: Object to form. 11:31

4 A. The concept that it is conveying, 11:31
5 again, I do not want to say that -- like, I'm 11:31
6 summarizing conversations with plans here, not 11:31
7 giving direct quotes. That's all I want to 11:31
8 say. 11:31

9 So as the general concept reflected 11:31
10 by the entire paragraph in an email, I am 11:31
11 trying to -- not a policy document or something 11:31
12 else. I am in a brief email trying to 11:31
13 summarize issues that I believe exist with an 11:31
14 extrapolation. And one of them is the 11:31
15 assurances that if they submitted data like fee 11:31
16 for service, they would be paid equivalent to 11:31
17 the calibration and they didn't need to worry 11:31
18 about finding other data to supplement 11:32
19 fee-for-service data. 11:32

20 Q. I understand that you were 11:32
21 summarizing. But were you endeavoring to 11:32
22 summarize accurately? 11:32

23 MS. KRIEG: Objection, form. 11:32

24 A. Oh, absolutely. 11:32

25 Q. Then you go on to state: "Now that 11:32

1 is doubly not true." What did you mean by 11:32
2 that? 11:32

3 A. I'm not sure why I said "doubly not 11:32
4 true." I'm trying to remember what that would 11:32
5 refer to. 11:32

6 I can see the singular of why it 11:32
7 would not be true with the point I was making 11:32
8 about the RADV extrapolation, that if you -- 11:32
9 like, in a theoretical world, if you could get 11:32
10 somebody to submit data, just claims, not do 11:33
11 any provider education, not in any way alter 11:33
12 how data came in, if you had that perfect plan 11:33
13 that did that and then you did RADV, you would 11:33
14 find some degree of error in those diagnosis 11:33
15 codes. And then extrapolating that error would 11:33
16 then create a difference between what was 11:33
17 started out as logically the same as the 11:33
18 fee-for-service data that went into the model 11:33
19 to then something that is less than the 11:33
20 fee-for-service data that went into the model. 11:33
21 That was the point I was making here. 11:33

22 Q. Okay. And why would this discrepancy 11:33
23 exist after a RADV audit? 11:33

24 MS. KRIEG: Object to form. 11:33

25 A. It only exists not in the RADV audit 11:33

1 itself, which is a small sample, 200 people, 11:33
2 you find things wrong, you correct those 11:33
3 things. It doesn't exist in the audit sample; 11:33
4 it exists when you extrapolate the findings of 11:33
5 an audit sample to then say we're going to 11:33
6 reduce your payment. 11:33

7 This was the argument I'm making, 11:34
8 that it causes a problem if you are going to 11:34
9 extrapolate the finding of a RADV against a 11:34
10 plan that coded exactly like fee for service, 11:34
11 as you had -- you know, you encourage everybody 11:34
12 to do that, they did that, then you extrapolate 11:34
13 on that, you're going to end up paying them 11:34
14 less than you would pay them if you just took 11:34
15 fee-for-service data and paid them. 11:34

16 Q. In that same paragraph there's a 11:34
17 sentence in which you write: "Trying to look 11:34
18 for additional diagnoses results in increased 11:34
19 coding intensity (for which CMS is now making 11:34
20 an adjustment)." Did I read that correctly? 11:34

21 A. Yes. 11:34

22 Q. And the adjustment you're referring 11:34
23 to in that sentence is the coding intensity 11:34
24 adjuster? 11:34

25 MS. KRIEG: Object to form. 11:34

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1 A. I believe so. 11:35

2 Q. Now, you conclude that section 2 by 11:35

3 saying in the last sentence, a statement in 11:35

4 parentheticals, and the statement reads: "I 11:35

5 have looked through QAs and searched the 11:35

6 website for certain key phrases and find no 11:35

7 formal documentation of this answer, 11:35

8 unfortunately." Did I read that question -- 11:35

9 that statement correctly? 11:35

10 A. You did.

11:35

11 Q. And what exactly were you looking for 11:35

12 on the website and on the QAs? 11:35

13 A. The statements that I say I recall 11:35

14 now, somebody having made and I even recall 11:35

15 then people having made, that there was no need 11:35

16 to go after alternative data because mere 11:35

17 submission of claims data would look the same 11:35

18 as the risk adjustment model and to worry 11:35

19 about, you know, the missing diabetes code was 11:35

20 not a relevant concern. And evidently, we 11:36

21 didn't actually write that answer down in a Q 11:36

22 and A; we wrote down different responses to how 11:36

23 alternative data sources could be done, but we 11:36

24 didn't go into that. 11:36

25 Q. And in your answer, you referenced 11:36

1 "people" and "we." In both instances, the 11:36
2 persons making the statements are people 11:36
3 affiliated with CMS? 11:36

4 A. That is correct. 11:36

5 Q. Are they government officials? 11:36

6 MS. KRIEG: Object to form. 11:36

7 Q. We're talking about government 11:36
8 people; correct? 11:36

9 A. Yes. 11:36

10 Q. Okay. In statement number 3, you 11:36
11 reference a PFFS. What is that? 11:36

12 A. Private fee for service. 11:36

13 Q. Okay. That's the traditional 11:36
14 Medicare FFS we have been referring to? 11:37

15 A. No. 11:37

16 Q. What is it? 11:37

17 A. The private fee-for-service was ... 11:37

18 Q. Please. 11:37

19 A. It was an option that was put in that 11:37
20 allowed a Medicare Advantage product to be 11:37
21 started that was called private fee for service 11:37
22 where I don't -- you know, I am not familiar 11:37
23 with all of the rules on that, but the 11:37
24 essential outlines of it were that they did not 11:37
25 have a network. They operated like 11:37

1 fee-for-service Medicare in that they would 11:37

2 reimburse any qualified provider for providing 11:37

3 services as opposed to having a narrow network. 11:37

4 Q. You go on to say: "They ideally 11:37

5 should have the best payment because it is most 11:37

6 like the original model calibration." Did I 11:37

7 read that correctly? 11:38

8 A. You did. 11:38

9 Q. Okay. And did you believe that to be 11:38

10 a true statement? 11:38

11 MS. KRIEG: Object to form. 11:38

12 A. I did. 11:38

13 Q. When you say "they should have the 11:38

14 best payment," are you making a relative 11:38

15 statement? Best payment compared to who? 11:38

16 MS. KRIEG: Object to form. 11:38

17 A. It's relative to anybody else that's 11:38

18 submitting risk adjustment data. Again, I 11:38

19 think "payment" is a probably a sloppy term. 11:38

20 It is accuracy, you know, risk adjustment 11:38

21 factors that most accurately represent the 11:38

22 model calibration because again, you don't have 11:38

23 this narrow network where you are influencing 11:38

24 the network in how the coding goes on. 11:38

25 Q. You go on to say, sir: "Again, 11:38

1 extrapolation for RADV does not provide an 11:38
2 equitable treatment for these plans and is not 11:38
3 consistent with how the payment methodology was 11:38
4 developed." Did I read that correctly? 11:39

5 A. You did. 11:39

6 Q. Was that a true statement when you 11:39
7 wrote it? 11:39

8 MS. KRIEG: Object to form. 11:39

9 A. It is a reflection of my opinion when 11:39
10 I wrote it. 11:39

11 Q. And did you hold that opinion when 11:39
12 you wrote it? 11:39

13 MS. KRIEG: Object to form. 11:39

14 A. I did. 11:39

15 Q. Do you hold it today? 11:39

16 MS. KRIEG: Object to form. 11:39

17 A. As long as they were -- as long as my 11:39
18 understanding that they were submitting like 11:39
19 fee for service, with the extrapolation that 11:39
20 was proposed at the time, I still hold that 11:39
21 opinion, yes. 11:39

22 Q. Okay. And what about your opinion 11:39
23 regarding how the payment methodology was 11:39
24 developed? Has your opinion regarding that 11:39
25 changed? 11:39

1 MS. KRIEG: Object to form. 11:39

2 A. Well, my understanding of how the 11:39
3 payment methodology was developed has not 11:39
4 changed. 11:39

5 Q. Do you recall having a oral 11:40
6 conversation with Mr. Hutchinson in connection 11:40
7 with your email? 11:40

8 A. The specific oral conversation? 11:40

9 Q. Let's start with the specific and 11:40
10 then we will go to the general. 11:40

11 A. No. 11:40

12 Q. Okay. Do you recall a general 11:40
13 discussion with Mr. Hutchinson regarding the 11:40
14 topics of your email? 11:40

15 A. I -- you mean do I recall in general 11:40
16 that I had oral discussions? Is that what 11:40
17 you're asking? 11:40

18 Q. Yes, sir. 11:40

19 A. Yes, in general, I recall having oral 11:40
20 discussions. A specific oral discussion versus 11:40
21 another one, I don't recall timing of any 11:40
22 specific oral discussion. 11:40

23 Q. And do you recall the substance of 11:40
24 any oral conversation with Mr. Hutchinson? 11:40

25 A. Of -- I would -- the substance of a 11:41

1 specific oral discussion or a series of oral 11:41
2 discussions? 11:41

3 Q. Mr. Grant, I'm just trying to 11:41
4 understand if you recollect talking to 11:41
5 Mr. Hutchinson about the subject of this email. 11:41

6 Do you have any such recollection? 11:41

7 A. The overall subject of the email 11:41
8 related to extrapolation. Let me -- this is an 11:41
9 email that is being written in response to a 11:41
10 proposed -- or not even a proposed. I mean, at 11:41
11 the time, they thought they were going forward 11:41
12 and marching forward when it wasn't even 11:41
13 considered a proposal at the time. It was 11:41
14 their policy for five pilot issuers how they 11:41
15 were going to deal with their RADV 11:41
16 extrapolation. So this was a series of 11:41
17 discussions critiquing that approach. 11:41

18 Whether any specific discussion had 11:41
19 all of these components in it, whether some of 11:41
20 these I raised later in an email without having 11:42
21 an oral discussion with them, I honestly could 11:42
22 not tell you. 11:42

23 Q. That's fair. 11:42

24 And do you remember the substance of 11:42
25 any of those discussions? 11:42

1 Do you remember Mr. Hutchinson's 11:42
2 position on any of the issues we've talked 11:42
3 about? 11:42

4 Do you remember the back-and-forth? 11:42

5 Any other details you can provide me 11:42
6 about discussions with Mr. Hutchinson about 11:42
7 these topics? 11:42

8 MS. KRIEG: Object to form. 11:42

9 A. So I would say again this was a long 11:43
10 series of discussions. The first ones I think 11:43
11 he was not -- he needed to understand where I 11:43
12 was coming from, so -- but I would say he was 11:43
13 open to having discussions, first and foremost, 11:43
14 so he was open to the discussion. 11:43

15 He listened to me. He would go back 11:43
16 and talk to folks and come back and say, my 11:43
17 folks say this isn't true. And I'd say, well, 11:43
18 I believe it is. And we would go further and 11:43
19 further. 11:43

20 And what you are seeing is after 11:43
21 probably -- if this is May, this is at least 11:43
22 six months of discussions about this topic with 11:43
23 him, I'm sending him an email and summarizing 11:43
24 some of the key things that he appears to have 11:43
25 sent to his folks and is at least wanting to 11:44

1 discuss it with them. 11:44

2 I can't vouch for what his opinion 11:44

3 was. I mean, he was in a position of 11:44

4 representing a program that had a policy, so he 11:44

5 can't reverse policy in any discussion with me, 11:44

6 and I wouldn't expect him to. 11:44

7 I mean, my expectation, as with 11:44

8 anybody that approaches a government official, 11:44

9 is, like, they cannot on the spot make a just 11:44

10 fiat policy change. They're going to have to 11:44

11 go through a process. 11:44

12 But my job is to represent what I 11:44

13 think is the issues with the policy as it 11:44

14 currently stands. Their job is to go back and 11:44

15 take it back and decide what they want to do 11:44

16 with what I presented to them, so -- and 11:44

17 frankly, because I'm out of that field now, I'm 11:44

18 not even sure what has happened even with the 11:44

19 original pilot plans. So, you know, I don't 11:44

20 stay in touch with Medicare Advantage risk 11:44

21 adjustment so I honestly have no idea where the 11:44

22 first five plans ended up. 11:45

23 Q. Okay. But at the time you wrote this 11:45

24 and you're informing Mr. Hutchinson that CMS 11:45

25 has told plans that fee-for-service coding 11:45

1 represents perfect payment, you are informing 11:45

2 Mr. Hutchinson of your honest opinions; right? 11:45

3 MS. KRIEG: Object to form. 11:45

4 A. Yes. 11:45

5 Q. Okay. And when CMS is informing 11:45

6 plans that use of fee-for-service coding is 11:45

7 perfect payment or represents perfect payment, 11:45

8 CMS knew that plans are doing chart review; 11:45

9 correct? 11:45

10 MS. KRIEG: Object to form. 11:45

11 A. I am not saying that's correct. 11:45

12 Q. You write, sir, in your email: 11:45

13 "Trying to look for additional diagnoses result 11:45

14 in increased coding intensity." Correct? 11:45

15 A. Yes. 11:45

16 Q. And doesn't looking for additional 11:45

17 diagnoses, isn't that a result that could occur 11:45

18 after performing chart review? 11:46

19 MS. KRIEG: Object to form. 11:46

20 A. So you are positing a bunch of things 11:46

21 in CMS people's heads that may or may not have 11:46

22 been true at the time that I am talking about. 11:46

23 So again, we are turning the clock back. We 11:46

24 have not yet risk-adjusted for physician data. 11:46

25 We are in the process of risk adjusting on a 11:46

1 hospital inpatient model. We are rolling out 11:46
2 an inpatient -- or a physician and outpatient 11:46
3 data collection, and the health plans are 11:46
4 objecting to our rollout because we're going to 11:46
5 miss diagnosis codes. 11:46

6 They're constantly saying we need to 11:46
7 be able to get other data in. We know who our 11:46
8 diabetics are, and they're not all diabetics on 11:46
9 claims. 11:46

10 So there was a long, protracted 11:47
11 discussion with plans about, okay, you say you 11:47
12 know who these people are. How could you 11:47
13 possibly account for it? And during that 11:47
14 discussion, we're saying you don't really -- we 11:47
15 do not believe this is a valid concern. You 11:47
16 think it's a valid concern. We're taking it 11:47
17 back with us. We understand your valid 11:47
18 concern. 11:47

19 So again, similar to the type of 11:47
20 conversation we just talked about me having 11:47
21 with Tom Hutchinson, this is now I'm in the 11:47
22 government back in 2003. Plans are saying we 11:47
23 object to your policy. We are saying we don't 11:47
24 think there's a basis for your objection. 11:47

25 But they are insisting that there is, 11:47

1 and they would like to know what we're going to 11:47
2 do about it. And we come up with an 11:47
3 alternative data sources methodology. Whether 11:47
4 anybody was using it, how they would use it in 11:47
5 2001, 2002, 2003, I have no idea whether 11:47
6 anything was -- anybody was doing anything like 11:47
7 that. We knew people were looking for options 11:48
8 and so we gave them, this is how you could do 11:48
9 it and then said we're not -- we're not saying 11:48
10 you should do this. 11:48

11 Q. Okay. I'm focused on 2009, the time 11:48
12 you write this email, sir. 11:48

13 A. But the conversations that this email 11:48
14 refers to, which you are taking a paragraph in 11:48
15 an email that is referring to conversations 11:48
16 that took place way back in the past. So 11:48
17 you're in 2009. I'm not talking about 2009 11:48
18 statements by CMS. 11:48

19 Q. In your email, you write "for which 11:48
20 CMS is now making an adjustment." 11:48

21 A. Correct. 11:48

22 Q. What period of time are you referring 11:48
23 to? 11:48

24 A. In that, I'm referring to in 2009. 11:48

25 Q. Okay. What adjustment is being made? 11:48

1 A. The coding intensity adjustment. 11:48

2 Q. Why is it being made? 11:48

3 MS. KRIEG: Object to form. 11:48

4 A. That goes back to what CMS's reasons 11:48

5 were. I was not part of the policy 11:48

6 development. We can all look at the record of 11:48

7 what CMS said. 11:48

8 Q. And when you wrote to Mr. Hutchinson, 11:48

9 did you go back and review the record? 11:48

10 A. Did I go back and review the record 11:49

11 of what CMS said? 11:49

12 Q. Yes, sir. 11:49

13 A. I reviewed the 2009 payment notice, 11:49

14 as I was external to CMS at the time the 11:49

15 payment notice went out. But on behalf of my 11:49

16 client, I absolutely reviewed the 2009 payment 11:49

17 notice extensively. 11:49

18 Q. So when you wrote plans were told 11:49

19 that if they stuck to how the data comes in to 11:49

20 fee for service, they would be paid correctly, 11:49

21 that statement was based on a review of the 11:49

22 record? 11:49

23 A. No. 11:49

24 Q. What was it based on? 11:49

25 A. That goes back to 2001, 2002, 2003. 11:49

1 This is where I'm saying that you are blending 11:49
2 different points in time. I'm talking about -- 11:49
3 alternative data sources is a discussion that 11:49
4 happened when I was in CMS. So you're taking 11:49
5 kind of a parenthetical statement in the middle 11:49
6 of a discussion about things that were said in 11:49
7 the past and me updating, like, in the current 11:49
8 world, this is what is happening. But the 11:49
9 discussions I'm talking about are discussions 11:50
10 that happened when I was in CMS. I was not in 11:50
11 CMS when the coding intensity adjustment came 11:50
12 out. So I think it's a blend of things, and 11:50
13 that's what's confusing here. It's an email. 11:50
14 Q. Mr. Grant, if you look at the first 11:51
15 page of the email, you do send another email to 11:51
16 Mr. Hutchinson a few months later in August of 11:51
17 2009. 11:52
18 Do you see that? 11:52
19 A. Yes. 11:52
20 Q. Why did you do that? 11:52
21 MS. KRIEG: Object to the form. 11:52
22 A. Yeah, I mean, it's hard to say. It 11:52
23 doesn't say much. It says "Note from before 11:52
24 with presentation." I honestly don't know what 11:52
25 the genesis of me sending this was. 11:52

1 Q. Did he ask it for it or was it 11:52
2 unsolicited? 11:52

3 MS. KRIEG: Object to the form. 11:52

4 A. I would be speculating at this point. 11:52
5 I don't remember how our conversations evolved. 11:52

6 MR. QURESHI: I'm going to mark as 11:53
7 the next Exhibit 1017. 11:53

8 (Exhibit No. 1017 was marked for 11:53
9 identification.) 11:53

10 BY MR. QURESHI: 11:53

11 Q. I've handed you Exhibit 1017, and 11:53
12 I'll tell you this is the PowerPoint 11:53
13 presentation for slides that were attached to 11:53
14 Exhibit 1016. Have you had a chance to review 11:53
15 it, sir? 11:54

16 A. Yes. 11:54

17 Q. Okay. Do you recall preparing 11:54
18 Exhibit 1017? 11:54

19 A. I recall that I prepared it. 11:54

20 Q. Okay. And I believe you mentioned 11:54
21 earlier that you didn't give it the title "RA 11:54
22 For Dummies," but that's how you characterized 11:54
23 it in the email we just looked at; is that 11:54
24 correct? 11:55

25 A. Correct. 11:55

1 Q. And I believe you also testified that 11:55
2 in addition to sending it to Mr. Hutchinson, 11:55
3 you would sometimes use it with clients to talk 11:55
4 about the risk adjustment program; is that 11:55
5 right? 11:55

6 A. That is correct. 11:55

7 Q. Do you recall when you prepared it? 11:55

8 A. Approximate time period would be late 11:55
9 2008, early 2009. And it may have been 11:55
10 changed. I don't know that it was like -- it's 11:55
11 probably -- it was probably updated through 11:55
12 time as well. 11:55

13 Q. Do you recall preparing it while you 11:55
14 were at Health Risk Partners? 11:55

15 A. Oh, yes. It was definitely while I 11:55
16 was at Health Risk Partners. 11:55

17 Q. Okay. And in preparing it, were you 11:55
18 endeavoring to be accurate? 11:55

19 MS. KRIEG: Object to the form. 11:55

20 A. I was endeavoring -- I mean, this is 11:55
21 a very simplified model. I was endeavoring to 11:55
22 show a principle with a very simplified model 11:56
23 which is not accurate to like the world, but it 11:56
24 presents an effect. I was trying to 11:56
25 demonstrate an effect. 11:56

1 Q. But you weren't trying to manufacture 11:56
2 information. You believed that the principle 11:56
3 that is being illustrated in these slides is a 11:56
4 genuine reflection of something you believed 11:56
5 occurred. 11:56

6 MS. KRIEG: Object to the form. 11:56

7 A. So what I would say is, yeah, I mean, 11:56
8 I used totally manufactured data because I just 11:56
9 made up amounts for the -- and created a very, 11:56
10 very simplified world, which is much simpler 11:56
11 than what a real risk adjustment model looks 11:56
12 like with multiple demographic factors, 11:56
13 multiple disease factors, to illustrate a 11:56
14 principle that I believed was true. 11:56

15 Q. And I believe in your email to 11:56
16 Mr. Hutchinson you said that this principle 11:56
17 would also hold true for more complex models. 11:56
18 If you want to go back to Exhibit 1016, you 11:57
19 certainly can. 11:57

20 A. Where was this at again? 11:57

21 Q. It's in the sentence that states: 11:57
22 "Same principles apply to more complex models, 11:57
23 obviously." 11:57

24 MS. KRIEG: Object to the form. 11:57

25 A. Yes, I see that, yeah. 11:57

1 Q. And you believed that? 11:57

2 MS. KRIEG: Object to the form. 11:57

3 A. I did. 11:57

4 Q. Okay. Sir, I'd like you to walk us 11:57

5 through the principle you're attempting to 11:57

6 illustrate. 11:57

7 MS. KRIEG: Object to the form. 11:57

8 A. There are a couple. So we -- I would 11:57

9 say there's principle 1 and principle 2 for 11:57

10 simplicity's sake so we can follow. Principle 11:57

11 1 is related to model calibration; principle 2 11:57

12 is related to RADV execution. 11:58

13 So principle 1 is that whenever you 11:58

14 calibrate a model, there are some degree of 11:58

15 diagnoses that are reported, but they are 11:58

16 incorrectly reported. So somebody is reported 11:58

17 as having condition; they do not have that 11:58

18 condition. 11:58

19 And there's a general kind of 11:58

20 principle that underlies risk adjustment. So 11:58

21 the underlying principle of risk adjustment is 11:58

22 we assume -- this is the basis on which we 11:58

23 build every risk adjustment model. We assume 11:58

24 that, on average, 65-year-olds have a certain 11:58

25 cost. They're all going to vary. No 11:58

1 65-year-old is going to cost the same, but 11:58
2 65-year-olds that are healthy cost a certain 11:58
3 amount, on average. 80-year-olds that are 11:58
4 healthy cost a certain amount on average. 11:59
5 People with diabetes on average cost a certain 11:59
6 amount. People with congestive heart failure 11:59
7 on average cost a certain amount. People with 11:59
8 diabetes and congestive heart failure cost a 11:59
9 certain amount, on average. 11:59

10 So this is then taking that 11:59
11 knowledge, playing God, and saying I magically 11:59
12 know what these values are. That's the way 11:59
13 this is set up. So I magically know that all 11:59
14 healthy people cost 500 bucks apiece and all 11:59
15 sick people cost \$1,500 because I've God-like 11:59
16 powers and I can figure that out already. 11:59

17 And it is operating under the 11:59
18 assumption that a person who is coded as sick 11:59
19 but is actually not sick is actually the same 11:59
20 as all the healthy people, they're just 11:59
21 incorrectly coded. 11:59

22 And you can choose to accept or not 11:59
23 accept that assumption. That is the assumption 11:59
24 that I was operating under is that there is no 12:00
25 difference between healthy coded as healthy and 12:00

1 healthy incorrectly coded as sick. 12:00

2 Q. Okay, so if I could pause you there, 12:00

3 Mr. Grant, is that sort of what the purpose is 12:00

4 of slide 2? You're referencing a healthy 12:00

5 personal mistakenly coded as sick and then 12:00

6 assigning the relative cost to that individual? 12:00

7 MS. KRIEG: Object to the form. 12:00

8 A. Yes. So this is again, with the 12:00

9 God-like power to know everybody's cost, I know 12:00

10 that these healthy people coded as sick cost 12:00

11 the same as all the other healthy people and I 12:00

12 magically already know they all cost \$500, an 12:00

13 unknowable fact when running a risk adjustment 12:00

14 calibration, but in this world I've created I 12:00

15 know this. And so I have two people thrown 12:00

16 into the sick category from a coding 12:00

17 perspective, but from a cost perspective 12:00

18 appropriately residing in the healthy category. 12:00

19 Q. Okay. 12:00

20 A. And as you see from this -- and this 12:01

21 is only -- by the way, it's a one-directional 12:01

22 look at this, I will point out too, just 12:01

23 looking at the incorrect coding, not going the 12:01

24 other direction. The incorrectly -- 12:01

25 incorrectly coded as sick, not healthy, 12:01

1 incorrectly coded as healthy. It's not a 12:01

2 robust presentation that has both sides. It's 12:01

3 a one sided -- 12:01

4 Q. I understood. 12:01

5 A. And then we just walk through it and 12:01

6 say we haven't thrown any sick people into the 12:01

7 healthy category erroneously, so healthy people 12:01

8 still cost 500 bucks apiece. But by virtue 12:01

9 adding two healthy people into the sick 12:01

10 population, you lower the perceived average 12:01

11 cost of the sick population and that results in 12:01

12 the healthy still predicting at \$500 and the 12:01

13 sick person at \$1,033. You've reduced kind of 12:01

14 the relative cost of sick to healthy. 12:01

15 Q. When you refer to the 1333 as a 12:02

16 result of healthy, two healthy persons being 12:02

17 coded as sick, this amount decreases from 1500 12:02

18 to 1333; is that correct? 12:02

19 A. Correct. 12:02

20 MS. KRIEG: Object to form. 12:02

21 A. Correct. 12:02

22 Q. Okay. 12:02

23 A. That's what I'm saying. 12:02

24 Q. Okay. 12:02

25 A. Again, very simple. It's not running 12:02

1 a real linear regression model. It's taking a 12:02
2 very simple view of the world: Healthy people, 12:02
3 sick people. 12:02

4 Q. And so -- 12:02

5 A. And unified costs too, unitary costs, 12:02
6 where every sick person costs the same amount, 12:02
7 every healthy person costs the same amount. 12:02

8 Q. So what is the principle that you're 12:02
9 illustrating with this example? 12:02

10 MS. KRIEG: Object to form. 12:02

11 A. That if there is a pattern of 12:02
12 overreporting of diagnosis codes in fee for 12:02
13 service, then that pattern would result in a 12:02
14 underprediction of the disease-related factors 12:03
15 in the model, and then the relative cost 12:03
16 differences between sick and healthy are 12:03
17 reduced. 12:03

18 Q. And, sir, is there, in fact, a 12:03
19 pattern of overreporting of diagnoses codes in 12:03
20 fee-for-service data? 12:03

21 MS. KRIEG: Object to form. 12:03

22 A. That's what nobody knows, at least 12:03
23 nobody that I know of knows. 12:03

24 Q. Are you aware of any errors in the 12:03
25 diagnosis codes and fee-for-service data? 12:03

1 MS. KRIEG: Object to form. 12:03

2 A. I would state it differently. I'm 12:03

3 unaware of any systematic study of that. There 12:03

4 may be, but I'm unaware of a systematic study. 12:03

5 Q. Putting aside a systematic study, 12:04

6 what is your personal belief? Are there errors 12:04

7 in diagnosis codes in fee-for-service data? 12:04

8 MS. KRIEG: Object to form. 12:04

9 A. It would be my belief that in any 12:04

10 data set, there would be some degree of error. 12:04

11 The question is always what the degree of error 12:04

12 is, not whether there is something wrong in 12:04

13 some -- you have -- you know, now we're 12:04

14 50 million people or whatever in fee for 12:04

15 service. You get all their claims. You get 12:04

16 over a billion claims a year. Every claim is 12:04

17 not perfect. The real question is not is there 12:04

18 an error, it's the degree of the error and it's 12:04

19 the relative undercoding and overcoding, 12:04

20 because both kind of error could exist. You 12:04

21 could fail to code a diagnosis code, which is 12:04

22 what the plans yelled at us about and wanted 12:04

23 alternative data sources, or you could pick up 12:04

24 a diagnosis code that should not have been 12:04

25 there. Either type of error could exist in 12:04

1 fee-for-service data and you would need to do a 12:04
2 systematic study to know the degree to which 12:04
3 that error exists and what the bias is. 12:05

4 Q. So you are aware that there are 12:05
5 errors, but you don't know the amount or extent 12:05
6 because you believe there's no systematic study 12:05
7 evaluating this issue? 12:05

8 MS. KRIEG: Object to form. 12:05

9 A. Again, "aware" is a strong term. I 12:05
10 would say it is my firm belief, having 12:05
11 processed data for years, that any data set has 12:05
12 errors in it. My experience with data would 12:05
13 say that every data set you ever deal with that 12:05
14 is a very large data set has some degree of 12:05
15 error and the only question is what that degree 12:05
16 of error is. And unless you study it, it is 12:05
17 not knowable what that degree of error is. 12:05

18 Q. And, sir, in slide 3, what are you 12:05
19 illustrating? 12:05

20 MS. KRIEG: Object to form. 12:05

21 A. So again, this is living in a -- 12:05
22 we're now moving from a slightly fictitious 12:05
23 world to an exceptionally fictitious world 12:05
24 where plan costs are the same as 12:06
25 fee-for-service costs, which is not even an 12:06

1 assumption that necessarily CMS would share, 12:06
2 let alone that every plan has the same 12:06
3 underlying cost. 12:06

4 But assuming that a goal was to pay 12:06
5 similar to how the model was calibrated, and 12:06
6 that plan costs generally trend the same way 12:06
7 fee-for-service costs do, that if you have an 12:06
8 underlying error in fee-for-service data that 12:06
9 overreports diagnosis codes and therefore 12:06
10 undercalculates a risk adjustment factor that 12:06
11 the plan would not be being paid the same as 12:06
12 fee for service. And if you assume their costs 12:06
13 were similar to fee for service, this would 12:06
14 result in an underpayment to the plan. 12:06

15 Q. The last bullet point of slide 3, 12:07
16 what are you illustrating in that? 12:07

17 MS. KRIEG: Object to form. 12:07

18 A. Again, I'm creating a fictitious 12:07
19 world where sick people in fee for service 12:07
20 costs 1500, sick people for the plan cost 1500, 12:07
21 you know how many sick people you have, you 12:07
22 know how many healthy people you have, and you 12:07
23 submit them entirely accurately. This is the 12:07
24 difference between what their actual cost is 12:07
25 and what you get paid. 12:07

1 Q. Slide 2 suggests that there's 12 12:07
2 people coded as sick; correct? 12:07

3 A. Yes. 12:07

4 Q. Two of those 12 are, in fact, 12:07
5 healthy; correct? 12:07

6 A. Yes. 12:08

7 Q. But in slide 3, there's only 10 sick 12:08
8 members who are coded as sick; is that right? 12:08

9 A. That is what this slide is showing, 12:08
10 yes. 12:08

11 Q. Okay. And are you attempting to 12:08
12 highlight in your hypothetical world the 12:08
13 differences between the fee-for-service data 12:08
14 where you have healthy coded as sick and then 12:08
15 in the plan data where there's only sick people 12:08
16 coded as sick? 12:08

17 A. No. 12:08

18 MS. KRIEG: Object to form. 12:08

19 A. No, I'm not purporting to do that. 12:08
20 I'm not suggesting that plans only code sick 12:08
21 people as sick. I'm creating a hypothetical 12:08
22 world where if a plan were to code only sick 12:08
23 people as sick and then vary from fee for 12:08
24 service as a result of doing that, because in 12:08
25 fee for service we had two people who were sick 12:08

1 that were not. So in this world now we've 12:08
2 changed it and said create a fake world where 12:08
3 plans submit perfect data and every code a plan 12:09
4 submits is perfect. This is the mathematical 12:09
5 result of that -- 12:09

6 Q. Okay. 12:09

7 A. -- in a world where we have the other 12:09
8 assumptions already present. 12:09

9 Q. Okay. What is meant by the first 12:09
10 bullet point -- 12:09

11 MS. KRIEG: Object to form. 12:09

12 Q. -- on page 3? 12:09

13 MS. KRIEG: Object to form. 12:09

14 A. This is kind of going back to the 12:09
15 email discussion of if you submit exactly like 12:09
16 fee for service, so if you -- if this 12:09
17 undercoding -- and it would equally apply to 12:09
18 overcoding, by the way. This is a 12:09
19 presentation, just assuming -- I mean, this is 12:09
20 assuming overcoding. It would also apply to 12:09
21 undercoding, I should say. That if you 12:09
22 submitted -- if your data looked exactly like 12:10
23 the data that went into the calibration, you 12:10
24 would be paid exactly as the model anticipates 12:10
25 you would be paid. If you vary from that in 12:10

1 either direction you're going to be paid 12:10
2 differently than the model anticipates you 12:10
3 being paid because you're going to get a risk 12:10
4 adjustment factor that's either higher or lower 12:10
5 than the model calibration would anticipate for 12:10
6 a person with those characteristics. 12:10

7 MR. QURESHI: May we take a break? 12:10

8 THE VIDEOGRAPHER: We are going off 12:10
9 the record. The time is 12:10. 12:10

10 (Recess taken.) 12:10

11 THE VIDEOGRAPHER: We are going 12:56
12 back on the record. The time is 12:55. 12:56

13 BY MR. QURESHI: 12:56

14 Q. Mr. Grant, are you familiar with an 12:56
15 organization called AHIP? 12:56

16 A. I am. 12:56

17 Q. What is AHIP? 12:56

18 MS. KRIEG: Object to the form. 12:56

19 A. It is the Association of Health 12:56
20 Insurance Plans, I think. They're the industry 12:56
21 organization that represents health plans. 12:56

22 Q. And during your tenure at Health Risk 12:56
23 Partners, did you participate in AHIP meetings? 12:56

24 A. Attend AHIP meetings, you mean? 12:56

25 Q. Attend, participate. 12:56

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1 A. I certainly went to the AHIP 12:56

2 conferences, and then I had -- I met with AHIP. 12:56

3 Q. Was Health Risk Partners a member of 12:56

4 AHIP? 12:56

5 A. No. Health Risk Partners is not a 12:56

6 health plan. 12:56

7 Q. Okay. In your interaction with AHIP, 12:56

8 did you ever prepare any written materials for 12:57

9 them? 12:57

10 MS. KRIEG: Object to the form. 12:57

11 A. I was part of the preparation. I 12:57

12 can't remember if I actually personally 12:57

13 prepared written materials or was just part of 12:57

14 the preparation, but I had a consulting 12:57

15 contract with AHIP. 12:57

16 Q. Okay. So this consulting 12:57

17 arrangement, was it with you personally or with 12:57

18 you through Health Risk Partners? 12:57

19 MS. KRIEG: Object to the form. 12:57

20 A. It was me through Health Risk 12:57

21 Partners. 12:57

22 Q. Okay. Approximately when were you 12:57

23 engaged in connection with this matter? 12:57

24 MS. KRIEG: Object to the form. 12:57

25 A. At some point in time I was at Health 12:57

1 Risk Partners. I honestly don't know the 12:57
2 dates. 12:57

3 Q. Okay. Sometime between 2008 and 12:57
4 2010? 12:57

5 A. Yes. 12:57

6 Q. And what was the purpose of the 12:57
7 engagement as you understand it? 12:57

8 MS. KRIEG: Object to the form. 12:58

9 A. It was to work on the RADV 12:58
10 extrapolation and to assist AHIP in responding 12:58
11 to the RADV extrapolation methodology. 12:58

12 Q. Responding to whom? 12:58

13 A. To CMS. 12:58

14 Q. And what types of activities did you 12:58
15 do to fulfill that objective? 12:58

16 MS. KRIEG: Object to the form. 12:58

17 A. I don't remember the exact 12:58
18 activities. The general types of things that I 12:58
19 did was I was in meetings with a working group 12:58
20 of plan representatives, a mix of people that 12:58
21 work on risk adjustment, actuaries from a 12:58
22 select group of AHIP's member plans. You know, 12:58
23 we discussed the official response that AHIP 12:58
24 would provide to CMS regarding their concerns 12:59
25 about the RADV extrapolation methodology. 12:59

1 Q. And the PowerPoint we looked at prior 12:59
2 to the break, Exhibit 1017, did that contain 12:59
3 any concerns about RADV? 12:59

4 MS. KRIEG: Object to the form. 12:59

5 A. Yes. 12:59

6 Q. And we will certainly get back to 12:59
7 that in a moment. I want to focus on AHIP for 12:59
8 the moment. 12:59

9 Who else from Health Risk Partners 12:59
10 was helping on this particular engagement with 12:59
11 AHIP? 12:59

12 MS. KRIEG: Object to the form. 12:59

13 A. I did this myself. I mean, we 12:59
14 obviously had a contract so there were -- the 12:59
15 people that did the contract and the president 12:59
16 approved my doing the consulting arrangement, 12:59
17 but the consulting arrangement was me with 12:59
18 them. 01:00

19 Q. As part of your engagement with AHIP 01:00
20 regarding this RADV issue you've referenced, 01:00
21 did you endeavor to ensure that AHIP's 01:00
22 presentations to the government were accurate? 01:00

23 MS. KRIEG: Object to the form. 01:00

24 A. I would say I was one of many people 01:00
25 who had input into their presentation. It was 01:00

1 their presentation, so I exerted my influence 01:00
2 on it, but it was their work product and their 01:00
3 member plans's work product in the end. I was 01:00
4 there in an advisory role. It was up to them 01:00
5 what they presented to the government and I had 01:00
6 no veto authority or anything like that over 01:00
7 it. 01:01

8 Q. Do you recall any instance in which 01:01
9 you had discomfort about positions or arguments 01:01
10 that AHIP was expressing to the government 01:01
11 regarding RADV? 01:01

12 MS. KRIEG: Object to the form. 01:01

13 A. So I recall that they had a decently 01:01
14 lengthy discussion of it that was prepared, and 01:01
15 I was involved in preparing that. I don't even 01:01
16 remember if I was the original writer or a 01:01
17 commenter on it. I honestly don't remember how 01:01
18 the actual development process worked, and I'd 01:01
19 have to look at a specific argument that was 01:01
20 made in it to say whether I agreed with every 01:01
21 single thing they said. 01:01

22 Q. Okay. 01:01

23 A. I don't recall what the specifics of 01:01
24 that document were. 01:01

25 Q. Understood. And my question was 01:01

1 really testing your recollection. 01:01

2 Do you recall today any instance in 01:01

3 which you disagreed with something they said or 01:01

4 argued or presented to the government? 01:01

5 Do you recall any such instance? 01:02

6 MS. KRIEG: Object to the form. 01:02

7 A. I don't recall this. I'm not going 01:02

8 to -- if I'm not recalling it, I'm not going to 01:02

9 say that there was not an instance, but I don't 01:02

10 recall, like, a specific disagreement that we 01:02

11 had about it. 01:02

12 Q. Okay. 01:02

13 (Exhibit No. 1018 was marked for 01:02

14 identification.) 01:02

15 BY MR. QURESHI: 01:02

16 Q. Mr. Grant, I'm going to hand you a 01:02

17 document that's marked Exhibit 1018. Please 01:02

18 take some time to review it. Mr. Grant, please 01:02

19 take as much time as you need to flip through 01:04

20 it. I'm going to focus on the cover email in 01:04

21 the document that is entitled "AHIP Issue 01:04

22 Paper." 01:04

23 A. Right. That's what I'm looking at 01:04

24 right now is the issue paper. 01:04

25 MS. KRIEG: Are there Bates numbers 01:05

1	to go with this?	01:05
2	MR. QURESHI: No. It was not a	01:05
3	document that was produced.	01:05
4	MS. KRIEG: Okay.	01:05
5	BY MR. QURESHI:	01:05
6	Q. Mr. Grant, I think the document you	01:06
7	are looking at is actually not the issue paper.	01:06
8	You're welcome to continue reviewing it, but I	01:06
9	think the issue paper has a formal cover page	01:06
10	that says "AHIP Issue Paper."	01:06
11	A. Oh. This says "Issues for	01:06
12	Discussion." I'm sorry.	01:06
13	Q. The formal title is "AHIP Issue	01:06
14	Paper."	01:06
15	A. I'm sorry.	01:06
16	Q. Please look at whatever you'd like to	01:06
17	look at. My questions are going to be on the	01:06
18	cover email and then actually page 1 of the	01:06
19	issue paper.	01:06
20	A. So you're sticking with the first	01:07
21	page right now?	01:07
22	Q. Yes, sir.	01:07
23	A. Okay.	01:07
24	Q. Sir, do you recall reviewing the	01:08
25	portion of Exhibit 1018 that is entitled "AHIP	01:08

1 Issue Paper Risk Adjustment Data Validation: 01:08

2 Policy and Payment Implications," January 4, 01:08

3 2010? 01:08

4 A. Yes. 01:08

5 Q. Did you draft it? 01:08

6 A. As I said before, I honestly don't 01:08

7 remember if I drafted this or just reviewed it 01:08

8 and contributed to it. 01:08

9 Q. And was your review and any 01:08

10 contributions in connection with your 01:08

11 engagement by AHIP to assist with RADV issues? 01:08

12 A. It was exclusively part of that 01:08

13 contract. That was kind of the nature of the 01:08

14 contract was to work with them in the 01:08

15 development of these papers. 01:08

16 Q. Okay. And who other than yourself 01:08

17 played a role in contributing and drafting the 01:08

18 white -- the issue paper? 01:09

19 MS. KRIEG: Object to the form. 01:09

20 A. I would -- you know, I was looking at 01:09

21 the names here. It's going to go back to there 01:09

22 was a whole work group and I do not remember 01:09

23 everybody that contributed to the issue paper. 01:09

24 Q. Was the issue paper presented to CMS? 01:09

25 A. That is my understanding. 01:09

1 Q. And how did you come about that 01:09
2 understanding? 01:09

3 A. Through the participation in the work 01:09
4 group. They would discuss that they were going 01:09
5 to go meet with CMS. I was not invited to 01:09
6 attend the CMS meeting. 01:09

7 Q. And what was the purpose of the issue 01:09
8 paper? 01:09

9 What was the work group trying to 01:09
10 accomplish? 01:09

11 MS. KRIEG: Objection to form. 01:09

12 A. They wanted to see the risk 01:09
13 adjustment data validation methodology altered. 01:10

14 Q. Why? 01:10

15 MS. KRIEG: Object to the form. 01:10

16 A. They were concerned about the impact 01:10
17 of extrapolating RADV sample findings to the 01:10
18 entire plan population and adjusting payments. 01:10

19 Q. What was the concern? 01:10

20 MS. KRIEG: Object to the form. 01:10

21 A. There were multiple concerns raised 01:10
22 in the issue paper and in the discussions we 01:10
23 had. One was around advance notice of the 01:10
24 intent to do this, so they were questioning 01:10
25 whether or not CMS had the authority to, after 01:10

1 having announced the payment methodology for 01:10
2 the year, come out with an adjustment to that 01:10
3 payment methodology after plan bids had been 01:11
4 submitted in response to the original payment 01:11
5 notice for that year. 01:11

6 Q. What else? 01:11

7 A. That's the first issue that is number 01:11
8 2 within the paper. And then the first issue 01:11
9 was the lack of knowledge of error rate within 01:11
10 fee for service that went into the data that 01:11
11 were used to calibrate the risk adjustment 01:11
12 model. 01:11

13 Q. And when you say issue 1, is that the 01:11
14 one on page 1 of the issue paper -- 01:11

15 A. Yes. 01:11

16 Q. -- as part of Exhibit 1018? 01:11

17 A. Yeah. 01:12

18 MS. KRIEG: Object to form. 01:12

19 Q. Sir, I'm going to read that title. 01:12
20 It states: "Payment accuracy and coding 01:12
21 accuracy/medical record documentation 01:12
22 completeness are not synonymous." Did I read 01:12
23 that correctly? 01:12

24 A. You did. 01:12

25 Q. What do you understand that to mean? 01:12

1 MS. KRIEG: Object to form. 01:12

2 A. What it means is -- I mean, I think 01:12

3 it gets to why -- I can tell you why the 01:12

4 statement is there. Is that helpful? 01:12

5 Q. I think it will be helpful, but I 01:12

6 first want to understand in your words what you 01:12

7 understand it to mean. 01:12

8 MS. KRIEG: Object to form. 01:12

9 A. I think without the background it's 01:12

10 hard to just like -- it's saying these two 01:12

11 things are not equivalent, but I think that's 01:12

12 based on understanding why that statement is 01:12

13 being made. 01:13

14 Q. Okay. Please. 01:13

15 A. So CMS is using -- CMS is using, as a 01:13

16 proxy for determining payment accuracy, they 01:13

17 are reviewing medical records to see if an 01:13

18 individual is said to have a diagnosis code 01:13

19 that that diagnosis code is documented in the 01:13

20 medical record because we're paying on the 01:13

21 basis of diagnosis codes at that point in time. 01:13

22 And then using that through an 01:13

23 extrapolation basically to adjust payments on a 01:13

24 broad scale suggests that finding the lack of a 01:13

25 diagnosis code in a medical record properly 01:13

1 documented suggests that the entire payment to 01:13
2 an organization is inaccurate. And this is 01:13
3 saying that is not a true statement, that you 01:13
4 can't on the basis of, like, medical record 01:13
5 documentation establish whether or not the 01:13
6 overall payment to an organization was 01:13
7 accurate. 01:14

8 Q. If you go down further on page 1, the 01:14
9 first sentence of the last paragraph states in 01:14
10 part: "Under the new CMS approach, the 01:14
11 relationship between coding error and payment 01:14
12 error is more complex than a simple attribution 01:14
13 of every medical record documentation 01:14
14 discrepancy to a level of payment error." 01:14

15 A. Where are you at? I'm sorry. 01:14

16 Q. Page 1, last paragraph, first 01:14
17 sentence. 01:14

18 A. Oh, okay. I got it, yeah. 01:14

19 Q. Do you see that sentence? 01:14

20 A. Yes. 01:14

21 Q. Okay. What do you understand that to 01:14
22 mean? 01:14

23 MS. KRIEG: Object to form. 01:14

24 A. Again, it's talking about 01:15
25 extrapolation. So it's differentiating an old 01:15

1 approach, the old approach being we'll review 01:15
2 medical records. If we find an error in a 01:15
3 specific medical record, we will determine that 01:15
4 that code is not an appropriate code and make 01:15
5 an appropriate adjustment. So in any case 01:15
6 where it is a determined fact that a medical 01:15
7 record does not support a diagnosis code, that 01:15
8 is by definition an inappropriate code not used 01:15
9 for payment. This is done on a sample basis, 01:15
10 so sample could be of various sizes, but only 01:15
11 those people within the sample are determined 01:15
12 to have an error and payment is adjusted for 01:15
13 everyone that has an error. 01:15
14 In this, the new CMS approach, that 01:15
15 is then interpreted to be representative of the 01:15
16 entire population and that multiple 01:15
17 individuals, those sampled and those not 01:15
18 sampled, having a level of payment error and 01:15
19 then saying this is the overall payment error 01:16
20 to an entire organization based on the findings 01:16
21 within the sample. 01:16
22 Q. Sir, if you would assume for a moment 01:16
23 that there is no extrapolation; instead, 01:16
24 there's a systematic audit of every single 01:16
25 person and code, would there still exist an 01:16

1 issue with respect to payment accuracy and 01:16

2 coding accuracy? 01:16

3 MS. KRIEG: Object to form. 01:16

4 A. I think it's a hypothetical because 01:16

5 CMS would never do that, so -- 01:16

6 Q. I understand it's a hypothetical. 01:16

7 A. So that's not the issue we were 01:16

8 raising. 01:16

9 Q. Okay. But I'm asking you to assume 01:16

10 that there is no extrapolation, no sampling. 01:16

11 With me so far? 01:16

12 A. Yes. 01:16

13 Q. Okay. Under those circumstances, if 01:16

14 there is a systematic audit of every single 01:17

15 member and deletion of unsupported codes, is 01:17

16 there comparability between the Medicare 01:17

17 Advantage data and fee-for-service data? 01:17

18 MR. HASEGAWA: Object to form. 01:17

19 MS. KRIEG: Object to form. 01:17

20 A. There definitely could be. I mean, 01:17

21 it depends on a lot of factors, but arguably -- 01:17

22 but again, it's a hypothetical. CMS does not 01:17

23 conduct an audit of that nature. It's super 01:17

24 expensive. 01:18

25 (Discussion held off the record.) 01:18

1 BY MR. QURESHI: 01:18

2 Q. Mr. Grant, the issue that you were 01:19

3 highlighting in your -- in the presentation 01:19

4 that you sent to Mr. Hutchinson in May of 2009, 01:19

5 it was a hypothetical situation you were 01:19

6 presenting? 01:19

7 MS. KRIEG: Object to form. 01:19

8 A. It is absolutely a hypothetical 01:19

9 situation I'm presenting. 01:19

10 Q. And you were presenting it to 01:19

11 illustrate a certain principle, I believe you 01:19

12 testified to. 01:19

13 MS. KRIEG: Object to form. 01:19

14 A. It illustrates a principle on certain 01:19

15 assumptions and so it's, like, hypothetical 01:19

16 data and a set of assumptions saying if it 01:19

17 works this way, this is what happens. 01:19

18 Q. Okay. And the last part of your 01:19

19 answer, "this is what happens," what happens? 01:19

20 MS. KRIEG: Object to form. 01:19

21 A. If -- so I will be very clear. If 01:19

22 there is a pattern where it is -- where fee for 01:20

23 service has errors only one direction and that 01:20

24 is overreporting of diagnosis codes and the 01:20

25 preponderance is error is in that way, that 01:20

1 there should be an underprediction of the costs 01:20
2 associated with people with the diagnosis codes 01:20
3 that are overreported. 01:20

4 Q. That issue that you just highlighted, 01:20
5 sir, that doesn't depend on whether CMS 01:20
6 extrapolates or whether it audits every single 01:20
7 chart. The problem is the same in either case; 01:20
8 correct? 01:20

9 MS. KRIEG: Object to form. 01:20

10 A. That would be true if the assumption 01:20
11 were also true. So there's a built-in 01:20
12 assumption that is an unproven assumption in 01:20
13 the presentation that is assuming a pattern of 01:21
14 overcoding, which is unknown due to the lack of 01:21
15 a fee-for-service study. And if you look at 01:21
16 what is recommended here, it is a 01:21
17 fee-for-service study so that you know. 01:21
18 Lacking knowledge, it's impossible to say 01:21
19 whether this assumption is true or not. 01:21

20 Q. And to your knowledge, has such a 01:21
21 study occurred? 01:21

22 MS. KRIEG: Object to form. 01:21

23 A. To my knowledge, no. Again, I 01:21
24 haven't worked on Medicare Advantage risk 01:21
25 adjustment since 2010 and not within CMS since 01:21

1 2005 -- 2000 -- early 2006. 01:21

2 Q. The last sentence on page 1 of the 01:21

3 AHIP issue paper that's part of Exhibit 1018, 01:22

4 would you please read that to yourself. 01:22

5 A. Yeah. 01:22

6 Q. Okay. Do you agree with that 01:22

7 statement? 01:22

8 MS. KRIEG: Object to form. 01:22

9 A. Yes, I agree with the principle of 01:22

10 that statement. 01:22

11 Q. Sir, when you were at AHIP -- I'm 01:22

12 sorry, when you were at Health Risk Partners, 01:22

13 when did you cease working on the AHIP 01:22

14 engagement? 01:23

15 A. As I previously said, I do not 01:23

16 remember the start and end dates of the 01:23

17 engagement. 01:23

18 Q. Do you recall when you left Health 01:23

19 Risk Partners? 01:23

20 A. I do. 01:23

21 Q. When was that? 01:23

22 A. That was July of 2010. 01:23

23 Q. Do you have any recollection of the 01:23

24 back-and-forth between AHIP and the government 01:23

25 after submission of the AHIP issue paper that 01:23

1 we just looked at? 01:23

2 MS. KRIEG: Object to form. 01:23

3 A. I have -- I don't have recollection 01:23

4 and I'm not sure if I was aware of all of it. 01:23

5 I may or may not have been but I, you know, I 01:23

6 don't recall at this point if I even knew what 01:23

7 all of their back-and-forth was. 01:23

8 Q. And other than yourself, was there 01:23

9 any other consultant that you're aware of that 01:23

10 was working with AHIP in connection with this 01:24

11 particular RADV engagement? 01:24

12 A. I don't believe there were any 01:24

13 consultants contracted by AHIP, but there may 01:24

14 have been health plans that contracted 01:24

15 consultants rather than having staff work it. 01:24

16 I would not have known the difference. 01:24

17 Q. Okay. Other than the members of the 01:24

18 working group, there's no one else that comes 01:24

19 to mind in terms of playing a consulting role 01:24

20 similar to the one you played? 01:24

21 A. I honestly don't remember. They may 01:24

22 have had consulting attorneys. I honestly 01:24

23 don't remember. 01:24

24 Q. Okay. Mr. Grant, I'm going to ask 01:24

25 you to turn back to Exhibit 1017. 01:24

1 A. This? 01:25

2 Q. Yes. 01:25

3 A. Okay. 01:25

4 Q. In particular, page 4. Might you 01:25

5 walk us through the three bullet points on page 01:25

6 4 of the presentation and explain to us what 01:25

7 you were describing? 01:25

8 MS. KRIEG: Object to form. 01:25

9 A. So this is basically the continuation 01:25

10 of example where we started with the plan, had 01:25

11 perfect knowledge, knew two individuals that 01:25

12 were coded as sick, were healthy, and did not 01:25

13 submit them. 01:25

14 So we are now saying -- we are now 01:26

15 positing a different world where a plan does 01:26

16 not know and so submits the two miscoded 01:26

17 individuals as they were coded and then 01:26

18 receives the payment. And what this says is 01:26

19 that in the end, then this adds up to being the 01:26

20 same amount that we were looking to see them 01:26

21 pay on the previous side where we said they got 01:26

22 less money. This makes up that difference by 01:26

23 submitting those two people the way they were 01:26

24 coded because they were coded the same way as 01:26

25 fee for service. 01:26

1 Q. Then after the first bullet there's a 01:26
2 dash. Can you explain what the text after the 01:26
3 dash means? 01:26

4 MS. KRIEG: Object to form. 01:26

5 A. So what you have for the difference 01:26
6 between healthy people and sick people is \$833 01:27
7 in this example. So you have two people now 01:27
8 that are getting that additional \$833, which is 01:27
9 a total of \$1,666, which is equal to the 01:27
10 shortfall that had been identified on the 01:27
11 previous slide. 01:27

12 Q. And what's meant by the second bullet 01:27
13 point? 01:27

14 MS. KRIEG: Object to form. 01:27

15 A. So now this is hypothesizing a world 01:27
16 in which the plan submitted these folks. And 01:27
17 again, this is like in a very large population 01:27
18 now so it's not 10. And this is very 01:27
19 simplified example. So now you create a very 01:27
20 large plan where this is happening 01:27
21 systematically throughout a large plan where 01:27
22 you're submitting data like fee for service, 01:27
23 CMS comes behind, does a RADV, and maybe it's a 01:27
24 small sample now, they find this difference, 01:28
25 extrapolate it. That takes you back to the 01:28

1 payment levels that were identified on the 01:28

2 previous slide and takes back the \$1,666. 01:28

3 Q. So in your example, what you 01:28

4 characterize as the shortfall would still 01:28

5 exist? 01:28

6 MS. KRIEG: Object to form. 01:28

7 A. So the shortfall exists once again 01:28

8 through this methodology, similar to what was 01:28

9 identified in the first slide. 01:28

10 Q. Okay. And then -- 01:28

11 A. Slide 3, I should say. 01:28

12 Q. What is meant by the last bullet 01:28

13 point? 01:28

14 MS. KRIEG: Object to form. 01:28

15 A. Well, essentially you've calibrated a 01:28

16 model and come up with an amount. And the 01:28

17 implicit assumption then is if you back up all 01:28

18 the codes in the model that you -- the model is 01:28

19 perfectly predicting costs for people with 01:29

20 those conditions. So this is going from an 01:29

21 assumption of if you code -- you know, this is 01:29

22 going from an assumption if you submit claims 01:29

23 data, you get paid right, to an assumption if 01:29

24 you can back it up with a medical record, 01:29

25 everything in a medical record is -- tells you 01:29

1 who has a condition, and \$1,333 is the right 01:29
2 amount for that condition as the model was 01:29
3 calibrated. 01:29

4 Q. So Mr. Grant, under the assumptions 01:29
5 you've made in your presentation, for the plan 01:29
6 to be paid appropriately, it needs to submit 01:29
7 the two miscoded persons. 01:29

8 MS. KRIEG: Object to form. 01:29

9 A. I mean, there's many different ways 01:29
10 you can get there. That is one way you could 01:29
11 get there. 01:30

12 Q. Okay. Mr. Grant, I'm interpreting 01:30
13 your answer as being yes, but then suggesting 01:30
14 there are alternative ways to get there. 01:30

15 A. Well, I would not interpret it as a 01:30
16 yes, because I think that's the least 01:30
17 appropriate way to get there. 01:30

18 Q. Okay. Can you explain what -- why 01:30
19 you would not answer that question as yes? 01:30

20 A. Because it's suggesting that the 01:30
21 right idea is to submit miscoded people. And, 01:30
22 you know, it could lead somebody to even 01:30
23 believe that the right idea would be to 01:30
24 intentionally submit miscoded people, and 01:30
25 that's not what this is meaning to say. This 01:30

1 is saying this is like how you get 01:30
2 mathematically equivalent, but it's not 01:30
3 suggesting that this is like really the right 01:31
4 approach. And that is why we did the paper. 01:31

5 In my mind, always the right approach 01:31
6 was a fee-for-service error rate. And then, if 01:31
7 you got this perfect, you would be less than 01:31
8 the fee-for-service error rate and then in a 01:31
9 RADV extrapolation, you would get credit. That 01:31
10 was always the conversations I had with CMS is 01:31
11 you need a two-directional RADV extrapolation 01:31
12 taking into account a fee-for-service error 01:31
13 rate. And that is a different discussion about 01:31
14 RADV extrapolation versus what is appropriate 01:31
15 data to submit. And then actually people have 01:31
16 an inducement to be RADV because if they 01:31
17 actually have perfect data, then they would get 01:31
18 credit compared to other people that might get 01:31
19 hit. 01:31

20 Q. So in your view, is it possible to 01:31
21 have perfect data without knowing what the 01:31
22 fee-for-service error rate is? 01:31

23 MS. KRIEG: Objection, form. 01:31

24 A. It's always possible to have perfect 01:31
25 data if you reviewed every medical record and 01:31

1 then submitted only the things that were backed 01:32
2 up by medical records. It's possible to have 01:32
3 perfect data. To get the alignment between 01:32
4 perfect data is a discussion of kind of RADV 01:32
5 extrapolation policy. 01:32

6 Q. And if there's differences between 01:32
7 fee-for-service data and Medicare Advantage 01:32
8 data that's subject to RADV audits or other 01:32
9 activities, there is what you've characterized 01:32
10 earlier, a misalignment? 01:32

11 MS. KRIEG: Object to form. 01:32

12 A. That is what argument we made there, 01:32
13 yes. 01:32

14 Q. Okay. So in your presentation, 01:32
15 Mr. Grant, Exhibit 1017, in your hypothetical 01:32
16 example, for the payment amount to be 01:33
17 appropriate, the plan has to be paid an amount 01:33
18 that reflects the relative error of 01:33
19 fee-for-service and Medicare Advantage data? 01:33

20 MS. KRIEG: Object to form. 01:33

21 A. I mean, yes, it's -- I'm trying to 01:33
22 understand what you're asking. Can you phrase 01:33
23 it again? I'm sorry. 01:33

24 Q. Sure. In order for a payment -- 01:33
25 again, reference to Exhibit 1017 and your 01:33

1 assumptions and the hypotheticals you've built 01:34
2 into the presentation -- 01:34

3 A. Right. 01:34

4 Q. -- to illustrate certain principles, 01:34
5 in evaluating the appropriateness of a payment, 01:34
6 you would have to take into account the 01:34
7 relative errors in fee-for-service data and 01:34
8 other data. 01:34

9 MS. KRIEG: Object to form. 01:34

10 A. In the context of a RADV, which is 01:34
11 the only way you're able to evaluate this. So 01:34
12 it is positing a future world in which a 01:34
13 fee-for-service error rate is known, and then 01:34
14 knowing a fee-for-service error rate and being 01:34
15 able to compare a plan's error rate, you could 01:34
16 make an appropriate adjustment to the 01:34
17 extrapolation. Again, the entire context of 01:34
18 the presentation is around RADV extrapolation. 01:34

19 Q. But the principle and the 01:34
20 hypothetical world that you present in the 01:34
21 series of slides at 1017, there's nothing in 01:35
22 there about extrapolation; correct? 01:35

23 MS. KRIEG: Object to form. 01:35

24 A. On page 4, RADV extrapolation 01:35
25 recovers \$1,666. It is very specifically, and 01:35

1 the only reason for the presentation was RADV 01:35
2 extrapolation. This was all around explaining 01:35
3 underlying error rates, how they might impact 01:35
4 payment, what implications it had for RADV 01:35
5 extrapolation. This is only about RADV 01:35
6 extrapolation. 01:35

7 Q. Yeah, I'm a little confused about 01:35
8 terminology, sir. I understood your 01:35
9 presentation to deal with a data set involving 01:35
10 22 people; correct? 01:35

11 A. Right. 01:35

12 Q. So what are you extrapolating? 01:35

13 MS. KRIEG: Object to form. 01:35

14 A. The 22 people is a simplified 01:35
15 example -- 01:35

16 Q. And focusing -- 01:35

17 A. -- of model calibration just to show 01:35
18 how overprediction and underprediction could 01:35
19 work. 01:35

20 Q. And that's all I'm focused on is the 01:35
21 simple model. I'm following along your 01:36
22 presentation. 01:36

23 A. That is to show a principle. I 01:36
24 don't, like, go through the math of exploding 01:36
25 this out into millions and millions of people 01:36

1 and, you know, 100,000 or 500,000 or 20,000 01:36
2 plan members against which a 200-member RADV 01:36
3 sample is taking place. 01:36

4 Q. And that's my point, sir, that the 01:36
5 problem you're highlighting or the issue you're 01:36
6 raising exists in a universe of 22 people even 01:36
7 if you don't extrapolate it out to millions of 01:36
8 people. Correct? 01:36

9 MS. KRIEG: Object to form. 01:36

10 A. No, I think that's -- yes and no, 01:36
11 because like if it has 22 people, you'd review 01:36
12 it all and you just get it right. You'd 01:36
13 calibrate the model accurately. I mean, no, 01:36
14 not at all. 01:36

15 It is taking 22 people just to make a 01:36
16 simple math thing. I could have used 01:36
17 22 million people and done the same thing. It 01:36
18 is strictly to -- the way calibration works is 01:37
19 large groups of people, not 22 people. So this 01:37
20 is not meant to have any applicability to the 01:37
21 real world other than just to show through 01:37
22 simple math a concept, a mathematical concept. 01:37

23 Q. The issue that you're highlighting, 01:37
24 you know, for example, on page 4, you talk 01:37
25 about the shortfall. That shortfall exists in 01:37

1 your example because there is misalignment 01:37

2 between the fee-for-service data and the plan's 01:38

3 data; correct? 01:38

4 MS. KRIEG: Object to form. 01:38

5 A. On page 4? 01:38

6 Q. Yes, sir. 01:38

7 A. No, not correct. 01:38

8 Q. Okay. 01:38

9 A. The plan's data in this example 01:38

10 perfectly matches fee-for-service data. It has 01:38

11 to do with RADV extrapolation. And then it's 01:38

12 not even really -- it's like, because this 01:38

13 isn't an extrapolation that's taking 22 people, 01:38

14 it's like it's trying to point out using the 22 01:38

15 people is like why you have the shortfall and 01:38

16 then you wouldn't even extrapolate on 22 01:38

17 people. So to take this too literally is 01:38

18 missing the point of the presentation. 01:38

19 The point is talking about 01:38

20 extrapolation. And when we had conversations 01:38

21 about this, everybody got that that's the 01:38

22 point. That's why we say this here. But we 01:38

23 are just using simple numbers. You don't 01:38

24 really extrapolate to get \$1,600 back. That 01:38

25 would be a direct payment recovery, and that 01:38

1 was all accepted as acceptable. It's when you 01:38
2 have these 22 people now speaking for 500,000 01:38
3 people and extrapolating that over the entire 01:39
4 population, that's where you start having a 01:39
5 problem. That's what this is talking about. 01:39

6 Q. But the problem that you're 01:39
7 illustrating in Exhibit 1017 is illustrated 01:39
8 with 22 people, and your point about 01:39
9 extrapolation is that you're magnifying the 01:39
10 problem once you begin extrapolating? 01:39

11 MS. KRIEG: Object to form. 01:39

12 A. Yes, but you're also really creating 01:39
13 the problem because you're paying for groups of 01:39
14 people. So when risk adjustment is generally 01:39
15 going to pay for a group of people, there are 01:39
16 degrees of inaccuracy in it, all right? 01:39

17 Every plan's degree of inaccuracy in 01:39
18 data is slightly different. Even CMS's 01:39
19 fee-for-service data probably varies year to 01:39
20 year how inaccurate it is to some degree 01:39
21 unknown. But it's like large, large groups of 01:39
22 people. 01:39

23 Here, we take this very small group 01:39
24 of people, get very precise on them, and then 01:39
25 extrapolate it out. So the problem is not 01:40

1 getting like if you identify a subgroup of 01:40
2 people and say they're wrong, they're wrong. 01:40
3 And that has little impact on a plan's payment. 01:40
4 Where this became a problem was going from a 01:40
5 process where you looked at very discrete 01:40
6 people and said if they're wrong, they're 01:40
7 wrong, we get the money back, to if they're 01:40
8 wrong, they're wrong, we get their money back 01:40
9 and then we're going to extrapolate that to 01:40
10 500,000 people in your plan and we're going to 01:40
11 collect, you know, millions or billions of 01:40
12 dollars back from you because we have found 01:40
13 this now to be an endemic problem that means 01:40
14 you were paid wrong by this. 01:40
15 From an individual basis, you're 01:40
16 definably paid wrong when you find an error in 01:40
17 a diagnosis code. But when we go from that to 01:40
18 saying that error where we individually found 01:40
19 your diagnosis code was not backed up by a 01:40
20 record, and now we're going to say that just 01:40
21 implies for everybody here we're going to take 01:40
22 a whole bunch of money back. That was the 01:40
23 problem we were pointing out here without 01:40
24 knowing what the underlying error rate was and 01:40
25 adjusting the extrapolation for that. So this 01:40

1 was always about extrapolation, not about 22 01:41

2 people. 01:41

3 Q. And in connection with not knowing 01:41

4 the underlying error rate, you're referring to 01:41

5 the underlying error rate in the 01:41

6 fee-for-service data? 01:41

7 A. Correct. 01:41

8 Q. And do you know that today? 01:41

9 MS. KRIEG: Object to form. 01:41

10 A. I have never known that. 01:41

11 Q. Okay. Do you know whether that's 01:41

12 been calculated? 01:41

13 MS. KRIEG: Object to form. 01:41

14 A. I am unaware of any calculation to 01:41

15 date that has been done on that. 01:41

16 Q. So the problem that you're 01:41

17 identifying in the presentation, what's been 01:41

18 done to correct it? 01:41

19 MS. KRIEG: Object to form. 01:41

20 A. Again, I haven't worked on MA since 01:41

21 2010. I don't know what they're doing to 01:41

22 address it -- 01:41

23 Q. When -- 01:41

24 A. -- if anything. 01:41

25 Q. When you left in 2010 were you aware 01:41

1 of anything that had been done to address that 01:41
2 problem? 01:41

3 MS. KRIEG: Object to form. 01:41

4 A. So I left the agency in 2008 and I 01:41
5 was an external observer, so even if things 01:42
6 were being done within the agency in 2010, they 01:42
7 would not necessarily have shared them with me. 01:42
8 It would have been deliberative process. It 01:42
9 would have been protected. So I don't know 01:42
10 what they were doing. And I wasn't working on 01:42
11 risk adjustment since early 2006. So like 01:42
12 whatever the agency was doing, I would not 01:42
13 have -- they wouldn't have and to share that 01:42
14 with me -- 01:42

15 Q. And my -- 01:42

16 A. -- so the -- 01:42

17 Q. -- question, sir, was -- 01:42

18 A. -- the -- up to my time in 2006 I was 01:42
19 unaware of it, and since then, I'm unaware of 01:42
20 it. But, I mean, since 2010 I haven't paid any 01:42
21 attention to Medicare Advantage adjustment. 01:42

22 Q. Okay. You've answered my question, 01:42
23 which was are you aware of anything that's been 01:42
24 done to correct this problem? And I believe 01:42
25 your answer is no. 01:42

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1 A. But I have no basis to be aware. 01:42

2 It's -- I'm being very clear it is not 01:42

3 indicative of whether anything has or has not 01:42

4 been done because I have no basis for any 01:42

5 awareness of that. 01:42

6 Q. During the time you were working on 01:43

7 risk adjustment issues were you aware of any 01:43

8 steps the government had taken to address the 01:43

9 problem you raise in your presentation? 01:43

10 MS. KRIEG: Objection to the form. 01:43

11 And don't disclose anything that's 01:43

12 deliberative. 01:43

13 THE WITNESS: Okay, so -- 01:43

14 Q. I just need a yes or no, sir. 01:43

15 THE WITNESS: Is that deliberative 01:43

16 or not? 01:43

17 MS. KREISEL: I think that you can 01:43

18 to the extent that they have been made 01:43

19 public, you know, but to the extent 01:43

20 that -- 01:43

21 THE WITNESS: So nothing that has 01:43

22 been made public. 01:43

23 MS. KREISEL: Okay. 01:43

24 BY MR. QURESHI: 01:43

25 Q. Sir, if you could please turn to 01:44

1 Exhibit 1016, this is the email that you sent 01:44
2 to Mr. Hutchinson in May of 2009. When you 01:44
3 tell Mr. Hutchinson that the principles that 01:44
4 you illustrate in your presentation apply to 01:44
5 more complex models, what are you attempting to 01:44
6 inform him of? 01:45

7 MS. KRIEG: Object to the form. 01:45

8 A. Can you rephrase that? I'm not clear 01:45
9 what you're asking. 01:45

10 Q. Sure. Why did you feel it necessary 01:45
11 to tell him that the principles illustrated in 01:45
12 your presentation apply to more complex models? 01:45

13 A. Okay. 01:45

14 MS. KRIEG: Objection, form. 01:45

15 A. It kind of goes back to the 01:45
16 discussion we just had about being super simple 01:45
17 in a thing where you have 22 people and you 01:45
18 know all these things and they're either sick 01:45
19 or healthy. 01:45

20 First of all, you know, you have way 01:45
21 more people in this. You do not have unitary 01:45
22 costs. You have multiple age groups. You 01:45
23 have -- so we have just said you're either 01:45
24 healthy or you're sick and we have put you into 01:45
25 one of two categories so it's a totally binary 01:45

1 model. You're a 1 or a 0, and that's it. 01:45

2 Here, what we have when we do risk 01:45

3 adjustment is a multivariant binary model with, 01:45

4 you know, over 100 variables in a model so 01:46

5 you're running all those through. So, you 01:46

6 know, the first question somebody might ask is 01:46

7 like, well, you know, that's really nice that 01:46

8 you divide the world into healthy and sick but, 01:46

9 you know, we have diabetics and CHF and kidney 01:46

10 failure and all these different things. Does 01:46

11 this still apply? 01:46

12 So I am arguing that when you run it 01:46

13 through -- when you take these principles and 01:46

14 apply them on a larger scale to a larger model, 01:46

15 the same principles apply. 01:46

16 Q. You also refer to flaws in the 01:46

17 calibration. Is this a reference to the 01:46

18 misalignment between fee-for-service data and 01:46

19 plan data? 01:46

20 MS. KRIEG: Object to the form. 01:46

21 A. No. I mean, it's irrespective of 01:46

22 plan data. It's more saying that the 01:46

23 calibration does not perfectly predict the cost 01:47

24 of a diabetic or somebody with CHF or somebody 01:47

25 with cancer, that there are imperfections due 01:47

1 to imperfections in the data, and that will 01:47
2 cause some form of error in the prediction so 01:47
3 that then when you're looking at all the 01:47
4 relatives, which is what the model ultimately 01:47
5 comes down to you, have a relative cost 01:47
6 prediction error that does not truly reflect it 01:47
7 if you knew every diabetic, every person with 01:47
8 cancer, every person with CHF. 01:47

9 Q. And in your response, you used the 01:47
10 word "prediction," and I believe earlier you 01:47
11 explained that when you say -- when you wrote 01:47
12 in your email that it pays wrong, you actually 01:47
13 meant to say that it predicts incorrectly. 01:47

14 MS. KRIEG: Object to form. 01:47

15 A. Yes. 01:47

16 Q. In Roman II in your email, sticking 01:48
17 with Exhibit 116 -- 01:48

18 A. Arabic numeral 2? 01:48

19 Q. Yeah. So you refer to perfect 01:48
20 payment and then explain that that means 01:49
21 replication of model calibration. So again, 01:49
22 you're referring to the perfection of a payment 01:49
23 with reference to model calibration; is that 01:49
24 correct? 01:49

25 A. Correct. 01:49

1 Q. And does the issue that you're 01:49
2 discussing in 2 have anything to do with 01:49
3 extrapolation? 01:49

4 A. The entire underlying point of the 01:49
5 entire discussion's extrapolation. 01:49

6 Q. And in the paragraph numbered 2, what 01:49
7 is the connection with extrapolation? 01:49

8 A. It is again creating a hypothetical 01:49
9 world, so hypothetical world in which a plan 01:49
10 could perfectly submit like fee-for-service. 01:49
11 And again, in the assumptions that I operate 01:50
12 under in the presentation, that overreporting 01:50
13 is worse than underreporting. So if you assume 01:50
14 overreporting is greater than underreporting 01:50
15 and a plan were to submit precisely like 01:50
16 fee-for-service then got extrapolated against, 01:50
17 they would be paid differently than the model 01:50
18 calibration. It does not result in the payment 01:50
19 accuracy that they are looking to obtain 01:50
20 through a risk adjustment data validation with 01:50
21 extrapolation. 01:50

22 Q. Just using that very same example of 01:50
23 overreporting, and a plan submits precisely 01:50
24 like fee-for-service, wouldn't they be paid 01:50
25 differently than model calibration? 01:50

1 MS. KRIEG: Object to the form. 01:51

2 A. Under what circumstance? They submit 01:51

3 it exactly like fee for service and what? 01:51

4 Q. If they submit exactly like fee for 01:51

5 service and then delete unsupported codes, they 01:51

6 would be paid differently than the model 01:51

7 calibration even without extrapolation. 01:51

8 MS. KRIEG: Object to the form. 01:51

9 A. It would have to be on an 01:51

10 exceptionally large scale. And in theory, yes. 01:51

11 But that's if they -- everything they did, they 01:51

12 did no medical record reviews to gain 01:51

13 diagnoses, they did no home visits, they did no 01:51

14 provider education about submitting, they did 01:51

15 nothing to alter the -- to increase the level 01:51

16 of diagnoses, so this is a hypothetical plan, 01:51

17 the existence of which I am totally unaware, 01:51

18 but in some hypothetical plan that absolutely 01:52

19 this was -- could get perfect, pristine 01:52

20 fee-for-service data, this could theoretically 01:52

21 be a problem, yes. 01:52

22 Q. Well, I want you now to assume, sir, 01:52

23 in this hypothetical world that the coding 01:52

24 intensity adjuster that we talked about 01:52

25 earlier, I want you to assume that it fully 01:52

1 offsets any activities that the plan undertakes 01:52
2 to code more completely, chart reviews, home 01:52
3 visits, whatever, but they're completely offset 01:52
4 by the coding intensity adjuster. If the plan 01:52
5 were to submit only the codes of people who are 01:52
6 truly sick, to use your presentation example, 01:52
7 then that plan would be underpaid. 01:52

8 MR. HASEGAWA: Object to form. 01:52

9 MS. KRIEG: Object to form. 01:52

10 A. In a hypothetical world that you are 01:52
11 creating that does not exist because, as 01:53
12 discussed previously, at least the initial 01:53
13 implementation of the coding intensity adjuster 01:53
14 was in no way going to get you there, in that 01:53
15 world, in theory, yes. But that's hypothetical 01:53
16 again. 01:53

17 Q. Are you aware of any study in which 01:53
18 CMS has evaluated whether the coding intensity 01:53
19 adjuster fully offsets the plan activities that 01:53
20 are done to code more fully? 01:53

21 MS. KRIEG: Object to form. 01:53

22 A. And again, it's the same answer for 01:53
23 anything on Medicare Advantage. I really would 01:53
24 have no basis to know that. 01:53

25 MR. QURESHI: May we take a break? 01:54

1 THE VIDEOGRAPHER: Going off the 01:54

2 record. The time is 13:54. 01:54

3 (Recess taken.) 01:54

4 THE VIDEOGRAPHER: Going back on 02:15

5 the record. The time is 14:50. 02:15

6 BY MR. QURESHI: 02:15

7 Q. Mr. Grant, I want you to again assume 02:15

8 that the coding intensity adjuster fully 02:15

9 offsets all the activities that a plan might 02:15

10 undertake to code more fully. I also want you 02:15

11 to assume that a plan audits every one of its 02:15

12 charts and deletes every unsupported code. The 02:15

13 problem that you highlight in your slide 02:16

14 presentation, Exhibit 1017, would still exist 02:16

15 in that scenario? 02:16

16 MS. KRIEG: Object to form. 02:16

17 A. In my opinion, if you could have that 02:16

18 scenario, yes. 02:16

19 Q. The problem would still exist? 02:16

20 A. The problem would still exist if you 02:16

21 have that scenario. 02:16

22 Q. Okay. Now I'd like to change the 02:16

23 assumption slightly. Once again, the coding 02:16

24 intensity adjuster fully offsets all activities 02:16

25 that the plan undertakes that code more fully, 02:16

1 but now the plan audits 50 percent of a chart, 02:16
2 of its charts, and deletes the unsupported 02:16
3 codes in that set. Would the problem still 02:16
4 exist? 02:16

5 MS. KRIEG: Object to form. 02:16

6 A. Okay, we have multiple assumptions 02:16
7 right? So we have the assumption that 02:17
8 overcoding is the bias in the data. We have 02:17
9 the assumption of perfect adjustment for plan 02:17
10 coding activities. To a degree, it exists. It 02:17
11 exists to a smaller amount. 02:17

12 Q. Same assumption regarding the coding 02:17
13 intensity adjuster, but now the plan is 02:17
14 auditing 25 percent of its charts and deleting 02:17
15 the unsupported codes. Does the problem still 02:17
16 exist? 02:17

17 MS. KRIEG: Object to form. 02:17

18 A. Again, assumption of overcoding, 02:17
19 endemic in fee for service, and assumption of 02:17
20 plan -- plan coding activities being 02:17
21 100 percent offset in theory it exists to the 02:17
22 degree that diagnosis codes are deleted. But 02:18
23 at some point, that stops. It's not clear 02:18
24 where because there's still variability in 02:18
25 there. No plan submits exactly like fee for 02:18

1 service so, I mean, we are, like, creating a 02:18
2 very artificial world, but that artificial 02:18
3 world again doesn't exist. There is a world 02:18
4 full of errors. Errors are not the same level 02:18
5 of error between fee for service and any plan 02:18
6 even if you didn't touch the data let alone 02:18
7 after you've touched the data, and coding 02:18
8 intensity is not unitary among all plans. 02:18

9 Q. So Mr. Grant, are you suggesting 02:18
10 that, putting aside our assumptions, that there 02:18
11 are a lot of variables that would impact any 02:19
12 evaluation of the magnitude of the problem 02:19
13 you're highlighting in Exhibit 1017? 02:19

14 MS. KRIEG: Object to the form. 02:19

15 A. Oh, there are a large number of 02:19
16 variables. That is very simplified example 02:19
17 with a lot of assumptions baked into it and a 02:19
18 very simplified risk adjustment model. 02:19

19 Q. Are you able to itemize the various 02:19
20 real-world facts that you would need to know to 02:19
21 assess the extent of the problem? 02:19

22 MS. KRIEG: Object to the form. 02:19

23 A. On the fly, I would hesitate to 02:19
24 brainstorm every fact you would need to know. 02:19

25 Q. And I -- 02:20

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1	A. You would have to do a lot of	02:20
2	thinking and lay it all out and probably peer	02:20
3	review it before you would be -- I mean, I	02:20
4	don't trust myself on anything in risk	02:20
5	adjustment without checking with like five	02:20
6	other people on it because it's complicated and	02:20
7	there's a lot of factors that go into it.	02:20

8	Q. Okay. And I certainly don't expect	02:20
9	you to provide a comprehensive listing of all	02:20
10	real-world facts, but if you might highlight	02:20
11	some that are on your mind that would impact	02:20
12	the extent and existence of the problem in	02:20
13	Exhibit 1017.	02:20

14 MS. KRIEG: Object to the form. 02:20

15	A. So I think -- so there's, first of	02:20
16	all, just the real-world -- not knowing the	02:20
17	real-world fee-for-service coding issue that is	02:20
18	outlined here, so this is based on an	02:20
19	assumption of what that issue is. That is an	02:20
20	unproven assumption. So it is a perception,	02:21
21	but it may or may not be, if you were to study	02:21
22	it, borne out by reality.	02:21

23	Within any plan from year to year,	02:21
24	when you conduct repeated RADVs you see highly	02:21
25	variable results just within a plan. You have	02:21

1 sample variants in RADVs. You have all sorts 02:21
2 of things that go on. So it's really hard to 02:21
3 put your finger on like this is this plan's 02:21
4 coding propensity, this is that plan's coding 02:21
5 propensity, whether it's actual changes the 02:21
6 plans undertake. 02:21

7 And then plans through time are 02:21
8 changing. They code differently. They engage 02:21
9 their doctors differently. They have, you 02:21
10 know, the degree to which any plan depends upon 02:21
11 its own data for risk adjustment versus people 02:21
12 from other plans, people from fee for service. 02:21
13 There are all kinds of things that we talked 02:21
14 about in our discussions of this that created 02:21
15 numerous differences between plans. 02:22

16 So there isn't kind of like this is 02:22
17 how plans are, this is how fee for service is. 02:22
18 Fee for service is constantly change and plan 02:22
19 data is probably even more highly variable 02:22
20 between plans and even plans year to year 02:22
21 depending on the characteristics of their 02:22
22 population. 02:22

23 You also have health risk 02:22
24 differences. So health risk mix is not the 02:22
25 same in plans as in fee for service necessarily 02:22

1 and between plans there's still a significant 02:22
2 amount of variance if you look at the average 02:22
3 risk scores, and that is going to change how 02:22
4 accurate coding is. So that may be reflective 02:22
5 of different levels of accuracy of coding, 02:22
6 different levels of amount of coding, and some 02:22
7 may reflect underlying risk differences. But 02:22
8 even with underlying risk differences, then you 02:22
9 get coding differences. You have regional 02:22
10 variation in coding accuracy. So all kinds of 02:22
11 things could factor into this. 02:22

12 Q. I take it from your answer that, 02:22
13 among other things, it needs to be a very 02:23
14 highly individualized analysis. 02:23

15 MS. KRIEG: Object to the form. 02:23

16 A. Well, and I think -- well, it's more 02:23
17 complicated than that. I think an analysis is 02:23
18 very hard to do if you are talking about MA 02:23
19 data. Fee-for-service data at least has kind 02:23
20 of a common way of coming in and operates under 02:23
21 common sets of assumptions. 02:23

22 As soon as you start paying for 02:23
23 something and then plans are submitting based 02:23
24 on the fact you pay for it and plans engage in 02:23
25 individual development activities for diagnosis 02:23

1 development, so some go and do home visits, 02:23
2 others do not, you're going to get differences 02:23
3 right there just by what development 02:23
4 activities, how much influence they have over 02:23
5 their provider network. And being able to like 02:23
6 study a plan and understand what a plan's 02:23
7 coding intensity would be very difficult to do 02:23
8 to attribute diagnosis coding differences 02:23
9 specifically at a plan level to coding 02:23
10 intensity. 02:23

11 Q. Sir, you've talked a couple of times 02:24
12 today about the error rate in fee-for-service 02:24
13 data and your unawareness of a error rate ever 02:24
14 being calculated. Is that accurate? 02:24

15 A. Correct for diagnosis codes, similar 02:24
16 to risk adjustment. 02:24

17 Q. Okay. 02:24

18 A. Yes. 02:24

19 Q. Now, did CMS ever talk about doing 02:24
20 it? 02:24

21 MS. KRIEG: Object to the form. 02:24

22 And to the extent you're, you know, 02:24
23 asking for deliberative process, you 02:24
24 can't reveal that. 02:24

25 A. Yeah. So, I mean, I talked with CMS 02:24

1 when I was outside of CMS about doing that. So 02:24
2 we definitely engaged in discussions when I was 02:24
3 outside of CMS. And, you know, during that 02:24
4 time, I got significant pushback of like the 02:24
5 challenges with doing it, how to construct a 02:25
6 RADV-like study when you don't have a health 02:25
7 plan, for instance. 02:25

8 Q. This is during the 2008-to-2010 -- 02:25

9 A. Correct. 02:25

10 Q. -- period when you were with Health 02:25
11 Risk Partners? 02:25

12 A. Yeah. 02:25

13 Q. While you're with the government, 02:25
14 either prior to joining Health Risk Partners or 02:25
15 after, did you participate in any discussions 02:25
16 regarding the calculation of an error rate for 02:25
17 fee-for-service data? 02:25

18 MS. KRIEG: I'm going to instruct 02:25
19 you not to answer to the extent that it 02:25
20 reveals deliberative process. 02:25

21 MR. QURESHI: I just want to know 02:25
22 if he was in those discussions. 02:25

23 Q. Did you participate in any 02:25
24 discussions on that topic? Yes or no. 02:25

25 MS. KREISEL: I don't think CMS has 02:25

1 said anything publicly on this topic, 02:25

2 so -- 02:25

3 MS. KRIEG: We might be able to 02:25

4 handle this pretty quickly. Why don't 02:25

5 we take a break and step out? 02:25

6 MR. QURESHI: Okay. 02:26

7 THE VIDEOGRAPHER: Going off the 02:26

8 record. The time is 14:25. 02:26

9 (Recess taken.) 02:26

10 THE VIDEOGRAPHER: We are going 02:32

11 back on the record. The time is 14:32. 02:32

12 BY MR. QURESHI: 02:32

13 Q. Before we took the break, Mr. Grant, 02:32

14 I believe I'd asked a question about whether 02:32

15 you had participated in any discussions on the 02:32

16 calculation of a fee-for-service error rate 02:32

17 while you were with the government. 02:32

18 A. Yes. 02:32

19 Q. With whom? 02:32

20 THE WITNESS: I can say that too, 02:32

21 right? 02:32

22 MS. KRIEG: You can say who. 02:32

23 A. With my staff when I ran the risk 02:32

24 adjustment division, and with Tom Hutchinson, 02:32

25 who I worked for. 02:32

1 Q. Anyone else? 02:32

2 A. Yeah, I have -- that's who I recall. 02:32

3 I'm not going to say it was not with anybody 02:32

4 else. I'm not sure. 02:32

5 Q. And was this one meeting or several 02:32

6 meetings? 02:32

7 A. With Tom on one occasion. I don't 02:33

8 know how many times with staff. 02:33

9 Q. In either your meetings with 02:33

10 Mr. Hutchinson or with your staff were there 02:33

11 written materials distributed? 02:33

12 A. No. 02:33

13 Q. Do you recall the substance of those 02:33

14 discussions? 02:33

15 A. The general substance, yes. 02:33

16 Q. Okay. What do you recall about those 02:33

17 discussions? 02:33

18 MS. KRIEG: I object and instruct 02:33

19 him not to answer to the extent that it 02:33

20 would reveal deliberative process. 02:33

21 MR. QURESHI: Is he able to tell me 02:33

22 anything about those discussions? 02:33

23 Because your objection is qualified 02:33

24 because it's only to the extent that it 02:33

25 would reveal the deliberative process. 02:33

1 Q. What can you tell me that doesn't 02:33
2 reveal deliberative process? 02:34

3 MS. KRIEG: Well, he has the 02:34
4 recollection of the meetings. I believe 02:34
5 that they are protected by the 02:34
6 deliberative process from my 02:34
7 understanding of speaking with 02:34
8 Mr. Grant. 02:34

9 MR. QURESHI: Okay. So is he going 02:34
10 to answer or not? 02:34

11 MS. KRIEG: I'm instructing him not 02:34
12 to answer on my understanding that the 02:34
13 meetings are all protected by the 02:34
14 deliberative process. 02:34

15 Q. When did the meetings occur? I just 02:34
16 need an approximate time frame. 02:34

17 A. With Tom Hutchinson, it would have 02:34
18 been in 2008 just before I left. And with my 02:34
19 staff, when I ran the risk adjustment division. 02:34
20 I'm not sure when. 02:34

21 Q. Did you ever ask -- did you ever 02:34
22 speak with Mr. Hutchinson about that topic 02:34
23 after you left the government? 02:34

24 A. Frequently. 02:34

25 Q. And what do you recall about those 02:34

1 discussions? 02:34

2 A. That's kind of the nature of the 02:34

3 things we have been previously discussing, that 02:35

4 I was objecting to the RADV extrapolation being 02:35

5 applied without knowledge of what the 02:35

6 underlying error in the fee-for-service data 02:35

7 was. 02:35

8 Q. While you were with the government 02:35

9 and having these conversations with your staff 02:35

10 and Mr. Hutchinson, did the government commence 02:35

11 calculating a fee-for-service error rate? 02:35

12 MS. KRIEG: Object and instruct the 02:35

13 witness not to answer on the basis of 02:35

14 deliberative process privilege. 02:35

15 Q. In connection with these discussions 02:35

16 with Mr. Hutchinson and your staff, did the 02:35

17 government ever do a RADV-like audit of medical 02:35

18 records in a fee-for-service population? 02:35

19 MS. KRIEG: Object and instruct the 02:35

20 witness not to answer on the basis of 02:35

21 deliberative process privilege. 02:35

22 BY MR. QURESHI: 02:35

23 Q. Mr. Grant, I'm going to hand you a 02:36

24 document that's been marked -- 02:36

25 MS. KRIEG: Can we go off the 02:36

1 record for one minute? 02:36

2 MR. QURESHI: Sure. 02:36

3 THE VIDEOGRAPHER: Going off the 02:36

4 record. The time is 14:36. 02:36

5 (Recess taken.) 02:54

6 THE VIDEOGRAPHER: Going back on 02:54

7 the record. The time is 14:54. 02:54

8 MS. KRIEG: I think we may have 02:54

9 obviated the need to assert privilege on 02:54

10 some of the prior questions that you 02:54

11 asked. My understanding of the 02:54

12 questions that you wanted to ask 02:54

13 Mr. Grant are whether he's aware from 02:54

14 when he was in government of whether 02:54

15 there were discussions of the need for a 02:54

16 fee-for-service error rate, what that 02:54

17 error rate should be, and whether there 02:54

18 was ever a RADV-like review of 02:54

19 fee-for-service data. Is that correct? 02:54

20 MR. QURESHI: I believe those are 02:54

21 the questions I've asked thus far, yes. 02:54

22 MS. KRIEG: Okay. So we don't 02:54

23 think we need to assert privilege over 02:55

24 those questions if you want to go ahead 02:55

25 and ask him. 02:55

1 MR. QURESHI: Okay. 02:55

2 BY MR. QURESHI: 02:55

3 Q. Mr. Grant, during the period of time 02:55

4 you were at the government, prior to leaving to 02:55

5 go to HRP, did you learn of a fee-for-service 02:55

6 error rate? 02:55

7 A. No. 02:55

8 Q. Okay. Were there discussions about 02:55

9 calculating such an error rate? 02:55

10 A. Not to my knowledge. 02:55

11 Q. Your meetings with Mr. Hutchinson and 02:55

12 your staff involving the fee-for-service error 02:55

13 rate, did they include coming up with a 02:55

14 methodology to calculate that error rate? 02:55

15 MS. KRIEG: I think that is beyond 02:56

16 the scope of what we intended him to 02:56

17 testify on. 02:56

18 MR. QURESHI: So you're going to 02:56

19 assert privilege about it? 02:56

20 MS. KRIEG: Yes. 02:56

21 MR. QURESHI: Okay. Is there 02:56

22 anything about your meeting with 02:56

23 Mr. Hutchinson and your meetings with 02:56

24 staff about the fee-for-service error 02:56

25 rate that you will allow him to testify 02:56

1 about? 02:56

2 MS. KRIEG: Yeah, I think if you 02:56

3 ask specific questions we can go from 02:56

4 there rather than having him give a 02:56

5 narrative. 02:56

6 BY MR. QURESHI: 02:56

7 Q. What were those meetings about, 02:56

8 Mr. Grant? 02:56

9 A. They were about how we would conduct 02:56

10 RADV. 02:56

11 Q. And during discussions about how to 02:56

12 conduct RADV, the topic of fee-for-service 02:56

13 error rate came up? 02:56

14 A. It did. 02:56

15 Q. Who introduced it? 02:56

16 A. I did. 02:56

17 Q. And what was your position? 02:56

18 MS. KRIEG: And that's -- at that 02:56

19 point, we instruct him not to answer. 02:57

20 Q. Did others weigh in on that topic? 02:57

21 A. They did. 02:57

22 Q. Including Mr. Hutchinson? 02:57

23 A. I'm not sure that he did. 02:57

24 Q. All right. Now let's focus on the 02:57

25 period of time that you came back to the 02:57

1 government in 2010, July, after working for 02:57
2 Health Risk Partners. Were you aware of any 02:57
3 discussions involving a fee-for-service error 02:57
4 rate calculation by the government? 02:57

5 A. Only to the extent that, like, the 02:57
6 industry had raised the issue and I knew it was 02:57
7 a subject of discussion. 02:57

8 Q. Did anyone with the government talk 02:57
9 to you about what was being done with respect 02:57
10 to that issue? 02:57

11 A. No. 02:57

12 Q. In your presentation, Exhibit 1017 02:58
13 and the accompanying email 1016, you express a 02:58
14 certain position regarding the fee-for-service 02:58
15 error rate; is that correct? 02:58

16 A. That is correct. 02:58

17 Q. And that position includes the need 02:58
18 for such an error rate to be calculated. 02:58

19 A. That was my position, yes. 02:58

20 Q. Okay. Did your position change over 02:58
21 time? 02:58

22 MS. KRIEG: Object to form. 02:58

23 A. Again, I think that depends on what 02:58
24 time we're talking about whether this can -- is 02:58
25 subject for the -- 02:58

1 MS. KRIEG: Are you asking him his 02:58
2 personal opinion as he sits here today 02:58
3 or for discussions he had while he was 02:59
4 at CMS? 02:59

5 MR. QURESHI: I didn't ask about 02:59
6 discussions. I want to know if his 02:59
7 position on the need to calculate the 02:59
8 fee-for-service error rate changed over 02:59
9 time. 02:59

10 MS. KRIEG: Object to form. 02:59

11 A. Yeah, I don't know when I first 02:59
12 thought about it this but from the time I 02:59
13 thought about it, I think the general opinion 02:59
14 has not changed. I'm sure, like, precisely 02:59
15 what I think about it has obviously grown 02:59
16 through time, and understanding changes through 02:59
17 time. 02:59

18 Q. And when you were with the government 02:59
19 and had not yet left to join Health Risk 02:59
20 Partners, you had thought about it? 02:59

21 A. Yes. 02:59

22 Q. So when you were with the government 02:59
23 before joining Health Risk Partners, you had 02:59
24 the same opinion regarding a fee-for-service 02:59
25 adjuster rate or a fee-for-service error rate 02:59

1 that you then put in your email at 1016; 02:59

2 correct? 03:00

3 MS. KRIEG: Object to form. 03:00

4 A. In the context of extrapolated RADV, 03:00

5 yes. 03:00

6 Q. Okay. 03:00

7 A. So that was -- that was how -- that's 03:00

8 the context, yes. 03:00

9 (Exhibit No. 1019 was marked for 03:00

10 identification.) 03:00

11 BY MR. QURESHI: 03:00

12 Q. Mr. Grant, I'm going to hand you a 03:00

13 document that's been marked 1019. You're 03:00

14 welcome to flip through as much of it as you 03:00

15 like before I focus on a specific page, and 03:00

16 that's the page Bates numbered 201 in the lower 03:00

17 right-hand corner. And the Bates number for 03:00

18 the page that I'm most interested in is 03:01

19 CMS0006201. 03:01

20 MS. KRIEG: We object, for the 03:02

21 record, to the use of this. We can't 03:02

22 stop you, but we have made clear that 03:02

23 this is a deliberative document. 03:02

24 MR. QURESHI: Right. And I think 03:02

25 we've made our position clear that these 03:02

1 documents were released by the 03:02
2 government under FOIA and produced with 03:02
3 redactions, indicating that the 03:02
4 government had undertaken some analysis 03:02
5 of it before releasing it. And I think 03:02
6 when you asked for these documents to be 03:02
7 returned, we asked you to point to any 03:02
8 authority that allowed documents 03:02
9 released pursuant to FOIA to be 03:02
10 returned, and I don't know you've ever 03:02
11 provided any such authority. Is that 03:02
12 consistent with your recollection? 03:02

13 MS. KRIEG: That's consistent with 03:02
14 our recollection. 03:02

15 THE WITNESS: Okay. 03:05

16 BY MR. QURESHI: 03:05

17 Q. Have you had a chance to review 03:05
18 Exhibit 1019, sir? 03:05

19 A. I have. 03:05

20 Q. Have you ever seen it before? 03:05

21 A. I have not. 03:05

22 Q. Do you know who prepared it? 03:05

23 A. I have no idea. 03:05

24 Q. If you turn to the page that I 03:05
25 mentioned earlier, it ends in 201. 03:05

1 A. I'm there. 03:05

2 Q. There's a reference in the sixth 03:05

3 bullet point regarding an estimation of a 03:05

4 fee-for-service adjuster to be 8.1 percent. 03:05

5 Do you see that? 03:05

6 A. I do. 03:05

7 Q. Had you ever heard that before? 03:05

8 A. I have not. 03:05

9 Q. Do you understand what a 03:05

10 fee-for-service adjuster is? 03:05

11 MS. KRIEG: Object to the form. 03:05

12 A. I have my understanding of what it 03:05

13 is. 03:05

14 Q. What is your understanding? 03:05

15 MS. KRIEG: Object to the form. 03:05

16 A. That you make some form of adjustment 03:05

17 to RADV extrapolation results based on 03:05

18 underlying error rates in fee for service. 03:05

19 Q. Mr. Grant, if you look at the bullet 03:05

20 point sort of in the middle of the page that 03:06

21 begins "Risk adjustment." See that? 03:06

22 A. Oh, yes. 03:06

23 Q. I'll read that and then ask you some 03:06

24 questions about it. It says: "In risk 03:06

25 adjustment, we are estimating the average cost 03:06

1 of any given condition given the people who are 03:06
2 reported to have it." Did I read that 03:06
3 correctly? 03:06

4 A. You did. 03:06

5 Q. Do you agree with that statement? 03:06

6 MS. KRIEG: Object to the form. 03:06

7 A. In the context of average cost within 03:06
8 fee for service, yes. 03:06

9 Q. Okay. At any point in time did 03:06
10 anyone with the government consult with you 03:06
11 regarding the fee-for-service error rate or the 03:06
12 fee-for-service adjuster rate calculation? 03:06

13 A. With respect to this that was done 03:07
14 here? 03:07

15 Q. Yes, sir. 03:07

16 A. No. 03:07

17 Q. Putting aside 1019, Exhibit 1019, did 03:07
18 anyone in the government ever consult with you 03:07
19 about a methodology for calculating the 03:07
20 fee-for-service error rate? 03:07

21 A. Certainly, I discussed it with them 03:07
22 when I was outside. I suggested many different 03:07
23 ways it could be done. 03:07

24 Q. What about when you were with the 03:07
25 government? 03:07

1 A. Well, I came back in 2010. I haven't 03:07
2 really been working on MA. 03:08

3 Q. So the answer to my question is no? 03:08

4 A. So I don't recall. I mean, I might 03:08
5 have had an informal discussion with someone, 03:08
6 but I don't recall -- there was no formal 03:08
7 consultation where I sat down and said this is 03:08
8 what I would do and help them to structure it, 03:08
9 if that's what you mean. 03:08

10 Q. I mean both formal and informal sir. 03:08

11 A. I couldn't tell you on informal. 03:08
12 Formally, no. 03:08

13 Q. And informally, you don't remember 03:08
14 the names or times or anything like that? 03:08

15 A. I'm not even sure if we did. That's 03:08
16 what I'm saying. I know I had many informal 03:08
17 discussions outside. I'm not sure if any of 03:08
18 those continued informally when I was back. 03:08

19 Q. And who are the people with whom you 03:08
20 had those discussions while you were with HRP? 03:08

21 A. Tom Hutchinson, Jennifer Harlow, 03:08
22 probably Sean, Rebecca Paul, Sean Creighton. 03:08

23 Q. Do you recall anything about those 03:09
24 discussions with any of the individuals you 03:09
25 mentioned? 03:09

1 MS. KRIEG: Object to form. 03:09

2 A. Yes. 03:09

3 Q. What do you recall? 03:09

4 MS. KRIEG: Object to form. 03:09

5 A. As kind of all of the other exhibits 03:09

6 show, I was advocating the right way to do 03:09

7 extrapolation in RADV would be to start with 03:09

8 underlying errors that exist regardless in all 03:09

9 fee-for-service data. And that is kind of 03:09

10 baked into an actuarial model as an underlying 03:09

11 assumption that's not openly acknowledged and 03:09

12 you have to go from an underlying assumption 03:09

13 that there may be some error rate to knowing 03:09

14 what that error rate is. 03:09

15 And then we talked about the 03:09

16 challenges of doing it. They would protest 03:09

17 that it -- you know, we run RADV, we run it a 03:09

18 very specific way. They would tell me they go 03:10

19 to a health plan, they have the health plan get 03:10

20 the records, then the health plan picks the one 03:10

21 best medical record, etc., etc. And here we 03:10

22 have fee-for-service, we have no health plan, 03:10

23 just really -- I mean, the early objections was 03:10

24 you can't do something that is RADV-like 03:10

25 because it's a different world. It's 03:10

1 fee-for-service; it's not Medicare Advantage. 03:10

2 The same dynamics don't apply. 03:10

3 And I would suggest you could still 03:10

4 as a government go to people that you have paid 03:10

5 claims to and request medical records similar 03:10

6 to plans, and that was kind of the nature of 03:10

7 the give-and-take on that. 03:10

8 Q. Were these oral conversations or 03:10

9 written or both? 03:10

10 A. There were certainly obviously 03:10

11 written things I submitted. I don't know how 03:10

12 many different emails they may have received 03:10

13 from me versus oral conversations, but clearly 03:10

14 I submitted an email to them, at least one. 03:10

15 There were written documents that I was part of 03:10

16 producing that were also given to them, some, 03:11

17 at least. I don't know which all made it into 03:11

18 their hands. And then there were certainly a 03:11

19 number of verbal discussions with them. 03:11

20 Q. And when did those discussions cease? 03:11

21 MS. KRIEG: Object to form. 03:11

22 A. They ceased when I came back to 03:11

23 government, at least. It may have stopped 03:11

24 before that, but certainly when I came back to 03:11

25 work on the Affordable Care Act. 03:11

1 Q. So none of the people that you've 03:11
2 mentioned, Mr. Hutchinson, Ms. Harlow, Sean 03:11
3 Creighton, Rebecca Paul, ever reconnected with 03:11
4 you when you came back to talk about this 03:11
5 topic? 03:11

6 MS. KRIEG: Object to form. 03:11

7 A. This is what I kind of already said. 03:11
8 I don't know if they might have, you know, 03:11
9 asked me a follow-up question informally. 03:11
10 They're still acquaintances of mine so they may 03:11
11 have asked me informal follow-up questions. We 03:11
12 didn't have like a sit-down formal meeting to 03:12
13 go through this nor did we have -- like, I was 03:12
14 busy on the Affordable Care Act implementation. 03:12
15 That was basically a full-time-plus job. 03:12

16 Q. Do you recall exchanging emails with 03:12
17 them on this topic after you came back? 03:12

18 A. I do not. 03:12

19 Q. Mr. Grant, when we adjourned your 03:12
20 deposition on March 20 and then reconvened 03:12
21 today did you do anything in that interim time 03:12
22 period to prepare for the deposition? 03:12

23 MS. KRIEG: Object to form. 03:12

24 A. I met with the attorneys yesterday. 03:12

25 Q. Okay. Other than meeting with the 03:12

1 attorneys for the government yesterday, did you 03:12

2 do anything else? 03:12

3 A. No. 03:12

4 Q. Did you review any documents? 03:12

5 A. Oh, I -- well, I reviewed the 03:12

6 transcript of the original deposition. 03:12

7 Q. When did you do that? 03:13

8 A. Over this past weekend. 03:13

9 Q. Okay. And the original deposition, 03:13

10 you mean the portion of the transcript from 03:13

11 March 20? 03:13

12 A. Correct. 03:13

13 Q. Did you look at any of the exhibits? 03:13

14 A. I'm not -- 03:13

15 Q. During the March 20 deposition I 03:13

16 showed you a series of exhibits. 03:13

17 Do you remember that? 03:13

18 A. Right. I don't think I was given any 03:13

19 exhibits to take with me, I don't think. All I 03:13

20 got was a deposition in the -- 03:13

21 Q. And so you reviewed the transcript 03:13

22 over the weekend. Did you discuss the 03:13

23 transcript with your lawyers? 03:13

24 A. I did. 03:13

25 Q. And when did that discussion take 03:13

1 place? 03:13

2 A. Yesterday. 03:13

3 Q. Other than the activities you've 03:13

4 mentioned, did you do anything else to prepare 03:13

5 for today's deposition? 03:13

6 A. No. 03:13

7 Q. Okay. Did you talk to anyone at CMS 03:13

8 other than the attorneys? 03:14

9 Did you talk to anyone in the 03:14

10 government other than the people who are here 03:14

11 about your deposition? 03:14

12 A. No, I mean, other than the fact that 03:14

13 I had one, but not the contents. 03:14

14 Q. Mr. Grant, is Health Risk Partners, 03:15

15 is it still in existence? 03:15

16 A. No. 03:15

17 Q. Was it acquired by another entity? 03:15

18 A. Yes. 03:15

19 Q. Okay. What was that entity that 03:15

20 acquired it? 03:15

21 A. Verisk. 03:15

22 Q. Are you still in contact with any of 03:15

23 your colleagues who formerly worked at Health 03:15

24 Risk Partners? 03:15

25 A. I have infrequent contacts with some 03:15

1 of my former colleagues. 03:15

2 Q. Sir, while you were at Health Risk 03:15

3 Partners, 2008 through I think July 2010, did 03:15

4 that entity engage in chart review on behalf of 03:15

5 plans? 03:15

6 MS. KRIEG: Object to form. 03:15

7 A. Yes. 03:15

8 Q. And were you involved in that 03:15

9 activity? 03:16

10 MS. KRIEG: Object to form. 03:16

11 A. To the extent that it was again 03:16

12 something that we provided for clients. I 03:16

13 don't review charts, to be clear. I'm not a 03:16

14 clinical coder. But, you know, it was one of 03:16

15 the many services that we offered our clients. 03:16

16 It was an important part of our business, so to 03:16

17 the extent that there were kind of overriding 03:16

18 client issues around it. 03:16

19 Q. And can you describe for us during 03:16

20 this time period when you had some involvement 03:16

21 with chart review activities at Health Risk 03:16

22 Partners how chart review worked? 03:16

23 MS. KRIEG: Object to form. 03:16

24 A. Could you be more specific? 03:16

25 Q. I would like to understand the 03:16

1 process of how Health Risk Partners conducted 03:16
2 chart review during this time. 03:16

3 MS. KRIEG: Object to form. 03:16

4 A. Again, that's really super general. 03:16
5 I mean, I have not clear -- you know, with 03:16
6 regard to what we -- I mean, the basic process 03:16
7 of a chart review is you have a set of charts 03:17
8 you're looking for, depending on what the 03:17
9 purpose of the chart review is, or maybe you 03:17
10 already have the chart so you might be doing a 03:17
11 re-review of charts. There are many different 03:17
12 chart review projects. So you review a chart, 03:17
13 medical record. Well, you get the chart. You 03:17
14 get your hands on the chart. We would put it 03:17
15 into a Sharepoint data -- database, so it was a 03:17
16 scanned chart, and then we had an application 03:17
17 in which you could enter the codes found on the 03:17
18 chart. And then kind of what happens next 03:17
19 depends on what you're doing it for. Are you 03:17
20 supporting a RADV? Are you doing a coding 03:17
21 quality initiative to review somebody else's 03:17
22 coding? I mean, there's all sorts of different 03:17
23 ways you do chart review. 03:17
24 Q. And in the example that you provided, 03:17
25 it was an additive undertaking? There would be 03:18

1 a review of the chart electronically to add 03:18

2 codes? 03:18

3 A. I didn't say that. 03:18

4 MS. KRIEG: Object to form. 03:18

5 A. I did not say that. 03:18

6 Q. I'm asking. 03:18

7 A. You would do a review of a chart, and 03:18

8 again, it was -- you could be doing it to a 03:18

9 support a RADV, then you were trying to figure 03:18

10 out -- you would code the chart, then you were 03:18

11 trying to figure out the best medical record. 03:18

12 This is the back in the days of you got one 03:18

13 medical record to submit to get a RADV so 03:18

14 you're going through as many charts as possible 03:18

15 in a sample of 200 people trying to find the 03:18

16 one best medical record to submit to Medicare. 03:18

17 In the case of the question is, you 03:18

18 know, did Joanna code these charts correctly, 03:18

19 we hired her as a coding entity to code the 03:18

20 charts. Now we want you to do a quality 03:18

21 assurance check on Joanne's coding. It's like 03:18

22 we are blind coding the charts and then they're 03:18

23 going to look at the differences and say Joanna 03:18

24 found all these codes you didn't find, and then 03:19

25 we're going to discuss it with the prior 03:19

1 coders. Or we could be doing it to add; we 03:19
2 could be doing it to also delete. I mean, 03:19
3 there are any number of reasons you could do a 03:19
4 chart review. 03:19

5 Q. Do you recall any instance during 03:19
6 this time period in which Health Risk Partners 03:19
7 undertook a chart review solely to identify 03:19
8 additional codes for an MA plan? 03:19

9 MS. KRIEG: Object to form. 03:19

10 A. I'm pretty sure we probably did at 03:19
11 least one of those. 03:19

12 Q. At least one? 03:19

13 A. At least that was the general intent 03:20
14 of it, yeah. Whether we only added codes I 03:20
15 think is a more complex question. 03:20

16 Q. Do you understand what is meant by 03:20
17 the phrase "blind coding"? 03:20

18 A. I do. 03:20

19 Q. Okay. What do you understand that to 03:20
20 mean? 03:20

21 MS. KRIEG: Object to form. 03:20

22 A. It's basically meaning that you're 03:20
23 going to give a chart to a clinical coder with 03:20
24 no expectation as to what they may or may not 03:20
25 find in that chart. So they don't have a 03:20

1 roster of diagnosis codes that they're coding 03:20
2 against. 03:20

3 MR. QURESHI: Take a break? I 03:20
4 think we are close to wrapping up here. 03:20

5 THE VIDEOGRAPHER: Going off the 03:20
6 record. The time is 15:20. 03:20

7 (Recess taken.) 03:20

8 THE VIDEOGRAPHER: Going back on 03:30
9 the record. The time is 15:30. 03:30

10 BY MR. QURESHI: 03:30

11 Q. Mr. Grant, I believe you testified 03:30
12 earlier there was at least one plan for which 03:30
13 you recall HRP performed a chart review while 03:30
14 you were there; is that correct? 03:30

15 A. Well, there's -- 03:30

16 MS. KRIEG: Object to form. 03:30

17 A. -- more than one plan that we 03:30
18 performed chart reviews for, yes. 03:30

19 Q. Yeah. For the purpose of adding 03:30
20 codes, you recall at least one plan? 03:30

21 A. Yes. 03:30

22 Q. And do you recall the identity of 03:30
23 that plan? 03:30

24 A. I do. 03:30

25 Q. Okay. What is the identity? 03:30

Page 308

1 A. It was Coventry. 03:30

2 Q. And in connection with that project, 03:30

3 were you the relationship manager with 03:30

4 Coventry? 03:30

5 A. I was the overall relationship 03:31

6 manager for Coventry, like all clients. We had 03:31

7 different people that managed the -- the very 03:31

8 specific project because we had a chart 03:31

9 retrieval process and we had a coding process. 03:31

10 So our coder managed the relationship with 03:31

11 respect to the coding and our chart retrieval 03:31

12 person was managing the relationship with 03:31

13 respect to -- I mean, we had -- I was actually 03:31

14 over all of them so we also had a client rep 03:31

15 for each one. So my client services rep would 03:31

16 be the day-to-day, manage the relationship and 03:31

```
17 keep track of, like, chart retrievals and go 03:31
```

18 back and forth with them on, like, do you want 03:31

19 to pay 20 bucks for this inpatient chart kind 03:31

20 of thing. 03:31

21 Q. Is it fair to say that you were 03:31

22 involved in that engagement? 03:31

23 A. Right. And I oversaw all of our 03:31

24 client engagements. I was the senior vice 03:31

25 president for client services. I had client 03:31

1 services rep that did the day-to-day for any 03:31
2 client, and then if it was a special project 03:32
3 that involved special skills, we might have 03:32
4 people that were further managing the 03:32
5 relationship with respect to that skill set 03:32
6 because it required specialized skill. 03:32

7 Q. Understood. 03:32

8 The one instance in which you 03:32
9 recalled in which there were review of charts 03:32
10 to add codes, do you recall whether there were 03:32
11 any efforts to reconcile those codes against 03:32
12 previously submitted claims data? 03:32

13 MS. KRIEG: Object to form. 03:32

14 A. So from a coding perspective, we did 03:32
15 totally blind coding, so the coders had no idea 03:32
16 what was previously submitted. We did have the 03:32
17 capacity not to duplicate submit diagnoses. We 03:32
18 weren't going one for one and trying to look at 03:32
19 claims data and see if every claim was 03:32
20 one-for-one backed by a diagnosis on that date. 03:33

21 Q. Again, I'm focused on this one 03:33
22 project for Coventry. As part of this effort, 03:33
23 did HRP compare the codes identified in the 03:33
24 blind coding effort against the claims data 03:33
25 that was submitted by providers and delete 03:33

1 codes that HRP's coders did not identify? 03:34

2 MS. KRIEG: Object to form. 03:34

3 A. I'm not sure. I believe we may have 03:34

4 done -- not systematically, not on a 03:34

5 large-scale basis, but I believe there were 03:34

6 cases where we did. 03:34

7 Q. And at that time, did you have a 03:34

8 belief that not engaging in such a systematic 03:34

9 effort was improper? 03:34

10 MS. KRIEG: Object to form. 03:34

11 A. At that time, no. 03:34

12 Q. Okay. At that time, did you think it 03:34

13 was fraud? 03:34

14 MS. KRIEG: Object to form. 03:34

15 A. No, I did not knowingly participate 03:34

16 in the fraudulent activity. 03:34

17 MR. QURESHI: I have nothing else. 03:34

18 MS. KRIEG: Okay. I think 03:34

19 relator's counsel have questions. 03:34

20 EXAMINATION 03:35

21 BY MR. HASEGAWA: 03:35

22 Q. Mr. Grant, I'm Steve Hasegawa. I 03:35

23 represent the relator, Ben Poehling, in this 03:35

24 case. I want to follow up on the last series 03:35

25 of questions that Mr. Qureshi just asked you. 03:35

1 Was there ever an occasion when you 03:35
2 were in private practice that you advised a 03:35
3 client not to delete a code that your group had 03:35
4 determined was invalid? 03:35

5 A. Not that I can recall. 03:35

6 Q. Do you have an opinion on whether a 03:35
7 plan should delete codes that it determines are 03:35
8 invalid, specific codes? 03:35

9 A. A code that one -- that you know for 03:35
10 a fact the code is invalid? 03:35

11 Q. Yes. 03:35

12 A. You're supposed to delete it. 03:35

13 Q. When did you first hold that opinion? 03:35

14 A. Oh, when we created the system for 03:35
15 submitting diagnosis codes back in the early, 03:35
16 mid 2000s. 03:36

17 Q. Have you ever held a contrary 03:36
18 opinion? 03:36

19 A. Not with respect to codes where you 03:36
20 know they are wrong. 03:36

21 Q. Okay. I think you have in front of 03:36
22 you somewhere Exhibit 1017. It's the Risk 03:36
23 Adjustment For Dummies presentation. 03:36

24 A. Okay. 03:36

25 Q. Was this presentation based on 03:36

1 empirical data? 03:36

2 A. No. 03:36

3 Q. Is it based on any statistical study 03:36

4 of the characteristics of errors in 03:36

5 fee-for-service data? 03:36

6 A. No. 03:36

7 Q. Is there anything in the model that 03:36

8 calculates the effect of fee-for-service 03:36

9 undercoding errors on an MA plan payment? 03:36

10 A. In which model? 03:36

11 Q. In the model reflected in 03:36

12 Exhibit 1017, the hypothetical model. 03:36

13 A. No. 03:36

14 Q. On page 3, you are calculate the 03:36

15 effect on a hypothetical plan of certain 03:37

16 hypothetical fee-for-service overcoding errors; 03:37

17 is that correct? 03:37

18 A. That is correct. 03:37

19 Q. Could the effect on plan payment as 03:37

20 represented in the presentation be different if 03:37

21 you were also to include the effect of 03:37

22 undercoding errors? 03:37

23 A. Yes. 03:37

24 Q. And could the effect on plan payment 03:37

25 as represented in the presentation be different 03:37

1 depending on whether there were more or fewer 03:37
2 undercoding errors than overcoding errors in 03:37
3 the fee-for-service data? 03:37

4 A. Yes. 03:37

5 Q. Could the effect on plan payment as 03:37
6 represented in the presentation be different 03:37
7 depending on the characteristics of the MA 03:37
8 plan's members? 03:37

9 A. I mean, I think that's what I said 03:37
10 before too so that it -- every plan is going to 03:37
11 have -- even if you knew what happened in 03:37
12 fee-for-service, there are many different 03:37
13 variables that affect how that would look for a 03:37
14 plan, even if they submitted data some other 03:37
15 fee-for-service because they have underlying 03:38
16 differences in health risk. 03:38

17 Q. And could the conclusion of whether 03:38
18 the plan is or isn't underpaid as a result of 03:38
19 the fee-for-service errors, the hypothetical 03:38
20 errors reflected in here, be answered 03:38
21 differently depending on the plan's coding 03:38
22 intensity? 03:38

23 A. So you're saying like if somebody 03:38
24 is -- coding intensity, meaning other things 03:38
25 done to make them different than 03:38

1 fee-for-service. 03:38

2 Q. Yes. 03:38

3 A. The answers definitely vary with 03:38

4 variance in coding intensity. 03:38

5 Q. Okay. Can you turn, please, to 03:38

6 Exhibit 1018. About three pages in, it 03:38

7 begins -- the header is "Revised Draft," and 03:38

8 there's some red-lining, but ultimately it's 03:39

9 January 4, 2010. 03:39

10 Do you see that page? 03:39

11 A. I do. 03:39

12 Q. At the bottom there's a section that 03:39

13 begins "Extrapolation," that has the header 03:39

14 "Extrapolation," and the second-to-last 03:39

15 sentence of that paragraph reads "Therefore" -- 03:39

16 actually, can you read that sentence that 03:39

17 begins "Therefore"? 03:39

18 A. "Therefore, in order to extrapolate 03:39

19 accurately and fairly, it is critical for CMS 03:39

20 to take into account the level of inaccuracy or 03:39

21 documentation shortcomings in the data that 03:39

22 were used in the model," in red-line. "Methods 03:39

23 that could be used to accomplish this goal 03:39

24 include." 03:39

25 Q. When you worked on this document and 03:39

1 the other documents that are attached to this 03:39

2 Exhibit 1018, did you have any understanding 03:39

3 that you -- that AHIP was addressing anything 03:39

4 other than RADV extrapolation? 03:39

5 A. No. 03:39

6 Q. And do any of the concepts in here 03:39

7 apply in the absence of extrapolation? 03:39

8 A. I don't know. 03:40

9 Q. Okay. If you turn to -- there are a 03:40

10 number of different page numbers at the bottom, 03:40

11 but there's one that begins page 2 and it has a 03:40

12 couple of methods listed on it. I think it's 03:40

13 maybe the eighth page of the presentation, the 03:40

14 eighth page of the document. 03:40

15 A. Now are we in the clean version of 03:40

16 it? 03:40

17 Q. Yes. Sorry. 03:40

18 A. There's two versions. 03:40

19 Q. Yes. 03:40

20 A. It's the same document. 03:40

21 Q. You're right, you're right. I'm 03:40

22 looking at a page. It's the clean version. It 03:40

23 says page 2 at the bottom and it has a method 03:40

24 number 1 and the beginning of method number 03:40

25 2 -- 03:40

1 A. Yeah. 03:40

2 Q. -- at the bottom. Do you see that 03:40

3 page? 03:40

4 A. Yeah. 03:40

5 Q. Were either of these methods -- well, 03:40

6 were these methods proposals for the 03:40

7 determination of either the level of error 03:41

8 present in Medicare fee-for-service data used 03:41

9 to develop the Part C risk adjustment model or 03:41

10 proxies for that data? 03:41

11 A. Well, I would say very -- to be very 03:41

12 specific, the first I would say is to develop a 03:41

13 measure. Of course, it is an estimate, so 03:41

14 every estimate is somewhat of a proxy. But it 03:41

15 is considered to be a statistically valid error 03:41

16 example that would be considered a very valid 03:41

17 proxy that would represent what we thought was 03:41

18 the best estimate of a fee-for-service error 03:41

19 rate. 03:41

20 The other one is the other methods 03:41

21 that are suggested in here with option A and 03:41

22 option B under method 2 are, by definition, 03:41

23 complete proxies. They do not involve the use 03:41

24 of any fee-for-service data. They are using 03:41

25 other data sources to back into an answer. 03:41

1 Q. Okay. Were any of the methodologies 03:41
2 as you understood them at the time this 03:41
3 document was being drafted intended to provide 03:41
4 a basis to recalibrate the entire Part C risk 03:42
5 adjustment model? 03:42

6 A. No. 03:42

7 Q. Well, why not just use this, the data 03:42
8 acquired using these methods, to recalibrate 03:42
9 the model? 03:42

10 A. So the problem with this is -- so 03:42
11 calibration's a complex set of calculations 03:42
12 that take millions of individuals, but each 03:42
13 individual is getting an individualized 03:42
14 calculation. But then it's -- you're doing a 03:42
15 least squares regression so you're trying to 03:42
16 figure out the explanation across millions of 03:42
17 individuals, the best explanation that tells 03:42
18 you what each thing is worth. 03:42

19 What you have here is a very small 03:42
20 sample. So, you know, I think if we were to 03:42
21 take the example in the other document we 03:42
22 looked at and said even 10,000 people, which is 03:43
23 a much larger sample than a RADV sample, but 03:43
24 even if you took 10,000 people, compare them to 03:43
25 10 million people or 20 million people, they're 03:43

1 going to be overwhelmed by the people that were 03:43
2 not in the sample. 03:43

3 You have no basis on which to alter 03:43
4 anything about a person that's not in the 03:43
5 sample because again, you're running all these 03:43
6 calculations. You can't just make up -- you 03:43
7 can't just fudge for all the people that aren't 03:43
8 in the sample some kind of randomly assigned 03:43
9 error rate because the error rates are actually 03:43
10 not random. Our expectation is that if you 03:43
11 overreport a diagnosis that the error will be 03:43
12 that you would underpredict the cost; if you 03:43
13 underreport a diagnosis, that you would over -- 03:43
14 that you would have some other kind of error 03:43
15 that would occur. 03:43

16 And so that's only knowable for the 03:43
17 10,000 people you have, but you don't calibrate 03:43
18 the model on those 10,000. You're going to 03:43
19 calibrate the model on 10 million people, 03:43
20 20 million people. And then we'll get all 03:43
21 overwhelmed and you don't have a way to tell 03:44
22 out of the 20 million people who else needs to 03:44
23 have their data altered in the way that you 03:44
24 would alter data for the 10,000 that you know 03:44
25 facts about. 03:44

1 So this is useful for extrapolation, 03:44
2 which again is using a similar principle. You 03:44
3 know, you're having a 200-person sample speak 03:44
4 for an entire plan enrollment. So this is 03:44
5 taking, like, a similar thing, saying, okay, 03:44
6 we're going to extrapolate an error rate, so in 03:44
7 either -- you're taking two extrapolation 03:44
8 methodologies, and that makes sense. But 03:44
9 calibration and extrapolation are very 03:44
10 different things so you don't extrapolate in 03:44
11 calibration. 03:44

12 Q. Could you use either of the or any of 03:44
13 the methodologies in this document to determine 03:44
14 with precision the exact effect of all 03:44
15 fee-for-service errors on payments to each 03:44
16 individual MA plan? 03:44

17 A. Absolutely not. 03:44

18 Q. Is calibration of the Part C risk 03:45
19 adjustment model without any errors at all a 03:45
20 realistic goal within the government's 03:45
21 financial constraints? 03:45

22 A. No. 03:45

23 Q. Why not? 03:45

24 A. Well, I think for two fundamental 03:45
25 reasons. First of all, the model itself has a 03:45

1 large degree of unexplained costs built into 03:45
2 it. Forget errors that go into it. Even if 03:45
3 you have no errors, you again do not have 03:45
4 unitary costs across a population. 03:45

5 So every diabetic does not cost the 03:45
6 same amount. Even every diabetic of the exact 03:45
7 same age does not cost the same amount. So 03:45
8 you're going to have some explained costs, and 03:45
9 that's what you're trying to get to. You're 03:45
10 trying to predict large groups of people 03:45
11 accurately. You're not trying to predict one 03:45
12 individual's cost accurately. You're trying to 03:45
13 get a reasonable relative risk score for people 03:45
14 that have health conditions, people that don't 03:46
15 have health conditions, people that have a mix 03:46
16 of health conditions. And you accept the fact 03:46
17 that there is no perfect way to do that and 03:46
18 it's a predictive model in the first place. 03:46

19 So underlying that in addition to all 03:46
20 other errors you have some amount of error in 03:46
21 the model that is induced by fee-for-service 03:46
22 error of an unknown magnitude, and it would 03:46
23 cost I don't even know what to -- to review 03:46
24 over a billion claims to get them 100 percent 03:46
25 accurate, only then to still have a lot of 03:46

1 unexplained variation in the model, that the 03:46
2 gain is not worth the cost that you had put in 03:46
3 it because there would still be plenty of 03:46
4 unexplained variation that doesn't get fixed by 03:46
5 doing this elaborate study. 03:46

6 Q. Does the existence of error within 03:46
7 the MA Part C risk adjustment model mean that 03:46
8 MA providers can submit knowingly incorrect 03:46
9 data? 03:46

10 A. No. 03:46

11 Q. Have you ever held the opinion that 03:46
12 it does? 03:46

13 A. No. 03:46

14 Q. Have you ever told anybody that the 03:46
15 existence of error within the model means that 03:47
16 MA providers can submit knowingly incorrect 03:47
17 data? 03:47

18 A. And can we define terms? 03:47

19 Q. Okay. 03:47

20 A. When you say "knowingly incorrect," 03:47
21 it is a very specific submission of a very 03:47
22 specific data element saying that I know is 03:47
23 wrong. 03:47

24 Q. A specific diagnosis code that is 03:47
25 known to be wrong. 03:47

1 A. Right. No. 03:47

2 Q. Does the existence of error within 03:47

3 the model mean that MA providers can refuse to 03:47

4 correct errors that they didn't know about when 03:47

5 they were submitted but that they later learned 03:47

6 were errors? 03:47

7 A. No. 03:47

8 Q. Have you ever told anybody that the 03:47

9 existence of error within the model means that 03:47

10 MA providers don't need to correct errors that 03:47

11 they know about? 03:47

12 A. No. 03:47

13 MR. HASEGAWA: I have nothing 03:47

14 further. 03:47

15 MR. QURESHI: Short redirect. 03:47

16 EXAMINATION 03:47

17 BY MR. QURESHI: 03:47

18 Q. Mr. Grant, if HRP in the instance 03:47

19 that you highlighted did the blinded review and 03:47

20 didn't do a systematic reconciliation with the 03:48

21 provider-submitted codes, is it your 03:48

22 understanding that HRP knew it was submitting 03:48

23 specific bad codes? 03:48

24 MS. KRIEG: Object to form. 03:48

25 A. We were not submitting any bad codes. 03:48

1 Q. Were you facilitating the submission 03:48
2 of specific bad codes by the plan in that 03:48
3 instance? 03:48

4 MS. KRIEG: Object to form. 03:48

5 A. No. I think -- that's not how we 03:48
6 looked at it. We -- the codes were already in. 03:48
7 We were not doing a review to systematically do 03:48
8 a complete audit of a plan and determine the 03:48
9 accuracy of codes. We were sometimes asked to 03:48
10 do that, and if we were asked to do that, we 03:48
11 could do a very careful review. 03:48

12 I mean, it's a different style review 03:48
13 when you want to put in the effort that you 03:48
14 need to to absolutely make sure that a code is 03:48
15 backed up. 03:49

16 Q. The calibration of the Part C model 03:49
17 that you were discussing in response to 03:49
18 Mr. Hasegawa's questions, are you aware that 03:49
19 the model is calibrated using a sample? 03:49

20 A. I believe it's a very large sample, 03:49
21 but I believe it is a sample, yes. 03:49

22 Q. Do you know what the percentage size 03:49
23 of the sample is? 03:49

24 Is it 25 percent? 30 percent? 03:49

25 A. I'm not -- 03:49

1 MS. KRIEG: Object to form. 03:49

2 THE WITNESS: Oh, sorry. 03:49

3 A. I'm not sure what the size of the 03:49

4 sample is. 03:49

5 Q. I see. Is it the CERT sample, 03:49

6 C-E-R-T? 03:49

7 A. Again, I do not know what sample is 03:49

8 used to calibrate the model. 03:49

9 Q. Did your responses to Mr. Hasegawa's 03:50

10 questions assume that there was no sampling 03:50

11 occurring? 03:50

12 MS. KRIEG: Object to form. 03:50

13 A. No. 03:50

14 Q. Have you ever heard that it's -- the 03:50

15 CERT sample is a 5 percent sample? Have you 03:50

16 ever been made aware of that? 03:50

17 A. I've heard of the 5 percent sample. 03:50

18 I haven't heard it called the CERT sample. 03:50

19 Q. And are you aware that it's the 03:50

20 5 percent sample that's used to calibrate the 03:50

21 model? 03:50

22 MR. HASEGAWA: Object to form. 03:50

23 MS. KRIEG: Object to form. 03:50

24 A. I -- it may have been. I'm not sure 03:50

25 if it always has been. It may have been. It 03:50

1 may still be. I don't know. 03:51

2 Q. And would that impact the responses 03:51

3 you provided to Mr. Hasegawa's questions? 03:51

4 MS. KRIEG: Object to form. 03:51

5 A. No. 03:51

6 MR. QURESHI: I have nothing 03:51

7 further. 03:51

8 MS. KRIEG: The government has 03:51

9 nothing, okay, so the deposition is 03:51

10 closed. 03:51

11 THE VIDEOGRAPHER: This marks the 03:51

12 end of the deposition. Going off the 03:51

13 record at 10:51. 03:51

14 03:51

15 (Deposition adjourned at 10:51 p.m.) 03:51

16

17

18

19

20

21

22 Subscribed and sworn to before me

23 this ____ day of _____, 20__.

24

25 NOTARY PUBLIC

1 C E R T I F I C A T E

2 DISTRICT OF COLUMBIA:

3 I, MARY ANN PAYONK, shorthand reporter,
4 do hereby certify that the witness whose
5 deposition is hereinbefore set forth was duly
6 sworn, and that such deposition is a true,
7 correct, and full record of the testimony
8 given.

9 I further certify that I am not related
10 to any of the parties to this action by blood
11 or by marriage, and that I am in no way
12 interested in the outcome of this matter.

13 IN WITNESS WHEREOF, I have hereunto set
14 my hand this 29th day of May, 2018.

15

16

17 _____
MARY ANN PAYONK, Shorthand Reporter

18

19

20

21

22

23

24

25

1 - INDEX TO WITNESSES -

2 WITNESS PAGE

3 JEFFREY GRANT

4 Examination by Mr. Qureshi 159, 322

5 Examination by Mr. Hasegawa 310

6

7 - INDEX TO EXHIBITS -

8 NO. DESCRIPTION MARKED

9 Exhibit No. 1014 2008 document re: 167

10 rates

11 Exhibit No. 1015 Document re: coding 180

12 intensity adjustment

13 Exhibit No. 1016 5/29/2009 email 191

14 Exhibit No. 1017 PowerPoint 224

15 presentation

16 Exhibit No. 1018 Email and attached 242

17 AHIP Issue Paper

18 Exhibit No. 1019 Document re: risk 293

19 adjustment

20

21 - INDEX TO CERTIFIED QUESTIONS -

22 Page/Line Text of the Question

23

24 286 1 What can you tell me that doesn't

25 reveal deliberative process?

1 INDEX TO CERTIFIED QUESTIONS (Cont'd.)

2 Page/Line Text of the Question

3 287 8 While you were with the
4 government and having these
5 conversations with your staff and
6 Mr. Hutchinson, did the government
7 commence calculating a
8 fee-for-service error rate?

9 287 15 In connection with these
10 discussions with Mr. Hutchinson and
11 your staff, did the government ever
12 do a RADV-like audit of medical
13 records in a fee-for-service
14 population?

15 289 11 Your meetings with Mr.
16 Hutchinson and your staff involving
17 the fee-for-service error rate, did
18 they include coming up with a
19 methodology to calculate that error
20 rate?

21 290 17 And what was your position?

22

23 <<INDEX END>>

24

25

1 NAME OF CASE: USA vs. UnitedHealth Group

2 DATE OF DEPOSITION: May 16, 2018

- 3 1. To clarify the record.
4 2. To conform to the facts.
5 3. To correct transcription error.

6 Page _____ Line _____ Reason _____
7 From _____ to _____

8 Page _____ Line _____ Reason _____
9 From _____ to _____

10 Page _____ Line _____ Reason _____
11 From _____ to _____

12 Page _____ Line _____ Reason _____
13 From _____ to _____

14 Page _____ Line _____ Reason _____
15 From _____ to _____

16 Page _____ Line _____ Reason _____
17 From _____ to _____

18 Page _____ Line _____ Reason _____
19 From _____ to _____

20 Page _____ Line _____ Reason _____
21 From _____ to _____

22 _____
23

24 JEFFREY GRANT

25 SUBSCRIBED AND SWORN TO BEFORE ME

THIS _____ DAY OF _____, 2018.

(Notary Public)

(Notary Public)

My Commission expires: _____

25

EXHIBIT 8

Medicare Advantage risk score primer: What you need to know about diagnoses supporting risk scores and revenue payment timing

Brad Piper, FSA, MAAA
Hillary Millican, FSA, MAAA



Risk scores are a crucial area of focus for successful Medicare Advantage (MA) plans because changes in risk scores directly affect plan revenue. However, risk scores are complex and are influenced by many factors, which can be confusing to those who are new to MA risk score development. This article will answer the following questions:

- What time period of diagnoses supports risk scores?
- When are revenue payments made?
- Who submits diagnoses used to create risk scores?
- Why is member retention critical for the success of a Medicare Advantage organization (MAO)?

MA revenue payments are risk-adjusted

The Centers for Medicare and Medicaid Services (CMS) risk-adjusts MA revenue payments to MAOs by member-specific risk scores. The primary goal of risk adjustment is to create a market where plans and providers compete on quality and efficiency, not risk selection. MAOs submit diagnoses to CMS to create member risk scores, which are then used to calculate member-specific revenue payments. These risk-adjusted amounts typically make up the majority of a plan's revenue.

Diagnosis submission and revenue payment timing are on detailed schedules

Risk-adjusted revenue payments for a given plan year are based on diagnoses submitted for the prior plan year. Using the 2018 bid year as an example, final 2018 risk scores are based on calendar year (CY) 2017 diagnoses. The initial payments for 2018 are paid before all diagnoses are due for 2017, so payments are first paid prospectively using diagnoses from an earlier time period (in this example, July 2016 through June 2017) and then retroactively adjusted based on CY 2017 diagnoses to true up any payment discrepancies. The figures below illustrate this timing.

PROSPECTIVE PAYMENTS

Figure 1 contains a timeline of prospective payments and the diagnosis dates of service on which they are based.

- CMS makes prospective payments for January 2018 through July 2018 based on July 2016 through June 2017 diagnoses submitted through mid-September 2017.
- CMS makes prospective payments for August 2018 through December 2018 based on January 2017 through December 2017 diagnoses submitted through early March 2018.

FIGURE 1: PROSPECTIVE PAYMENTS - 2018 RISK SCORES

	2016		2017				2018			
	JULY-SEPT	OCT-DEC	JAN-MAR	APR-JUNE	JULY-SEPT	OCT-DEC	JAN-MAR	APR-JUNE	JULY-SEPT	OCT-DEC
JAN-JUL INITIAL PAYMENT										
DATES OF SERVICE	Dates of Service for 2018 Jan-July Risk Scores									
SUBMISSION DEADLINE					X					
PAYMENT MONTHS							Prospective Payments			
AUG-DEC INITIAL PAYMENT										
DATES OF SERVICE			Dates of Service for 2018 Aug-Dec Risk Scores							
SUBMISSION DEADLINE							X			
PAYMENT MONTHS									Prospective Payments	

FIGURE 2: RETROACTIVE PAYMENTS - 2018 RISK SCORES

	2017				2018				2019		
	JAN-MAR	APR-JUNE	JULY-SEPT	OCT-DEC	JAN-MAR	APR-JUNE	JULY-SEPT	OCT-DEC	JAN-MAR	APR-JUNE	JULY-SEPT
MIDYEAR PAYMENT											
DATES OF SERVICE	Dates of Service for 2018 Midyear Risk Scores										
SUBMISSION DEADLINE					X						
PAYMENT MONTHS							X				
FINAL PAYMENT											
DATES OF SERVICE	Dates of Service for 2018 Final Risk Scores										
SUBMISSION DEADLINE									X		
PAYMENT MONTHS											X

RETROACTIVE PAYMENTS

Figure 2 contains a timeline of retroactive payments. All payments are based on diagnoses from January 2017 through December 2017.

- CMS makes retroactive payments for January 2018 through July 2018 in August 2018. These retroactive payments are based on CY 2017 diagnoses submitted through March 2018. This is also called the midyear sweep payment.
- CMS makes the final retroactive payments for January 2018 through December 2018 in July 2019. These retroactive payments are based on CY 2017 diagnoses submitted through January 2019. This is also called the final sweep payment.

Payments in 2018 are initially paid based on a time period that includes 2016 diagnoses. However, through retroactive adjustments, the final 2018 payments to the plan are ultimately based only on CY 2017 diagnoses. If the risk scores based on CY 2017 diagnoses are higher than risk scores used for initial payment, the MAO will receive additional revenue. If the risk scores based on CY 2017 diagnoses are lower than risk scores used for initial payment, the MAO will be required to return a portion of the initial revenue. Ultimately, the diagnoses for the prior year control the risk scores, and thus the revenue, in the following year.

The timing of payments and diagnosis submission dates shown in the figures above are based on historical practice. Though not typical, these dates can be modified by CMS. Therefore, MAOs should monitor announcements released by CMS for adjustments to these dates. Please refer to the Medicare Managed Care Manual, Chapter 7 – Risk Adjustment, for more information.¹

Control of the diagnoses from the prior year varies by member source

As discussed above, risk scores are based on diagnoses from the prior year. If an MAO wants to determine who controls a member's current risk score, and thus the MAO's current revenue, the MAO should examine who enrolled that member in the prior year.

The four primary sources of membership for MA plans include:

1. Existing MA members within the MAO
2. Members transitioning from other MAOs
3. Members converting from traditional fee for service (FFS)
4. Members who age into Medicare

1. Existing MA members within the MAO: For a member who remains in the MA plan from one year to the next, the MAO that influences the member's risk score receives the revenue for that member the next year. If an MAO wants to optimize its revenue, the MAO should carefully review the submitted diagnosis codes for the prior year and submit any missing diagnosis codes to CMS. To remain compliant, the MAO must also remove any inappropriate codes. "Late" submission of diagnoses is permitted as long as they are submitted within the required time period described above. Retaining these members is paramount to success. A significant MAO investment is required to submit complete and accurate risk score information, and the return on that investment is quickly diminished if members select another MAO or traditional FFS Medicare during open enrollment.

2. Members transitioning from other MAOs: In contrast, risk scores for members who come from another MA plan are initially determined by the prior MAO. The new MA plan is subject to the diagnosis submission efforts, also known as coding efforts, of the prior MA plan. If the prior MAO invested substantial effort to ensure that the member was coded properly and then the member changes MAOs, the new MAO

¹ CMS. Medicare Managed Care Manual: Chapter 7 – Risk Adjustment. Retrieved August 19, 2017, from <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf>.

will receive the increased revenue the next year. Conversely, if the prior MAO did not put much effort into capturing and submitting a member's diagnosis codes, the payment may be insufficient. However, per its June 20, 2017, memo,² CMS specifies that "organizations are able to submit diagnosis codes to RAPS [risk adjustment processing system] for years when a beneficiary was enrolled in a plan of a different parent organization (but not if the beneficiary was in Fee-for-Service Medicare the year before)." Thus, the new MAO has an opportunity to provide diagnosis information that the prior MAO did not submit.

3. Members converting from traditional FFS: Members who come from traditional FFS typically have lower risk scores than MA members. This is not necessarily because members from FFS have fewer diagnoses but instead because MAOs educate their providers on the importance of proper and complete diagnosis coding. In some cases, MAOs agree to pay incentives to providers, which are in part based on appropriate risk score coding; these agreements financially incentivize providers to submit complete and accurate diagnoses. Aside from Medicare demonstrations such as the Medicare Shared Savings Program (MSSP), traditional FFS physicians are paid by the services performed and not how completely the members are coded. These members usually have the largest potential for improvement in their risk scores. However, just like members coming from other MA plans, the effort the plan puts into submitting member diagnoses will not affect the payment for that member until the following year.

4. Members who age into Medicare: Members who age into Medicare do not receive risk scores based on their diagnoses information until they have a full calendar year of Medicare eligibility. Until that time, a member receives a default new enrollee risk score. This means a member who turned 65 in February 2017 will receive this default risk score for 2017 and 2018. The member's 2019 risk score will be based on diagnoses submitted by the MAO in 2018. In this case, a plan may need to wait nearly two years to receive a payment based on the member's specific diagnoses.

Retention is key to realizing a return on a risk score investment

Increasing risk scores through appropriate diagnosis coding and submission requires significant effort from the MAO, which does not translate into an actual increased revenue payment until roughly a year later. Even if the MAO has a long-term strategy to improve risk scores, members can leave the

plan and the gains from any risk score improvement investment by the MAO will be realized by another MAO (or not at all). MAOs must be focused on retaining members to help reduce the likelihood that the MAO will lose these optimally coded members to competitors. Retention is important to MAOs for many reasons, not the least of which is reaping the significant rewards of efforts to properly code member diagnoses.

Please note that the opinions stated in this article are those of the authors and do not represent the viewpoint of Milliman.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Brad Piper and Hillary Millican are members of the American Academy of Actuaries and meet the qualification standards for sharing the information in this article. To the best of their knowledge and belief, this information is complete and accurate. They relied on CMS for select information contained in this paper.

This information is intended to discuss fundamental MA risk score concepts including dates of service of diagnoses that support risk scores, revenue payment timing, and which organization submits diagnoses for each member type. This information highlights select areas and is not an exhaustive discussion of MA risk scores or payments. This information may not be appropriate, and should not be used, for other purposes. Milliman does not intend to benefit and assumes no duty of liability to parties who receive this information. Any recipient of this information should engage qualified professionals for advice appropriate to its own specific needs.

For additional information on risk scores, please visit <http://www.milliman.com/insight/healthcare/>.

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2 CMS memo dated June 20, 2017. Subject: RAPS Submission of Data Collection Year Diagnosis Codes.

EXHIBIT 9



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**Monday, August 6 –
Tuesday, August 7, 2012**

Encounter Data



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Policy, Monitoring, and Compliance



Module 3 (Professional Submission) and Module 4 (Institutional Submission) provide detailed guidance on proxy data submission requirements



If MAOs and other entities have any questions about submission of proxy claim information, with regard to any situation outlined in the Participant Guide, contact CMS at eds@ardx.net

2.4.3 Chart Reviews

Chart reviews may be performed by MAOs and other entities for the purpose of diagnosis code validation. Because diagnoses drive risk adjustment, all chart review encounters must be supported by the medical record. MAOs and other entities may submit chart reviews that are linked to an original encounter stored in EDS (linked ICN chart reviews) or chart reviews that are not linked to an original encounter stored in Encounter Operational Data Store (EODS) (unlinked ICN chart reviews). All chart review encounters should be flagged by MAOs and other entities.



Module 3 (Professional Submission) and Module 4 (Institutional Submission) provide detailed guidance chart review submission

2.4.4 Bundled Claims

Bundled claims refer to the bundling of claim lines meeting the definition of the National Correct Coding Initiative (NCCI) or the bundling of claim lines in adjudication to match the benefit structure of the MAO or other entity. The NCCI was developed to promote correct coding methodologies and to control improper coding. The purpose of the NCCI edits is to prevent improper payment when incorrect code combinations are reported. Only claims bundled using the NCCI will be accepted for encounter data submission. The Coding Policy Manual found on the CMS website can be utilized by MAOs and other entities as a general reference tool.

2.4.5 Minimum Data Elements

Minimum data elements are required to properly process and price encounters. MAOs and other entities must include at least the minimum data elements when submitting encounter data, including paper, 4010, and foreign provider generated encounters, as well atypical provider submissions. The EDS Minimum Data Elements and EDS Companion Guides provide details on the required elements.



www.csscooperations.com

2.4.6 Home Health Submission

EDS is not currently accepting Home Health encounter submissions from MAOs and other entities. CMS will provide further guidance on the submission of this data in the near future.



Example

Happy Health Plan received a paper claim from Dr. Smith, which did not contain an NPI. In order to convert the paper claim submission into an encounter, Happy Health Plan must include a Billing Provider NPI default value of 1999999984, and the required minimum data elements. In addition, Happy Health Plan must include Loop 2300, PWK01='OZ' and PWK02='AA'.

3.5.6 4010 Submission

MAOs and other entities submitting encounters generated as a result of a 4010 submission in which the provider's NPI was not provided may utilize the appropriate default NPI, as well as Loop 2300, PWK01='PY', PWK02='AA'. Use of PWK segment in coordination with the default NPI will allow the EDPPPS to flag the encounter appropriately for future analysis. 4010 generated encounters will price according to the data provided on the encounter and the diagnoses will be eligible for risk adjustment extraction.

It is important to note that failure to utilize the PWK segment appropriately will cause the encounter to be processed as an atypical provider submission, resulting in the encounter bypassing the pricing module and deeming the diagnoses ineligible for risk adjustment.



Example

Green Plan received a 4010 submission from Dr. Washington, which did not contain an NPI. In order to convert the 4010 submission in an encounter, Green Plan must include a Billing Provider NPI default value of 1999999984, and the required data elements. In addition, Green Plan must include Loop 2300, PWK01='PY' and PWK02='AA'.

3.5.7 Chart Reviews

Historically, chart reviews have been performed by MAOs and other entities for the purpose of obtaining diagnosis codes that were either not originally submitted by the provider or were submitted by the provider in error. Based on this information, CMS collects chart review data as a part of the encounter data process. All chart review encounter data must be from an appropriate provider "specialty," from an allowed provider type (inpatient, outpatient, physician), and within 25 months of the data collection period. Further, all diagnoses codes submitted through chart review must be based on a face-to-face visit and supported by a medical record.

Because not all chart reviews are able to be linked back to a previously adjudicated claim in the MAOs adjudication system, CMS allows for MAOs and other entities to submit chart review encounters that are linked to a previously submitted and accepted encounter (linked ICN) and chart review encounters that are not linked to a previously submitted and accepted encounter (unlinked ICN). All chart reviews, whether linked to an ICN or unlinked, must be able to be validated through the medical record.



The term "chart review" refers to all medical reviews

3.5.7.1 Chart Review Submission

MAOs and other entities are required to use the 837-P format to submit Professional encounters that are a result of chart reviews. MAOs and other entities can perform the following actions through a chart review encounter submission:



- Add specific diagnoses to full encounters
- Delete specific diagnoses from a full encounter
- Replace one chart review encounter with another chart review encounter
- Add and delete diagnoses on a single encounter

The chart review submission option must not be used to replace a full encounter.

To identify the data populated on the encounter is the result of a chart review, the PWK segment, PWK01='09', PWK02='AA' within the 2300 Loop must be used. Submission of the following elements will indicate the encounter is a result of a chart review:

- Report Type Code, PWK01='09'
- Attachment Transmission Code, PWK02='AA'
- Reference Identification Qualifier, REF01='F8'(if the chart review is linked to an ICN)
- Claim Original Reference Number, REF02=ICN of the previously accepted encounter (if the chart review is linked to an ICN)
- Claim Frequency Code, CLM05-3 = '1' for original



MAOs and other entities should refer to the 837-P Companion Guide for linked ICN and unlinked ICN chart review business cases

CMS has defined the minimum data elements required to submit any encounter data. In doing so, it is assumed that chart reviews will not always provide the minimum data elements, specifically the procedure code, and possibly the POS. MAOs and other entities may provide any valid procedure code and POS in order to pass translator and CEM level editing.



Please see section 2.4.2 of the Policy, Monitoring, and Compliance Module for instructions on submitting proxy claim information.

For chart review data that can be linked to an encounter but the encounter is in error (i.e., not yet accepted by EDS), MAOs and other entities must wait until the error is corrected and is accepted by EDS. If a claim has exceeded the 13-month timely filing rule and was not accepted by EDS, yet the chart review data can be linked to the claim, MAOs and other entities must submit the encounter as an unlinked chart review encounter. All chart review encounters must be submitted within 25 months of the beginning of the data collection period.

3.5.7.2 Chart Review – Addition of Specific Diagnoses

One function of a chart review submission is to add at least one (1) diagnosis code obtained through a medical record review/chart review. MAOs and other entities may use either the linked ICN or unlinked ICN method, pending if a claim was previously submitted and accepted in the EDPPPS. In order to add at least one (1) diagnosis code as a result of a chart review, MAOs and other entities must include the minimum data elements.

When an MAO or other entity submits a linked chart review encounter containing PWK01='09', PWK02='AA' in the 2300 loop because at least one (1) additional diagnosis code was found in the medical record, only the minimum data elements and the diagnosis code that was not included on the previously submitted and accepted encounter are permitted to be included on the chart review encounter. MAOs and other entities must include the following data as well as the minimum data elements required for all encounter data submissions:



- 2300 CLM05-3 = '1' = Original
- 2300 PWK01 = '09'
- 2300 PWK02 = 'AA'
- 2300 REF01 = 'F8'
- 2300 REF02 = ICN from accepted and stored encounter
- 2300 HI01-1 = 'BK' (first diagnosis code only)
- 2300 HI01-2 = **Added diagnosis code(s)**



Example

A-One Health Plan performed a quarterly medical record review at Health Care Associates and discovered that diagnosis 402.10 – Benign Hypertensive Heart Disease without Heart Failure was not included on the original encounter submission for Gwendolyn Nguyen. A-One Health Plan must submit a linked chart review, with Loop 2300 CLM05-3='1', PWK01='09', PWK02='AA', REF01='F8', REF02 must include the original accepted ICN, HI01-1='BK', and HI01-2= 402.10 (the new diagnosis code). In addition, all required minimum data elements must be submitted.

3.5.7.3 Chart Review – Deletion of Specific Diagnoses

MAOs and other entities may need to delete diagnoses from a previously submitted and accepted encounter stored in EODS as a result of a chart review. While guidelines are established to accommodate deletion of specific diagnoses, it is critical to note that all minimum required data elements for the submission of 5010 encounter data must be submitted for linked and unlinked chart review deletion submissions. In order to delete diagnoses from an accepted encounter stored in EODS as a result of a chart review, MAOs and other entities must include the following data, as well as the minimum data elements required for all encounter data submissions:

- 2300 CLM05-3 = '1' = Original
- 2300 PWK01 = '09'
- 2300 PWK02 = 'AA'
- 2300 REF01 = 'F8'
- 2300 REF02 = ICN from accepted and stored encounter (for linked chart review)
- 2300 HI01-1 = 'BK' (first diagnosis code only)
- 2300 HI01-2 = **Deleted diagnosis code(s)**
- 2300 REF01 = 'EA'
- 2300 REF02 = '8' (Indicates the deletion of diagnosis code listed HI01-2)



Example

During a medical record review, Statewide Community Care is reconciling chart review data and finds that Dr. Aron Martinez has submitted diagnosis 429.3 - Cardiomegaly in error for patient, Mr. Ian Richards. Statewide Community Care must submit a linked chart review with Loop 2300 CLM05-3='1', PWK01='09', PWK02='AA', REF01='F8', REF02 must include the original accepted ICN, HI01-1='BK', and HI01-2= 429.3 (the diagnosis being deleted), REF01='EA', REF02='8'. In addition, all required minimum data elements must be submitted.



3.5.7.4 Chart Review – Additions and Deletions of Specific Diagnoses on a Single Encounter

MAOs and other entities may need to add diagnoses, as well as delete diagnoses from a previously submitted and accepted encounter stored in EODS as a result of a chart review. In order to do so, MAOs and other entities must include the following data and the minimum data elements required for all encounter data submissions:

- 2300 CLM05-3 = '1' = Original
- 2300 PWK01 = '09'
- 2300 PWK02 = 'AA'
- 2300 REF01 = 'F8'
- 2300 REF02 = ICN from accepted and stored encounter (for linked chart review)
- 2300 HI01-1 = 'BK' (first diagnosis code only)
- 2300 HI01-2 = **Added diagnosis code(s)**
- 2300 REF01 = 'EA'
- 2300 REF02 = Deleted diagnosis code(s)



Example

Fresh Perspective Health Plan performed a random medical record review for Dr. Arlene Zynga and located a chart discrepancy for patient, Ms. Tracy Bennett. The diagnosis of 714.0 – Rheumatoid Arthritis was not valid for the service Dr. Zynga provided. Fresh Perspective Health Plan also noted in Ms. Bennett's medical record that diagnosis 403.90 – Kidney Disease due to Hypertension was omitted from the original encounter submission. Fresh Perspective Health Plan must submit a linked chart review with Loop 2300 CLM05-3='1', PWK01='09', PWK02='AA', REF01='F8', REF02 must include the original accepted ICN, HI01-1='BK', HI01-2=403.90 (the new diagnosis code), REF01='EA', REF02=714.0 (the deleted diagnosis code). In addition, all required minimum data elements must be submitted.

3.5.7.5 Chart Review – Correct/Replace a Chart Review Encounter with Another Chart Review Encounter

There may be instances in which MAOs and other entities submitted a chart review encounter in error, which necessitates that a correct/replace chart review encounter to be submitted. Correct/replace chart review encounters may only correct or replace other previously submitted and accepted chart review encounters and must not be submitted to correct or replace full encounters. MAOs and other entities must include the following data, as well as the minimum data elements required for all encounter data submissions:

- 2300 CLM05-3 = '7' = Correct/Replace
- 2300 PWK01 = '09'
- 2300 PWK02 = 'AA'
- 2300 REF01 = 'F8'
- 2300 REF02 = ICN from accepted and stored chart review encounter

Correct/replace submissions provide the final representation of the encounter; therefore, all correct information included on the original chart review must also be included on the correct/replace chart review submission. Upon EDFES and EDPPPS editing, the original chart review encounter will be flagged as "inactive" and the correct/replace chart review encounter will be flagged as the active record.

**Example**

Fit Health Plan performed a follow-up medical record review at Madagascar Internal Medicine due to discrepancies in encounter data submission. The representative found that the additional diagnoses provided for one of Dr. Madagascar's patients in the initial chart review were incorrect. Fit Health Plan must a chart review with Loop 2300 CLM05-3='7', PWK01='09', PWK02='AA', REF01='F8', and REF02 must include the original accepted ICN. In addition, all required minimum data elements must be submitted.

3.5.7.6 Chart Review Duplicate Logic

Once a chart review encounter passes through the EDPPPS, it is stored in an internal repository, the EODS. If another chart review encounter is submitted that matches specific values to another stored chart review encounter, it will be rejected and will be considered a duplicate. The chart review encounter will be returned to the submitter on the MAO-002 reports with error message 98325 – Exact Duplicate of a Service Line within this Claim or a Previously Priced Claim, identifying it as a duplicate chart review encounter. Table 3K below provides the duplicate logic for linked ICN and unlinked ICN chart review encounters.

TABLE 3K – CHART REVIEW DUPLICATE LOGIC

Linked ICN Chart Review Duplicate Logic	Unlinked ICN Chart Review Duplicate Logic
Health Insurance Claim Number (HICN)	Health Insurance Claim Number (HICN)
Date of Service	Date of Service
Diagnosis Code	Diagnosis Code
Internal Control Number (ICN) From a Previously Stored Chart Review	

3.5.8 Correct/Replace

In order to correct/replace an encounter that has been previously accepted through the EDPPPS, MAOs and other entities may submit correct/replace encounters to the EDS. Correct/replace encounters will supersede previously accepted encounters.

Correct/replace encounters may be submitted for any modification to a previously accepted encounter, including but not limited to, billing or payment information, provider information, diagnosis codes, or procedure codes.

3.5.8.1 Correct/Replace Submission

In order to pass translator and CEM level edits, the correct/replace encounter must be submitted as the final encounter and include all applicable data. MAOs and other entities must indicate correct/replace encounters by populating Loop 2300, CLM05-3='7' and Loop 2300, REF01='F8' and REF02=ICN of the previously accepted encounter.



MAOs and other entities may reference the Correct/Replace business case in the 837-P Companion Guide for operational guidance

EXHIBIT 10

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE
MEDICARE PLAN PAYMENT GROUP

DATE: February 18, 2015

TO: All Medicare Advantage, Prescription Drug Plan, Cost, PACE, and Demonstration Organizations

FROM: Cheri Rice /s/
Director, Medicare Plan Payment Group

SUBJECT: Guidance for Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments to the Centers for Medicare & Medicaid Services (CMS)

On May 23, 2014, CMS published final regulations to implement procedures for the reporting and returning of overpayments requirement in the Affordable Care Act (ACA). These regulations, 42 CFR §§ 422.326 and 423.360, were effective beginning July 22, 2014. This document announces the process for reporting and returning overpayments in accordance with the new regulations. The process that implements these regulations is effective beginning January 1, 2015.

Pursuant to section 6402 of the Affordable Care Act (ACA), which established section 1128J(d) of the Social Security Act (the Act), every organization offering a Medicare Advantage (MA) plan and/or sponsor offering Part D benefits, including any PACE organization that is a Part D sponsor, is required to report and return to CMS any overpayment it received no later than 60 days after the date on which the organization or sponsor identified the overpayment.

The purpose of this memorandum is to provide organizations and/or sponsors with operational guidance for reporting and returning overpayments.

If you have questions about the guidance contained in this memorandum, please submit them to the appropriate contact as provided in this memorandum.

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I. Overpayment Requirements

The term “overpayment” is defined in section 1128J(d)(4)(B) of the Act as, “any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliations, is not entitled under such title.” Failure to comply with this statutory requirement may result in potential liability under the False Claims Act (31 USC § 3729).

CMS issued regulations at 42 CFR §§ 422.326 and 423.360 which establish the process for an organization offering a Medicare Advantage (MA) plan and/or a sponsor offering Part D benefits to report and return any overpayment it received no later than 60 days after the date the organization or sponsor identifies the overpayment (79 FR 29843 at 29958). Section 423.360 applies to Part D sponsors, which include PACE organizations offering a PACE plan that includes qualified prescription drug coverage (see definition of “Part D sponsor” in 42 C.F.R. § 423.4).

An organization or sponsor has identified an overpayment when it determines that it received an overpayment due to the organization or sponsor submitting erroneous data to CMS. The following four general categories of data submissions that have the potential to result in overpayments are subject to the guidance contained in this memorandum:

- Risk Adjustment (Risk Adjustment Processing System (RAPS) data and encounter data)
- Prescription Drug Event (PDE) and Direct and Indirect Remuneration (DIR)
- Low Income Premium Subsidy (LIPS) for Employer Group Waiver Plans (EGWPs)¹
- Other

Additional information about these categories is provided throughout this memorandum.

Enrollment-Related Overpayments: If an organization or sponsor needs to submit corrections to enrollment data to resolve an overpayment, it must follow the normal process for correcting enrollment data. See the Plan Communications User Guide for more information: http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelppdesk/Plan_Communications_User_Guide.html

II. Reporting Overpayments

A. Overpayment Categories, Applicable Reconciliation, and Look-Back Periods

MA organizations and Part D sponsors are required to report and return any overpayment that they identify within the six most recently completed payment years², referred to hereinafter as the “look-back period.” The report and return obligation begins on the day after the applicable reconciliation for the payment year. The sections below provide more information about the look-back period and when the applicable reconciliation occurs for Part C and Part D.

- *Risk Adjustment*

Generally, if an overpayment results from the submission of risk adjustment data (i.e., RAPS data and encounter data), the obligation to report an identified overpayment for a given payment year begins on the day after the Part C applicable reconciliation date, which is the final risk adjustment data submission deadline under § 422.310(g). That deadline generally occurs about thirteen

¹ This category of overpayment occurs when a sponsor discovers it received a Low Income Premium Subsidy payment for an enrollee from both CMS and the enrollee’s Employer Group Waiver Plan.

² In this context, the term “completed payment year” refers to a calendar year for which the applicable reconciliation date has passed.

months after the end of the data collection year. (Note that overpayments may result from the submission of encounter data starting with 2014 dates of service.). Please note that the reporting deadline for Part D risk adjustment data is the same as the Part C risk adjustment data submission deadline, but the applicable reconciliation dates for Part C and Part D in the overpayment context are different.

- *Prescription Drug Event or Direct and Indirect Remuneration*

If an overpayment results from the submission of incorrect PDE or DIR data, the obligation to report an identified overpayment for a given year begins on the day after the Part D applicable reconciliation date (i.e., the later of the deadlines for submitting PDE or DIR data for the applicable year). That deadline generally occurs towards the end of June in the year directly following the payment year.

- *Low Income Premium Subsidy for Employer Group Waiver Plans*

If an overpayment arises when the total of the LIPS payment comes from CMS and the EGWP contribution for a beneficiary exceeds the amount of his or her premium, the obligation to report the overpayment (i.e., the portion of CMS's LIPS payment that exceeds the premium amount) for a given year begins on the day after the Part D applicable reconciliation date for that year (i.e., the later of the deadlines for submitting PDE or DIR data for that year).

- *Other*

Overpayments that are a result of incorrect data submissions by MA organizations and Part D sponsors that do not fall into the Risk Adjustment, PDE, DIR, or LIPS for EGWPs categories will be classified as "Other." In addition, an overpayment that results from the submission of data that an organization or sponsor may have lost as a result of a thoroughly-documented catastrophic loss of stored data is also classified as "Other." If the "Other" overpayment falls under Part D, the obligation to report an identified overpayment for a given year begins on the day after the Part D applicable reconciliation date for that year (i.e., the later of the deadlines for submitting PDE or DIR data for that year). If the "Other" overpayment relates to Part C, the obligation to report an identified overpayment for a given year begins on the day after the Part C applicable reconciliation date, which is the final risk adjustment data submission deadline under § 422.310(g).

The following table shows the look-back periods for the 2015 through 2020 calendar years:

Calendar Year	Look-back Period Prior to the Applicable Reconciliation*	Look-back Period After the Applicable Reconciliation*
2015	2013-2008	2014-2009
2016	2014-2009	2015-2010
2017	2015-2010	2016-2011
2018	2016-2011	2017-2012
2019	2017-2012	2018-2013
2020	2018-2013	2019-2014

*Part C applicable reconciliation typically occurs around 13 months after the end of the risk adjustment data collection year. Part D applicable reconciliation typically occurs around 6 months after the end of the payment year.

B. Reporting Process

1. General

Once an organization or sponsor has identified an overpayment, it must report it to CMS no later than 60 days after the date on which it identified it received the overpayment by contacting the MAPD help desk at 1-800-927-8069 or mapdhelp@cms.hhs.gov and opening a Remedy ticket. If an organization or sponsor reports an overpayment to the help desk by email, the subject line of the email should include the phrase “Overpayment Report.” Note that organizations and sponsors should not open an overpayment Remedy ticket until after the applicable reconciliation date for the applicable payment year has passed.

MA organizations and Part D sponsors must ensure confidentiality of enrollee information. Please observe HIPAA security and privacy rules, and ensure that appropriate safeguards for securing protected health information and personally identifiable information (PHI/PII) are used when submitting any materials to the MAPD helpdesk.

In order to create a Remedy ticket for the incident, the organization or sponsor must provide the help desk representative with the following information:

- Plan User Information: EUA (4 Digit) or IACS (7 digit)
- Parent Organization
- Contract Number(s)
- Overpayment Reason Category:
 - Risk Adjustment Data (RAPS and encounter data) - when corrected data is being submitted, otherwise use the “Other” category
 - PDE/DIR - when corrected data is begin submitted, otherwise use the “Other” category
 - LIPS for EGWP
 - Other (e.g., catastrophic loss of data)
- Payment Year for Overpayment
- Explanation for Inaccurate Payment Data (provide detailed explanation for why payment data are inaccurate)
- Supporting Documentation (if applicable, see Section II.B.3)

2. Remedy Ticket Creation

The process for creating Remedy tickets is slightly different depending on the type of overpayment category involved.

Risk Adjustment, LIPS for EGWP, and Other Categories

For Risk Adjustment (RAPS and encounter data), LIPS for EGWP, or Other categories, the help desk will create one Remedy ticket for each overpayment category, contract number, and payment year. For example, the help desk will create one Remedy ticket for an organization that reports a RAPS overpayment for contract H8888 for the 2011 payment year. If the organization also needs to report a RAPS overpayment for the same contract but for the 2010 payment year, the help desk will need to create a separate Remedy ticket for that incident.

PDE/DIR Category

If an overpayment falls into the PDE/DIR category, the help desk will create one Remedy ticket for each parent organization and payment year. If the sponsor needs to report PDE/DIR data that results in an overpayment for the same payment year for multiple contracts, it should do so under the same Remedy ticket number (a sponsor may subsequently revise the number of contracts by contacting the help desk and updating the original Remedy ticket). But, if a sponsor needs to report an overpayment for more than one payment year, it will need to open separate tickets for each year.

Number of Remedy Tickets to Create

Organizations and sponsors are responsible for determining how many overpayment tickets need to be created prior to contacting the help desk. The following examples may help organizations and sponsors understand how many tickets should be created:

- Example 1: An MA organization offering Part D benefits (MAPD) identified overpayments for contract H8888 and H9999 for payment year (PY) 2009. The overpayments are based on incorrect risk adjustment, PDE, and DIR data. The MAPD needs to open the following Remedy tickets:
 - Remedy ticket 1 includes risk adjustment overpayments for H8888
 - Remedy ticket 2 includes risk adjustment overpayments for H9999
 - Remedy ticket 3 includes PDE/DIR overpayments for H8888 and H9999
- Example 2: An MA organization identified risk adjustment overpayments for contracts H8888 and H9999 for PY 2008 and PY 2009. The organization needs to open the following Remedy tickets:
 - Remedy ticket 1 includes H8888 for PY 2008
 - Remedy ticket 2 includes H9999 for PY 2008
 - Remedy ticket 3 includes H8888 for PY 2009
 - Remedy ticket 4 includes H9999 for PY 2009

3. Submission of Supporting Documentation

An organization or sponsor should send supporting documentation to CMS when it is reporting an overpayment in the “Other” category. In these instances, the organization or sponsor should provide supporting documentation that addresses:

- The reason for the loss of the data (if applicable), including a catastrophic system loss;
- The reason for the overpayment; and
- An auditable estimate of the overpayment amount, including how the estimate was derived for each Remedy ticket.

The attached documentation should be in a Microsoft Word, WordPerfect, or searchable PDF format. Spreadsheets should be submitted in Microsoft Excel.

If the organization or sponsor opened the Remedy ticket by phone, or the initial email to the help desk did not include the supporting documentation, the subject line of the subsequent email should include the Remedy ticket number(s) associated with the supporting documentation.

Part D sponsors reporting an overpayment will also have to request a reopening of the payment year(s) in which the submission of inaccurate data occurred. The Part D sponsor will make the reopening request through the existing process and will not submit the reopening request as supporting documentation. See the section III.B “Overpayments Involving PDE or DIR Data” below for more information.

4. Contact Information for the “Other” Category

In addition to satisfying all of the other reporting requirements described in this section of the memorandum, an organization or sponsor that reports an overpayment in the “Other” category should provide the name, telephone number, and email address of a person who is permitted to discuss how the overpayment will be returned to CMS (i.e., by offset, electronic funds transfer, or check). The contact information may be submitted with the supporting documentation, or it may be provided to the help desk by telephone and associated with the Remedy ticket.

If the organization or plan is reporting an overpayment that is based on data that the organization or sponsor no longer has due, for example, to a catastrophic system loss, it should also provide the supporting documentation described in section II.B.3.

5. Updating Existing Remedy Tickets

An organization or sponsor may need to update an existing Remedy ticket when it discovers additional overpayments that match the description of an overpayment in an existing Remedy ticket (e.g., when an organization discovers it needs to delete additional risk-adjustment data occurring in the 2010 payment year for H8888 after it already opened a Remedy ticket for risk adjustment data for that contract number and payment year). The organization or sponsor may add that information to the existing Remedy ticket by emailing the help desk.

The subject line of the email should include the following phrase “Update Remedy ticket number” and the Remedy ticket number.

The following information should be included in the body of the email:

- Parent Organization
- Contract Number(s)
- Overpayment Error Category (Risk Adjustment, PDE/DIR, LIPS for EGWP, or Other)
- Payment Year for Overpayment

III. Returning Overpayments

Once an organization or sponsor reports an overpayment to the help desk and has obtained a Remedy ticket, it must return the associated overpayment to CMS no later than 60 days after the date on which the organization or sponsor identified the overpayment. Overpayments involving risk adjustment (i.e., RAPS and encounter data), PDE, or DIR data are returned to CMS by the process of sending the corrected data to the appropriate CMS system in accordance with the existing instructions provided by CMS for the submission of such data. The majority of this section discusses how the data are submitted to CMS.

However, there are situations where the return of an overpayment may not involve the submission of corrected data, for example, when the data are no longer available due to a catastrophic system loss. In those instances, CMS will either conduct a payment offset against the contract's prospective monthly payments, or may request that the MA organization or Part D sponsor send the funds directly to CMS in order to return the overpayment.

CMS generally expects that an organization's or sponsor's return of overpayments will be implemented with the submission of corrected data. CMS' systems will then recover the returned overpayment through routine processing according to our payment systems' schedules. See Section III.D for information on handling the rare exception when corrected data cannot be submitted to CMS.

The following sections outline how the specific categories of overpayments must be returned to CMS.

A. Overpayments Involving Risk Adjustment Data

1. General

A risk adjustment-related overpayment involves erroneously submitted diagnoses that were submitted to CMS prior to the risk adjustment data submission deadline but were not deleted by the risk adjustment data submission deadline. These diagnoses may be included in both Part C and/or Part D risk scores. The diagnoses must be deleted through an overpayment risk adjustment file submission to RAPS no earlier than the day after the organization reports the overpayment to the help desk and obtains a Remedy ticket number. If the organization attempts to submit the delete file to RAPS sooner than that, the submission will be rejected by the system.

Overpayments must be submitted to RAPS in the following format:

1. The entire RAPS file must only contain deletes;
2. Only one payment year can be submitted per file;
3. The PROD-TEST-IND in the AAA record must be populated with OPMT;
4. The assigned Remedy Ticket Number must be placed in the OVERPAYMENT-ID field in the BBB record;
5. The contract number that is in the BBB record must match the contract number that is in the assigned Remedy ticket;
6. The payment year of the deletes being processed must be populated in the PAYMENT-YEAR field on the BBB record; and
7. The DELETE-IND field in the CCC record must be populated with a 'D' for each diagnosis code on the file.

CMS updated the RAPS File Format to include the Overpayment fields described above. An organization will use the overpayment fields only when reporting overpayments to CMS.

For more information about the new RAPS file format and RAPS error codes, please see the memorandum "Announcement of the November 2014 Software Release" published by CMS through the Health Plan Management System (HPMS) on August 12, 2014, or visit <http://www.csscooperations.com>.

For guidance on deleting and correcting encounter data, please see the information from the August 14, 2014 Encounter Data National Technical Assistance materials, available at <http://www.csscooperations.com> (Medicare Encounter Data/Training Information).

2. Recovery Process

The risk adjustment-related overpayments will be addressed through our routine payment processes. CMS will announce the prior payment years for which we will rerun risk scores on an annual basis and will provide rerun-specific schedules as they become available. When CMS completes a rerun for the payment year in order to incorporate reported risk adjustment overpayments (deletes), the payment adjustments will be automatically processed by the Medicare Advantage and Prescription Drug System (MARx) and will appear on the corresponding Monthly Membership Report (MMR). CMS will announce when each completed risk score rerun will go into payment in the corresponding monthly payment letter that is sent to organizations and sponsors.

3. Contact Information

Questions regarding the return and recovery of identified RAPS-related overpayments may be sent to riskadjustment@cms.hhs.gov. Questions regarding encounter data may be sent to encounterdata@cms.hhs.gov.

B. Overpayments Involving PDE or DIR Data

1. General

PDE data or DIR data may be the source of a Part D-related overpayment. After receiving a Remedy ticket number from the help desk, the Part D sponsor will return the Part D-related overpayment to CMS in accordance with the guidance contained in this section.

The Part D sponsor will request a reopening through the Part D Payment Reconciliation Support Contractor, currently Acumen, LLC, in accordance with reopening instructions provided in the HPMS memorandum “The Part D Reopenings Process and the Part D Appeals Process” published on May 8, 2008. Pursuant to that guidance, the Part D sponsor should provide sufficient documentation of the reason(s) for the reopening request. The documentation should include the Remedy ticket number associated with the Part D-related overpayment. The Remedy ticket number should be provided in the column titled, “Reason for Reopening Request” in the reopening spreadsheet.

The Part D sponsor may submit an electronic copy of the reopening request and all applicable documentation to PartDPaymentSupport@acumenllc.com

Alternatively, the Part D sponsor may send the reopening request and all applicable documentation to:

Acumen, LLC
Attn: Part D Payment Support
500 Airport Blvd., Suite 365
Burlingame, CA 94010

2. Overpayments Involving PDE Data

If PDE data is the source of the Part D-related overpayment, the Part D sponsor will adjust, delete, or resubmit the PDE data to rectify the reported overpayment. Corrected PDE data may be submitted immediately after a Remedy ticket number is assigned for the overpayment.

As described in the HPMS memorandums “Updates to the Prescription Drug Event (PDE) layout and the Coverage Gap Discount Program (CGDP) Reconciliation Reports,” published on September 4, 2014, and “Updates to the Prescription Drug Event (PDE) layout- Adjustment Reason Code and Adjustment Reason Code Qualifier,” published on October 3, 2014, the Part D sponsor will use the Adjustment Reason Code

Qualifier field and the Adjustment Reason Code field on the PDE to associate the Remedy ticket number with each adjusted, deleted, or resubmitted PDE to rectify the reported overpayment. The Part D sponsor will submit the PDEs with an Adjustment Reason Code Qualifier of '1' and an Adjustment Reason Code that is the 12-digit Remedy ticket number with leading zeroes (i.e., 000001234567).

Note that the Part D sponsor should only associate the Remedy ticket number with the PDEs that are the direct cause of the overpayments. For example, a Part D sponsor finds that it paid for a National Drug Code (NDC) that is not a Part D drug, which results in the beneficiary entering into the catastrophic phase earlier than he or she should have. To correct the overpayment, the Part D sponsor will report the overpayment to the help desk, receive a Remedy ticket number, and adjust or delete the PDE associated with the non-Part D NDC in accordance with the point-of-sale claims adjustment guidance released through HPMS on July 3, 2013, for benefit years 2012 and beyond. The Part D sponsor will use the Adjustment Reason Code Qualifier field and the Adjustment Reason Code field on the PDE to associate the Remedy ticket number with the adjusted or deleted PDE. If the sponsor needs to adjust subsequent PDEs, the Adjustment Reason Code is not required on the subsequent PDE adjustments.

3. Overpayments Involving DIR Data

If DIR data is the source of the Part D-related overpayment, the Part D sponsor will modify the DIR data to rectify the reported overpayment. DIR overpayments may be returned after a Remedy ticket number is assigned to the reporting entity (i.e., the Part D sponsor may request a reopening). The Part D sponsor should submit the revised DIR data in a manner consistent with the annual Medicare Part D DIR Reporting Requirements released mid-year. The resubmission window for submitting DIR reports for previous benefit years occurs in the month of July. The Part D sponsor will satisfy the requirement to return the overpayment by submitting a reopening request to Part D Payment Reconciliation Support Contractor, which is currently Acumen, LLC, and subsequently resubmitting the DIR report for the applicable year during the next DIR resubmission window. See, for example, the HPMS memorandum "Final Medicare Part D DIR Reporting Requirements for 2013," Section G "Resubmitting Summary DIR Reports for Prior Coverage Years" published on May 28, 2014. When resubmitting the DIR report, the sponsor should report the Remedy ticket number in the "Explanation for Resubmission" text box in the DIR submission information. In this text box, the sponsor should report the Remedy ticket number and the dollar amount adjusted for each DIR column associated with the overpayment on the report. If insufficient information is reported in this text box, CMS may contact the sponsor to provide additional information in the "Explanation for Resubmission" text box.

4. Recovery Process

CMS will recover overpayments involving PDE or DIR data through the routine Part D payment processes. The reopening schedule will be developed by CMS and announced through HPMS memoranda. CMS may reopen and revise an initial or reconsidered payment determination consistent with 42 CFR § 423.346. However, CMS typically performs one global reopening each year. We anticipate being able to recover the majority of overpayments through this global reopening process but may perform targeted reopenings at our discretion consistent with § 423.346.

5. Contact Information

Questions regarding the return and recovery of identified Part D-related overpayments may be sent to pdejan2011@cms.hhs.gov.

C. Overpayments Involving LIPS for EGWP Members

1. General

An overpayment occurs when the total of the LIPS payment from CMS and the EGWP contribution for a beneficiary exceeds the premium amount. In this case, the plan sponsor must return the portion of CMS's LIPS payment that exceeds the premium amount. Since there is no automated method for determining the amount that an EGWP is paying on behalf of a member, CMS must manually collect the LIPS overpayment. Plans currently report the LIPS overpayment amounts to the CMS Regional Offices. Effective January 1, 2015, a sponsor should report a LIPS overpayment by obtaining a Remedy ticket and submitting a Microsoft Excel spreadsheet to the help desk indicating the contract numbers and associated overpayments. The submission of this spreadsheet will satisfy the requirement of returning the LIPS overpayment made to the EGWP.

2. Recovery Process

CMS will offset the LIPS overpayment amount from a future monthly payment to the plan sponsor. When the overpayment is processed, CMS will announce the adjustments in the appropriate monthly plan payment letter, and organizations or sponsors can verify the adjustments on the Plan Payment Report.

3. Contact Information

Questions regarding the return and recovery of overpayments involving LIPS for EGWP members may be addressed to the help desk.

D. Overpayments in the "Other" Category

1. General

Once an organization or sponsor has reported an overpayment in the "Other" category to the help desk, obtained a Remedy ticket, and submitted the required documentation described in section II.B.3, a CMS representative will contact the organization or sponsor to discuss how the overpayment will be returned to CMS (i.e., by offsetting a monthly payment, electronic funds transfer, or check).

2. Recovery Process

Once an overpayment return method is determined, the CMS representative will provide information about how to return the payment to CMS. If an offset is possible, the return requirement is met on the date the agreement to offset is reached. If the funds must be returned to CMS by electronic transfer or check, the return requirement is met when CMS receives the electronic transfer or check.

3. Contact Information

Questions regarding the return and recovery of identified "Other"-related overpayments may be addressed to the help desk.

IV. How Overpayments will be Processed by CMS and Closing Remedy Tickets

CMS will process overpayments differently depending on the category of overpayment that is being returned to CMS.

If an overpayment is returned to CMS by submitting revised Risk Adjustment, PDE, or DIR data to the appropriate system, CMS will use our routine processes to recover the overpayment. This will depend on

the schedule for conducting reruns/reopenings for that data type and payment year. When a rerun/reopening has been completed, the associated payment adjustments will be processed and reported in a subsequent monthly payment and MMR/plan payment report.

Overpayments returned by electronic transfer or check will be processed upon receipt. If CMS is able to offset a sponsor's monthly payment to resolve an overpayment, it will be processed in a future payment.

CMS will close the associated Remedy ticket when the overpayment has been processed. MA organizations and Part D sponsors will receive a notice from the Remedy system when tickets are closed. Once a ticket is closed, it may not be reopened for updating.

V. Risk Adjustment Data Validation (RADV)

MA organizations that are selected for a RADV audit will be subject to special procedures relating to risk adjustment data and overpayments. MA organizations that are selected for a RADV audit will receive information about these procedures at the start of the RADV audit process.

EXHIBIT 11

Medicare Managed Care Manual

Chapter 1 - General Provisions

Table of Contents *(Rev. 125, 02-10-17)*

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10 – Legislative History

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

The Balanced Budget Act of 1997 (BBA) (Public Law 105-33) established a new Part C of the Medicare program, known then as the Medicare+Choice (M+C) program, effective January 1999. As part of the M+C program, the BBA authorized CMS to contract with public or private organizations to offer a variety of health plan options for beneficiaries, including both traditional managed care plans (such as those offered by Health Maintenance Organizations (HMOs) under §1876 of the Social Security Act) and new options that were not previously authorized. Four types of M+C plans were authorized under the new Part C of Medicare:

- Coordinated care plans (CCPs), including:
 - HMOs (with or without Point-of-Service (POS) options;
 - Provider Sponsored Organizations (PSOs); and
 - Preferred Provider Organizations (PPOs).
- Medicare Medical Savings Account (MSA) plans;
- Private Fee-for-Service (PFFS) plans; and
- Religious Fraternal Brotherhood Societies (RFB).

The Part C program of Medicare was renamed the Medicare Advantage (MA) Program pursuant to Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173), which was enacted on December 8, 2003. The MMA updated and improved the choice of plans for beneficiaries under MA, and changed the way benefits are established and payments are made. Under the MMA, beneficiaries may choose from additional plan options, including regional PPO (RPPO) plans and special needs plans (SNPs). Title I of the MMA further established the Medicare prescription drug benefit (Part D) program, and amended the MA program to allow, and in some cases require, MA plans to offer prescription drug coverage. More information about prescription drug requirements can be found in the Medicare Prescription Drug Benefit Manual at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html> page.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) (Public Law 110-275) was enacted, revising and amending statutory provisions governing the MA and Part D programs. Among these were provisions that established new rules for PFFS plans, SNPs, and Section 1876 cost plans.

In 2010, the Patient Protection and Affordable Care Act (Public Law 111-148) and the Health Care and Education Reconciliation Act (Public Law 111-152) were enacted and

are collectively referred to as the Affordable Care Act (ACA). The ACA includes significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the ACA concerning the MA and Part D programs largely focus on beneficiary protections, MA payments, and simplification of MA and Part D program processes.

CMS implemented the MA and Part D provisions specified in the ACA through regulations at 42 CFR 422 and 423.

20 - Types of Medicare Advantage (MA) Plans **(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)**

20.1 - Overview of MA Plans **(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)**

Terms in this chapter follow the definitions at §422.2.

There are three basic types of MA plans: CCPs (Section 20.2); MSA plans (Section 20.3); and PFFS plans (Section 20.4).

Two other types of MA plans characterized by special enrollment are the RFB societies which are affiliated with a church and may only enroll RFB members (Section 30.1) and Part B-only plans which restrict enrollment to beneficiaries who only have Part B of original Medicare (Section 30.2).

20.2 - Coordinated Care Plans (CCPs) **(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)**

As defined at 42 CFR 422.4(a)(1), a CCP is a plan that includes a network of providers that are under contract or arrangement with the MA organization to deliver the benefit package approved by CMS. A CCP must at least (i) furnish all Part A and Part B services (except for hospice) (42 CFR 422.101(a)); (ii) conduct quality improvement activities (42 CFR 422.152(a)–(b)); (iii) provide sufficient access, as defined by CMS, to services including continuity of care (42 CFR 422.112(a)–(b)); and (iv) disclose required information about benefits and costs to enrollees (42 CFR 422.111(b)(2)).

CCPs may use mechanisms to control enrollee utilization of services. Mechanisms may include requiring referrals from a gatekeeper (usually the enrollee's primary care provider (PCP)) or prior authorization for an enrollee to receive certain covered services (42 CFR 422.4(a)(1)(ii)).

20.2.1- Health Maintenance Organizations (HMOs) **(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)**

HMO - An HMO is generally the most restrictive of the CCP types. HMOs may control enrollees' utilization of services by requiring enrollees to go through a gatekeeper,

usually the enrollees' PCP, to obtain referrals for services the PCP does not furnish and to obtain all services from network providers (42 CFR 417.448(a)).

HMO-POS - Some HMOs offer coverage of certain specified plan-covered services outside of the plan network. Offering that out-of-network access to some covered services requires that the HMO offer a point-of-service (POS) supplemental benefit and may also require the HMO to obtain state licensure to offer an HMO-POS. The HMO-POS must specify in writing which services it offers out-of-network, maximum enrollee out-of-pocket cost sharing, and any annual limits on the benefits offered under the POS benefit.

20.2.2 - Preferred Provider Organizations (PPOs)

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

A PPO is a CCP plan that provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the plan's network of providers (42 CFR 422.4(a)(1)(v)(B); Section 1852(e)(3)(iv) of the Social Security Act). PPOs may be local or regional (42 CFR 422.4(a)(iii)(C)).

Local PPOs - A local PPO has a service area that is specified by the organization offering the plan and approved by CMS. Its service area typically will consist of one or multiple counties. However, as noted in Chapter 4 of the Medicare Managed Care Manual, Section 140, CMS may allow service areas to contain partial counties if the plan can demonstrate that this is necessary, non-discriminatory and in the best interests of the plan enrollees (See also 42 CFR 422.2 (definition of service area)).

Regional PPOs (RPPOs) - The MMA introduced the RPPO option in an effort to expand access to MA managed care to include Medicare beneficiaries living in rural areas. RPPOs may be offered only in one or several, but not in parts, of the 26 MA regions established by CMS for RPPOs. See <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/MAPDRegions.pdf> for the location of the MA regions; each MA region consists of one or more states. RPPOs must offer a uniform benefit package across the service area, must establish a 'catastrophic' maximum enrollee out-of-pocket cost sharing limit, and must establish a provider network approved by CMS. In those portions of its service area where it is possible, RPPOs should meet network adequacy criteria for original Medicare services by having written contracts with a full network of providers. In more rural areas, RPPOs may request an exception to CMS's requirement that the RPPO have written contracts in order to meet network adequacy criteria (42 CFR 422.112(a)(1)(ii)).

RPPO plans offered by MA organizations must be licensed or otherwise authorized under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers one or more MA plans.

See Chapter 4 of the Medicare Managed Care Manual for information on deductibles as well as catastrophic limits on cost sharing for RPPOs. Annually, CMS issues information

about deductibles and cost sharing for the following contract year in the Call Letter. Current and past Call Letters may be accessed at:
<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>

20.2.3 - Special Needs Plans (SNPs)

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

A SNP may be offered as any of the CCP types and must satisfy CMS' SNP requirements. SNPs must exclusively enroll special needs individuals as appropriate to the SNP type (42 CFR 422.4(a)(1)(iv)).

The MMA designated three specific segments of the Medicare population as special needs individuals: (1) institutionalized individuals; (2) those entitled to Medical Assistance under a State Plan under Title XIX (Medicaid) (i.e., dual eligibles); or (3) those who have “a severe or disabling chronic condition” who would “benefit from enrollment in a specialized MA plan (Section 1859 of the Act and 42 CFR 422.2). Corresponding to these segments of the Medicare population there are three types of SNPs: I-SNPs for institutionalized individuals, D-SNPs for dual eligible individuals and C-SNPs for chronic-condition individuals.

See chapter 16b for more details on these requirements.

20.3 - Medical Savings Account (MSA) Plans

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

The BBA authorized MSA plans on a demonstration basis when it created the M+C program. The MMA of 2003 made Medicare MSAs a permanent type of MA plan option and extended the beneficiary protection from balance billing by non-contracting providers to include MSA enrollees (42 U.S.C. § 1395w-28(b)(3)(A); 42 CFR 422.4(a)).

An MSA has two parts: 1) A high deductible MA plan and 2) a Medical Savings account (42 CFR 422.4(a)(2)).

1. In a high deductible MA plan:

- a. Enrollees pay no premiums to the MSA plan except as required to cover supplemental benefits (42 CFR 422.262(b)(2));
- b. Enrollees pay out of pocket for all services until they reach the deductible amount (42 CFR 422.103(a); 42 U.S.C. § 1395w-28(b)(3)(A)(i)); and
- c. The MSA plan pays for all Medicare covered services, after the high-plan deductible is met (42 CFR 422.103(c); 42 U.S.C. § 1395w-28(b)(3)(A)(iii)).

2. Medical Savings Account: The organization offering the MSA plan deposits money

into a special savings account at the beginning of each calendar year. Only the plan can make deposits into the MSA account; plan enrollees cannot deposit their own money. The amount of deposit can change each year and may also earn interest. Any money left in the account at the end of the year will remain in the account and will be added to the new deposit the following year if the enrollee chooses to continue enrollment.

Enrollees are responsible for handling the money in their account, including deciding whether to pay for health care services using medical savings account funds or other funds.

An MSA plan:

- Must, after the enrollee has met the plan deductible, cover in full all original Medicare Part A and B services subject to the requirements at 42 CFR 422.101 and section 1852(a)(1). (See also section 1859(b)(3) of the Act and 42 CFR 422.103(a));
- May offer supplemental benefits but may not apply the patient portion of the cost of those services to the patient's deductible (Section 1859(a)(3)(B)(ii)); and
- May not offer a Part D benefit. However, plan enrollees may choose to simultaneously enroll in a Prescription Drug Plan (PDP) (42 CFR 422.4(c)(1)–(2)).

MSA plans must meet all other requirements of MA plans.

For further information on MSA plans including special tax requirements see: <https://www.medicare.gov/Pubs/pdf/11206.pdf>

20.4 - Private Fee-for-Service (PFFS) Plans **(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)**

All PFFS plans must cover all Part A and Part B original Medicare services whether or not the PFFS plan has a full network of contracted providers. If the PFFS plan is not in a network area, and does not have a full network of contracted providers, it must pay for covered services furnished to enrollees by providers with whom they do not have written contracts by paying at least the original Medicare rate (Section 1852(d)(4) of the Act and 42 CFR 422.114(a)(2)).

PFFS plans may differ in their network requirements. For a given contract year, a network area is any area that the Secretary determines to have “at least 2 network-based plans” (Section 1852(d)(5)(B) of the Act). CMS annually announces which counties are network areas in the Advance Notice. Effective 2011, a PFFS plan operating in a network area must meet Medicare Advantage network adequacy criteria consistent with the CMS network management module by having a full network. This means the PFFS plan must have written contracts with a sufficient number and range of providers to provide coverage for all Part A and Part B original Medicare services. Similarly, a PFFS

employer/union plan that has waivers under section 1857(i) of the Act must operate as a full network plan (irrespective of its service area) (42 CFR 422.114(a)(3) and (4)).

PFFS plans operating in non-network areas may choose to meet network adequacy criteria for original Medicare services by having full networks, or they may choose to meet network adequacy criteria by stating in their terms and conditions of payment that they will pay providers with whom the plan does not have a written contract at least the original Medicare rate.

PFFS plans may offer qualified Part D. If the PFFS plan chooses not to cover Part D, the PFFS plan enrollees may simultaneously enroll in a PDP (42 CFR 422.4(c)(1), (3)).

PFFS plans are further discussed in chapter 16a.

30 - Other MA Plans

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

30.1 – Religious Fraternal Society (RFB) Plans

(Rev.124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

RFB plans are MA plans that are offered by an RFB society; the RFB society must limit enrollment exclusively to members of the RFB society (42 CFR 422.57) and may be approved to offer any MA plan type (e.g., HMO, PPO, PFFS).

An RFB society is an organization that is described in §501(c)(8) of the Internal Revenue Code of 1986, is exempt from taxation under §501(a) of that code and is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches. See section 1859(e)(3)(A) of the Act; 42 CFR 422.2.

30.2 – Part B only Plans

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

An MA Part B only plan is a plan offered to individuals eligible for Part B who do not have Part A coverage. Part B only plans are required to cover the Medicare benefits that are covered under Part B and any supplemental benefits the plan may offer. Regulations at 42 CFR 422.50 prohibit creating new Part B only plans except for EGWPs that are granted a waiver. Non-EGWP Part B only plans created before the MMA may continue operating as long as they have membership and provided they do not enroll new Part B only members. For a complete discussion of Part B only plans offered by Employer Group Waiver Plans (EGWPs), see chapter 9 of this manual.

For information on Part B only beneficiaries enrolling in Medicare cost plans under section 1876 of the Social Security Act, see Section 40.

40 - Medicare Cost Plans and Health Care Prepayment Plans (HCPP)

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

Medicare cost plans and HCPP plans are not MA plans because they are authorized under a different section of the Social Security Act than MA plans.

40.1 - Medicare Cost Plans

(Rev. 125, Issued: 02-10-17, Effective: 02-10-17, Implementation: 02-10-17)

Medicare cost plans are operated by a legal entity licensed as an HMO in accordance with a cost reimbursement contract under Section 1876 of the Social Security Act and Title 42, Part 417 of the Code of Federal Regulations. Medicare payment to the HMO is based on the reasonable costs of providing services to their enrollees.

Medicare cost plans may enroll both Part A/B as well as Part B only beneficiaries (Section 1876(d) of the Social Security Act). Medicare cost plan enrollees are not restricted to the HMO network for receipt of covered Medicare services (i.e., covered Part A and Part B services may be received through non-HMO plan sources and are reimbursed separately by original Medicare).

Cost plans may offer either Part D or non-qualified prescription drug coverage but may not offer both (42 CFR 417.440(b)). Plan enrollees not electing Part D coverage from the plan, either because the plan does not offer it or because they did not elect it, may enroll in a PDP.

Under Section 1876 (h)(5) of the Social Security Act, no new cost plan contracts are accepted by CMS. CMS will, however, accept and review applications to modify cost plan contracts in order to expand service areas (42 CFR 417.402(b)).

Section 1876(h)(5)(C) of the Social Security Act requires that beginning CY 2016, CMS non-renew cost plans in service areas or portions of service areas in which at least two competing MA local or two MA regional coordinated care plans that meet specified enrollment thresholds are available. *The Medicare Access and CHIP Reauthorization Act of 2015 delays non-renewal of plans affected by the cost plan competition requirements through CY 2018. This means cost plans that would otherwise be non-renewed in all or a portion of a plan's service area as a result of the cost plan competition requirements, will be able to continue to offer the plans through contract year 2018.*

For further information on Medicare Cost plans see *Chapter 17* of this manual.

40.2 – HCPP Plans

(Rev. 124, Issued: 11-10-16; Effective: 11-10-16; Implementation: 11-10-16)

An HCPP operates like a Medicare cost plan but exclusively enrolls Part B only beneficiaries and only provides Part B benefits (42 CFR 417.800(a)(1)(B), (d)(1)).

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R125MCM	02/10/2017	Update of Chapter 1	02/10/2017	N/A
R124MCM	11/10/2016	Update of Chapter 1 of the Managed Care Manual	11/10/2016	N/A
R95MCM	01/07/2011	Chapter 1, "General Provisions"	01/07/2011	N/A
R81MCM	04/25/2007	Updates to Chapter 1, "General Provisions"	04/25/2007	N/A

[Back to top of chapter](#)

EXHIBIT 12

From: Nelson, Steve H [/O=UHG-EXCHANGEMAIL/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SNELS59]
Sent: Wednesday, April 30, 2014 1:54:41 PM
To: cheri.rice@cms.hhs.gov
CC: Johnson, Thad C; Schumacher, Daniel J; Erickson, Karen L; Nelson, Steve H
Subject: 2012 Attestation and follow-up from yesterday's meeting

Dear Cheri,

I wanted to thank you and your colleagues for taking the time to meet with us yesterday. We appreciate the time and attention that you and others in CMS leadership have provided on the issue of our 2012 risk adjustment data submissions and our annual risk adjustment data certifications. As we mentioned, prior annual certifications have been on paper, and we have thus had the ability to add notes explaining our understanding of the certifications and our ongoing data remediation efforts. This year, however, the certifications are electronic, and there does not appear to be an opportunity to reflect our understanding. The purpose of our meeting yesterday and this email is to explain our understanding of the certifications.

First, as with our past certifications, the 2012 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.

Second, the certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.

Third, the certifications only cover risk adjustment data for 2012 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.

Fourth, as we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2012 dates of service that we ultimately determine should be deleted consistent with this email.

Fifth, as we discussed yesterday, CMS recently issued a proposed rule that would, if finalized, require MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. During our conversation yesterday and other recent conversations, CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that MA plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. We currently have a process through which we review certain medical records to determine the accuracy of risk adjustment diagnoses and submit appropriate deletes. This process already has resulted in the identification of and, in some instances, the submission of deletes for 2012 dates of service. But based on the proposed rule, including the preamble, and recent conversations with CMS, we suspended that process for 2012 dates of service while we consider whether to make changes. Pursuant to our discussion, however, we will soon submit for deletion those diagnosis codes that have undergone a complete review and that we have therefore identified as appropriate deletes. In the near future, we will determine whether to continue our review process for the diagnosis codes which were still under review at the time we suspended our process. In the meantime, we will not delete these codes.

The certifications that we submit today are made subject to these clarifications. Please let us know if you have any questions. Again, thank you for your time and attention on this matter.

EXHIBIT 13

Message

From: Nelson, Steve H [steve_nelson@uhc.com]
Sent: 6/26/2015 11:41:30 AM
To: cheri.rice@cms.hhs.gov
Subject: 2013 CMS RAF Attestation

Cheri,

Similar to last year, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you last year, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our discussion and understanding regarding the certifications.

- As with our past certifications, the 2013 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate
- The certifications use the phrase best knowledge, information, and belief, which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2013 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2013 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule last year that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed last year, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing consideration of a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision. That decision remains operative for 2013 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson

Chief Executive Officer

UnitedHealthcare Medicare & Retirement

EXHIBIT 14

Paul, Rebecca (CMS/CM)

From: Rice, Cheri M. (CMS/CM)
Sent: Tuesday, June 7, 2016 11:22 AM
To: Kreisel, Johanna (OS/OGC)
Cc: Paul, Rebecca (CMS/CM); Harlow, Jennifer A. (CMS/CM); Reed-Asante, Monica (CMS/CM); Chaudhuri, Ilna (CMS/CM); Simons, Kellie M. (CMS/CM); Tudor, Cynthia G. (CMS/CM)
Subject: FW: 2014 CMS RAF Attestation

Redacted

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Tuesday, June 7, 2016 10:21 AM
To: Rice, Cheri M. (CMS/CM) <Cheri.Rice@cms.hhs.gov>
Subject: 2014 CMS RAF Attestation

Cheri,

As we have done the past several years, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you in the past, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing regarding our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our prior discussion and understanding regarding the certifications.

- As with our past certifications, the 2014 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2014 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are continuously engaged in the ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2014 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule two years ago that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to

determine the accuracy of risk adjustment diagnoses. As we discussed at that time, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS two years ago, CMS's withdrawal of the proposed rule, and CMS's announced plans to use a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision at the time. That decision remains operative for 2014 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

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EXHIBIT 15

MODEL CALIBRATION FACTOR

Jennifer Harlow, Director, DPV
Lateefah Hughes, DPV
Jonathan Smith, DPV

CMS0005881

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Exhibit 15 - 0301

Risk Adjustment in Medicare Advantage

- MA plans submit diagnosis data to CMS
- Diagnosis data are used to risk adjust CMS' payments to plans
- CMS assigns a relative value to each disease category (diabetes, congestive heart failure)
- The more diagnoses submitted, the higher the plan's payment

Risk Adjustment in Medicare Advantage

- CMS policy requires that plans only submit diagnoses that are documented in a physician, hospital inpatient or hospital outpatient medical record
- Until RADV, virtually no enforcement mechanism to ensure that diagnoses submitted by plans met this and other requirements

Risk Adjustment Data Validation

- In 2008, CMS launched RADV audit initiative
- Under RADV, CMS identifies statistically valid sample of beneficiaries for each audited plan
- Plan is asked to produce medical record documentation for each diagnosis claimed by the plan
- CMS coders review documentation
- Extrapolate from sample findings to estimate net overpayments due to undocumented diagnoses

RADV Audits

- Nearing completion of five pilot audits for 2007
- Nearing completion of 32 additional audits for 2007
- Need to finalize sampling and extrapolation methodology

Error in FFS Diagnoses

- In RADV audits, we expect coding perfection from MA plans
- In FFS Medicare, some portion of diagnoses on FFS claims are not documented in medical records
- Aside from DRGs, these diagnoses do not typically drive payment in FFS
- Under RADV, plans are being held to a different (higher) standard for diagnoses

Why does FFS Diagnosis Error Matter?

- CMS uses diagnosis and cost information from FFS claims to assign values to each condition category for MA payment purposes
- Inclusion of undocumented diagnoses tends to reduce risk adjustment values

Why does FFS Diagnosis Error Matter?

	Diabetes on Claim?	Diabetes in medical record?	FFS Cost
Beneficiary A	Yes	Yes	\$4000
Beneficiary B	Yes	Yes	\$4000
Beneficiary C	Yes	Yes	\$4000
Beneficiary D	Yes	No	\$0
		Total	\$12,000
		Diabetes Value for MA payment	\$3,000

Why does FFS Diagnosis Error Matter?

	Diabetes reported by MA plan?	Diabetes in medical record?	CMS Payment to Plan	Plan Cost	RADV	CMS Payment to Plan
Beneficiary A	Yes	Yes	\$3000	\$4000		\$3000
Beneficiary B	Yes	Yes	\$3000	\$4000		\$3000
Beneficiary C	Yes	Yes	\$3000	\$4000		\$3000
Beneficiary D	Yes	No	\$3000	\$0	(\$3000)	\$0
Beneficiary E	Yes	No	\$3000	\$0	(\$3000)	\$0
		Total	\$15,000	\$12,000	(\$6,000) ^{CMS0005889}	\$9,000

Model Calibration Factor

- Model Calibration Factor (aka “FFS Adjustor”) takes into account how CMS payments would change if perfection standard that is applied under RADV was also used when calculating risk adjustment model values
- Ensures that RADV and MA payments are on same documentation standard
- MCF applied as an offset to recovery amounts under RADV

Model Calibration Factor

- MCF currently under development
- Will be calculated by applying RADV review to claims from FFS CERT program

EXHIBIT 16

Agenda

Background

- We released our latest payment error estimate for Medicare Advantage last November which was based on 2009 payments.
- We had an overall payment error rate of 11% -- which was driven almost entirely by errors in the diagnosis data that are submitted to CMS for risk adjustment purposes.
- Our primary corrective action to bring down this error rate is our RADV audit initiative in which we pick a subset of plans and audit the accuracy of the diagnosis data that they've submitted.
- We'll talk specifically about how later in the deck, but we think the RADV audit initiative can also be helpful as one tool to address the aggressive coding patterns of some Medicare Advantage organizations that Rick described at our last meeting.

Basic RADV Audit Methodology

- Slide 4 describes the basic mechanics of each RADV audit.
- For each audited plan, we identify a sample of beneficiaries (stratified into groups by risk score).
- For each disease or condition, known as an HCC, we request that the plan provide medical record documentation to verify the accuracy of each reported condition.
- For example, if a particular beneficiary was reported to have diabetes and congestive heart failure, we would request medical record documentation to support the diabetes and medical record documentation to support the congestive heart failure.
- We then have coding experts reviewed the medical records to determine what conditions are documented in the medical record.
- Based on that review, we then calculate what the payment to the plan should have been for those beneficiaries.
- Then extrapolating those sample errors to the universe of beneficiaries enrolled in that plan contract, we calculate an aggregate contract-level payment error for the plan.

Current Status

- In terms of the current status of the RADV audits, we have audited 37 contracts all for payment year 2007.
- We have preliminary medical record review findings for each of those audited contracts.
- The next step before finalizing these audits, or proceeding with audits for future payment years, is to finalize a few outstanding policy issues, including how we extrapolate the sample findings
- In December of 2010, we released for public comment our proposed methodology for extrapolating the sample findings to plans' aggregate payments.
- We got a lot of comments from the industry.
- There is intense interest given the dollars at stake.
- We're going to focus today on the four main outstanding questions/issues raised by plans that we need to finalize before moving forward.
- There are four main issues that we need to decide before publishing the final extrapolation methodology and proceeding with recoveries of overpayments.

- First, we need to decide whether we want to stay with 2007 as the first year for RADV or whether we should move to a later year.
- Second, we need to determine how many audits we will do for each payment year and how we select the plans to audit.
- Third, we need to finalize the methodology for calculating how much each plan owes and whether we include a FFS adjustor in that methodology.
- Finally, we need to decide what documentation we will allow plans to submit to prove whether a beneficiary truly has a particular condition.

Timing of RADV Audits.

- First, there is the issue of what year to begin with for RADV audits.
- The RADV audits are being done on our own initiative and not in response to a statutory or regulatory mandate.
- So we have complete discretion about when to start them.
- As I mentioned, the first and only year we have begun to audit is 2007.
- Plans have argued that the RADV audits are really a game changer and that they fundamentally change how much plans can expect to get paid in the years in which they are audited.
- Plans argue that they need to take potential RADV recoveries into account when they do their bids so they ensure they get the revenue they need.
- Plans argue that in 2006 when they did their bids for 2007 they didn't know about RADV and now we are retroactively changing the payment rules.
- We don't find that argument very persuasive and neither does OACT who reviews the bids.
- RADV is not changing our payment methodology it is just a mechanism to enforce the rules.
- In addition, if we take their argument to the logical extreme, we could only start auditing in a year when plans have perfect and complete advance knowledge of the RADV process and extrapolation methodology, which at this point would be 2013.
- We might want to pick a later year, however, to shorten the timeframe between when the audit is conducted and the payment year we are auditing.
- The 2007 audits have taken much longer than we ever dreamed possible.
- Our original goal when we started them in 2008 was to begin taking back money in 2008.
- The process has been drawn out because we needed to issue a reg on the appeals process before we could begin.
- Also the 2007 audits have been a learning process for us and the plans and as we've gone we've added steps and additional safeguards to the audit protocol to ensure that we have a process that will withstand challenge during appeals and litigation.
- If we move forward with 2008, we would be reviewing records from 4 to 5 years ago.
- Unfortunately, the longer the lag between the payment year and the audit, the more difficult it is for plans to track down medical records from providers that have moved or are no longer practicing.
- So to shorten the timeframe, we recommend starting with payment year 2011.
- This is the first year that we can implement the shortest lag possible – which is about 2 years.

- If we go that route, then we start the audits as soon as our final payment reconciliations are done for 2011 later this year and we would recoup overpayments in early 2014?.
- For the 2007 audits, we propose to close them out by recouping overpayments for the individual beneficiaries in the sample rather than extrapolating the findings to each plan's entire payment.

How many RADV Audits.

- Going forward we also need to decide how many RADV audits to do each year.
- Given our current staffing and contractor resources, we can do up to 80 audits per year.
- As we discussed, we have done approximately 30 audits for 2007.
- We propose recommending 30 audits in anticipation that this is an item we can give on for OMB and go up to as high as 80 audits.

(b)(5)

Model Calibration Factor.

- The next issue is the extrapolation methodology that we're going to use in RADV.
- The approach that we laid out in our December guidance was pretty straightforward and we don't recommend making any significant changes -- with one exception.
- Plans have argued that we should incorporate a FFS adjustor into the extrapolation methodology.
- The industry has argued that in the RADV audits we are holding them to a standard of perfection for diagnosis coding but that physician claims in FFS Medicare often include diagnoses that aren't supported in the medical record.
- And this wouldn't matter except that we use FFS claims data to develop our risk adjustors for Medicare Advantage.
- So when we estimate the relative cost of any given condition, we use diagnosis and cost data from FFS Medicare.
- So implicit in all of the adjustments we make to plans payments to account for the relative risk of their populations, are the factors that we developed using FFS data.
- So we've got one documentation standard for RADV, which is perfection.
- And we've got another documentation standard for risk adjustment, which reflects a certain level of codes that aren't documented in a medical record.
- For our payments to be as accurate as possible, we should be using the same standard for both.

- To answer this issue, we can incorporate a FFS adjustor that estimates how much higher the plan's payment would be if the model had been built using perfect data.
 - This factor would reduce the estimated RADV overpayments due from each plan.
 - We think this approach makes sense and from a technical point of view is the right thing to do.
 - It also will help bring the overpayments into a range that is more realistic for plans to be able to accommodate.
-
- To estimate the FFS adjustor, we have done a RADV-like audit of 10,000 medical records from the CERT sample.
 - Based on this CERT RADV audit, we estimate the FFS adjustor to be 8.1%.
 - The approach we used to develop this estimate can be modified to dial the estimate down.
 - The FFS adjustor has a significant effect on RADV recoveries.
 - If we had no FFS adjustor, we would recoup about \$900 million for the 2007 audits. With a 8.1% FFS adjustor, we would recoup about \$500??
 - It is possible to modify the approach for calculating the FFS adjustor that results in a lower (or higher) adjustor.
 - If we use a 4.8% adjustor, recoveries total XX.
 - We think the 8.1% adjustor is the best approach – because is the most conservative estimate we think it puts us in the best position to withstand litigation challenges.
-
- In risk adjustment, we are estimating the average cost of any given condition given the people who are reported to have it.
 - If we include diagnoses for beneficiaries who don't actually have the disease, or for whom the medical record documentation is not clear, this tends to reduce the estimated average cost of various conditions and therefore our risk adjustment factors.
 - So plans argue that we are paying them as if they are getting beneficiaries who look like FFS rather than the higher average cost of the beneficiaries we are allowing to be claimed in MA under the RADV audits.

Documentation Standards.

- The third issue is what documentation plans will be allowed to submit as evidence for the diagnoses they submitted.
- So under our current rules, plans must submit medical record documentation to confirm each diagnosis they have claimed.
- So, for example, if they told us that a beneficiary had diabetes and congestive heart failure, they would submit medical record documentation from one date of service to support the diabetes and medical record documentation from the same or another date of service to support the congestive heart failure.
- The documentation must be from the year prior to the payment year and must be from an acceptable provider type, i.e., hospital inpatient, hospital outpatient or physician.
- The plans have pushed back on these documentation requirements.
- They want to submit medical record documentation from time periods other than the prior year.

- They also want to use non-medical record documentation like prescriptions or claims to support diagnoses.
- They also want us to allow plans, when necessary, to combine evidence from these various sources.
- So under this approach, even though there is no single source that definitely shows that a beneficiary has a particular diagnosis, plans could combine multiple records that taken together would suggest that the beneficiary has the diagnosis.
- Our recommendation is to hold firm with the requirements that the only acceptable documentation are medical records from hospitals or physicians from the proper time period.
- First, it is important to make sure that the standards we use in RADV are consistent with the standards we use in calibrating our risk adjustment model.
- If we allow data from time periods other than the prior year or from sources other than hospitals or physicians, then our RADV audits will be out of sync with our risk adjustment model and we will be paying plans more than we should.
- Second, if we deviate from medical records as the source of documentation, we will have no consistent standard.
- And then we are in very dangerous territory with being able to ensure that we are applying uniform set of rules to determine when the documentation is sufficient and when it isn't.
- What we do recommend, however, to address the industry's concerns is to allow plans to submit as many medical records as they like.
- So rather than limiting plans to one medical record, we would be accept multiple records.
- Our coders would code each record until they find a record that supports the condition in question.
- As we do with the one best medical record, we would also gives plans credit for any additional diagnoses we find in that record that we not initially claimed.
- One of the underlying problems here is that outside of the hospital setting, physicians are not consistent in following coding guidelines and there are issues with the quality of medical record documentation that are not unique to MA providers.

Anticipated Reactions to CMS' Recommendations

- For the model calibration factor, the MA industry will be very supportive.
- We have discussed this concept with the OIG; they appear at least at a staff level to understand the technical reasons for making such an adjustment.
- So if we decide to move forward with such an adjustment, we don't expect criticism from the OIG.
- On the documentation standards, the plans will oppose our proposed position and will use this as one of the legal challenges they make to RADV.
- The OIG, on the other hand, supports our proposed approach.
- On using 2011 as the first year for RADV audits, the plans will be supportive that we will not extrapolate for 2007, 2008 or 2009. However, they will continue to argue that we should skip 2010 and 2011 as well.
- It is unclear where the OIG will come out on this issue.
- They too have done 2007 audits, but have not completed them.

- They are likely to skip 2008 for the same reason we are considering to shorten up the timeframe between the audit and the data collection period.

Background

- As you know, we have a large payment error rate in Part C.
- It is approximately 11% and it is driven almost exclusively by error in diagnosis codes submitted to CMS by Medicare Advantage organizations.
- As you know, under our risk adjustment methodology we are largely reliant on plans to report diagnosis information.
- The more diagnoses plans submit, generally the higher their payment.
- Back in 2008, we launched our Risk Adjustment Data Validation initiative as our primary corrective action to reduce this payment error.

RADV Contract-Level Audits

Basic RADV Methodology

- Under our RADV audits, we confirm whether or not the diagnoses submitted by the audited plan are documented in the patient's medical record.
- Under these audits, we select a statistically valid sample of diagnoses for each audited plan.
- We then ask the plan to submit medical record documentation that prove that the beneficiary truly has the reported condition.
- We have teams of medical coding experts that review the documentation.
- Based on their review, we calculate an error rate for the sample, and extrapolate the error rate to the total payment made by the CMS to the plan for the year.
- This extrapolation approach means that significant dollars are at risk for audited plans.
- We first announced our plan to extrapolate back in 2008 and, at that time, began RADV audits of 5 pilot plans and 32 additional plans for calendar year 2007 payments.

EXHIBIT 17

Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model

Gregory C. Pope, M.S., John Kautter, Ph.D., Randall P. Ellis, Ph.D., Arlene S. Ash, Ph.D., John Z. Ayanian, M.D., M.P.P., Lisa I. Iezzoni, M.D., M.Sc., Melvin J. Ingber, Ph.D., Jesse M. Levy, Ph.D., and John Robst, Ph.D.

This article describes the CMS hierarchical condition categories (HCC) model implemented in 2004 to adjust Medicare capitation payments to private health care plans for the health expenditure risk of their enrollees. We explain the model's principles, elements, organization, calibration, and performance. Modifications to reduce plan data reporting burden and adaptations for disabled, institutionalized, newly enrolled, and secondary-payer subpopulations are discussed.

INTRODUCTION

Medicare is one of the world's largest health insurance programs, with annual expenditures exceeding \$200 billion. It provides health insurance to nearly 40 million beneficiaries entitled by elderly age, disability, or ESRD. Approximately 11 percent of Medicare beneficiaries are enrolled in private managed care health care plans, with the rest in the traditional FFS program. The 1997 BBA modified the Medicare managed care (MMC) and other capitated programs, collectively called

M+C.¹ Medicare pays private plans participating in M+C a monthly capitation rate to provide health care services to enrolled beneficiaries.

Historically, capitation payments to MMC plans were linked to FFS expenditures by geographic area, with payments set at 95 percent of an enrollee's county's adjusted average per capita cost (AAPCC). The AAPCC actuarial rate cells were defined by: age, sex, Medicaid enrollment (indicating poverty), institutional status (for nursing home residents), and working aged status (for beneficiaries with employer-based insurance where Medicare is a secondary payer). Separate county factors were calculated for the aged and non-aged disabled (under 65 years), and at the State-level only (due to small numbers), for ESRD-entitled beneficiaries.

The AAPCC payment methodology explains only about 1-percent of the variation in expenditures for Medicare beneficiaries, and does not pay more for sicker people. Thus, research showed that the managed care program was increasing total Medicare Program expenditures, because its enrollees were healthier than FFS enrollees, and the AAPCC did not account for this favorable selection (Brown et al., 1993; Riley et al., 1996; Mello et al.,

Gregory C. Pope and John Kautter are with RTI International. Randall P. Ellis and Arlene S. Ash are with Boston University. John Z. Ayanian is with Harvard Medical School and Brigham and Women's Hospital. Lisa I. Iezzoni is with Harvard Medical School and Beth Israel Deaconess Medical Center. Melvin J. Ingber, Jesse M. Levy, and John Robst are with the Centers for Medicare & Medicaid Services (CMS). The research in this article was funded by CMS to RTI International under Contract Numbers 500-95-048 and 500-00-0030. The views expressed in this article are those of the authors and do not necessarily reflect the views of RTI International, Boston University, Harvard Medical School, Brigham and Women's Hospital, Beth Israel Deaconess Medical Center, or CMS.

¹ The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) renames the M+C program Medicare Advantage. However, since this renaming does not officially take place until 2006, we continue to use M+C.

This analysis shows that a parsimonious risk-adjustment model with a substantially reduced number of diagnostic categories is almost as predictive as a full model. But parsimony has a cost. In limiting the number of conditions that affect payment, many serious, high-cost diagnoses—especially rare ones—will be ignored. MCOs enrolling beneficiaries with excluded diagnoses will be disadvantaged, and beneficiaries with such conditions may not be well served by MCOs.

CMS considered these results, and consulted with clinicians, on the tradeoff between number of diagnostic categories and predictive power, and also other criteria for diagnostic categories to include in risk adjustment, such as well-defined diagnostic criteria and clinical coherence and homogeneity. It was important that the HCC hierarchies not be disrupted by deletion of higher-ranked HCCs while lower-ranked HCCs were retained. After this process, CMS selected 70 HCCs to include in the CMS-HCC model. The choices reflect a balance among the competing considerations of reducing data collection burden, maximizing predictive power, including rare, high-cost conditions, and selecting only well-defined and clinically coherent conditions. Generally, the higher-cost, more severe conditions at the top of the HCC disease hierarchies were retained, while some lower-cost, more frequent and more discretionary conditions at the bottom of the hierarchies were pruned. For example, in the coronary artery disease hierarchy, AMI (heart attack), other acute IHD (e.g., unstable angina), and angina pectoris/old myocardial infarction were retained, but chronic IHD (e.g., coronary atherosclerosis) was excluded.

After the CMS-HCC model was finalized, a list of approximately 3,000 of the more than 15,000 ICD-9-CM diagnosis codes was identified that are sufficient to define the

model's 70 HCCs. In addition, because the CMS-HCC model does not give extra credit for multiple reports of the same diagnosis, MCOs need only report a single encounter during the relevant year of data collection that establishes the diagnosis. The information required for the single encounter is: (1) beneficiary identification number, (2) date (to establish that the diagnosis was made during the relevant reporting period), (3) setting (to establish that the diagnosis was made in one of the allowed hospital or physician settings), and (4) ICD-9-CM diagnosis code. In short, MCOs are required to report only the minimum.

Concern about the quality of diagnostic reporting is the greatest in physician offices, where diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals. The auditing standard that CMS has promulgated for reporting of physician office diagnoses is that a physician has established the diagnosis in the medical record, and that medical coders have recorded it in accordance with ICD-9-CM rules. CMS will conduct coding audits, but not clinical audits. That is, CMS will require MCOs to demonstrate that a diagnosis is present in the medical record on the specified date and has been coded according to ICD-9-CM. CMS will not require clinical verification of these diagnoses, such as diagnostic test results.

CMS-HCC Model Calibration

We calibrated the CMS-HCC model to 1999-2000 Medicare 5-percent sample FFS data for beneficiaries entitled by age or disability (beneficiaries entitled by ESRD were excluded). The model is prospective, meaning that diagnoses collected in a base year (1999) are used to predict expenditures in the following year (2000). An

EXHIBIT 18



Federal Register

Thursday,
April 15, 2010

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480
Medicare Program; Policy and Technical
Changes to the Medicare Advantage and
the Medicare Prescription Drug Benefit
Programs; Final Rule

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Medicare & Medicaid
Services**

42 CFR Parts 417, 422, 423, and 480

[CMS–4085–F]

RIN 0938–AP77

**Medicare Program; Policy and
Technical Changes to the Medicare
Advantage and the Medicare
Prescription Drug Benefit Programs**

AGENCY: Centers for Medicare &
Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy.

DATES: *Effective Date:* These regulations are effective on June 7, 2010. However, we note that because health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011, except where otherwise noted.

FOR FURTHER INFORMATION CONTACT:
Alissa Deboy, (410) 786–6041, General information and Part D issues.
Sabrina Ahmed, (410) 786–7499, Part C issues.
Terry Lied, (410) 786–8973, Collection of information requirements and regulatory impact analysis issues.
Kristy Nishimoto, (410) 786–8517, Part C and D enrollment and appeals issues.
Jennifer Smith, (410) 786–2987, Part C and D compliance and sanction issues.
Frank Szefflinski, (303) 844–7119, Part C payment issues.

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- 11. Transition Process Under Part D (§ 423.120(b)(3))
- 12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§ 423.464)
- 13. Time Limits for Coordination of Benefits (§ 423.466)
- 14. Use of Standardized Technology Under Part D (§ 423.120)
- 15. Absence from Service Area for More Than 12 Months Under Part D (§ 423.44)
- 16. Prohibition of Mid Year Mass Enrollment Changes by SPAPS Under Part D (§ 423.464(e))
- 17. Non-renewal Beneficiary Notification Requirement Under Parts C and D (§ 422.506 and § 423.507)
- 18. Notice of Alternative Medicare Plans Available to Replace Non-Renewing Plans Under Parts C and D (§ 422.506(a)(2)(ii) and § 423.507(a)(2)(ii))
- 19. Timeframes and Responsibilities for Making Redeterminations Under Part D (§ 423.590)
- 20. Requirements for Requesting Organization Determinations Under Part C (§ 422.568)
- 21. Organization Determinations Under Part C (§ 422.566 and § 422.568)
- 22. Representatives (§ 422.561, § 422.574, and § 422.624)
- 23. Disclosure Requirements Under Parts C and D (§ 422.111(g) and § 423.128(f))
- 24. Definition of MA Plan Service Area (§ 422.2)
- C. Changes to Provide Plan Offerings With Meaningful Differences
 - 1. Meaningful Differences in Bid Submissions and Bid Review (§ 422.254, § 423.265, § 422.256, and 423.272)
 - 2. Transition Process in Cases of Acquisitions and Mergers (§ 422.256 and § 423.272)
 - 3. Non-renewing Low-enrollment Plans (§ 422.506(b)(1)(iv) and § 423.507(b)(1)(iii))
 - 4. Medicare Options Compare and Medicare Prescription Drug Plan Finder

D. Changes To Improve Payment Rules and Processes

This section addresses three payment issues under Part C. These provisions are outlined in Table 4.

TABLE 4—IMPROVING PAYMENT RULES AND PROCESSES

Provision	Part 417/422	Part 417/422	Part 423	Part 423
	Subpart	Section	Subpart	Section
Risk Adjustment Data Validation	Subpart F	§ 422.2	N/A	N/A.
Dispute and Appeals Process	Subpart G	§ 422.311		
Payments to Medicare Advantage Organizations-Actuarial Valuation	Subpart F	§ 422.254	N/A	N/A.
Determination of Acceptable Administrative Costs by HMO/CMP	Subpart O	§ 417.564	N/A	N/A.
Cost Contract and Health Care Prepayment Plans (HCPPs).				
Calculation of the Minimum Percentage Increase under Part C	Subpart G	§ 422.306	N/A	N/A.

1. Definitions Related to Risk Adjustment Data Validation Appeals (§ 422.2) and Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures (§ 422.311)

In the October 22, 2009 proposed rule, we proposed regulations establishing an appeals process to be used by MA organizations to appeal the error calculation resulting from Risk Adjustment Data Validation (RADV) audits. As explained in the preamble of that proposed rule, under RADV audits and medical records are reviewed to determine whether they support diagnosis codes (known as Hierarchical Condition Codes, or HCCs) submitted to us under the MA risk adjustment methodology. Under this methodology, certain diagnosis codes are considered to signify higher costs for the enrollee, and therefore, we pay a higher amount to the MA organization for an enrollee to reflect these higher costs. If, in fact, a diagnosis code was not justified by the enrollee's medical condition, the higher payment amount associated with that diagnosis code would have been an overpayment. Under the RADV audit process we plan to recover the overpayments identified during the RADV audit. The appeals process we proposed in the October 22, 2009 proposed rule was intended to provide a mechanism for MA organizations to appeal the error calculation associated with the overpayments identified under RADV audits. We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process, but on the RADV audit process and underlying MA payment policy producing the overpayment findings and our definitions proposed at § 422.2. Since neither the statute nor existing MA program regulations

currently specify a process for appealing overpayments resulting from RADV audits, the appeals process we proposed was based on our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act.

Specifically, we proposed adding a new § 422.311 to part 422, subpart G, to specify RADV dispute and appeal rights for MA organizations. We proposed regulatory provisions allowing MA organizations that undergo RADV audit(s) to—(1) submit physician and other practitioner signed attestations relating to physician and other outpatient medical records that had a missing signature, or credentials that resulted in a payment error finding; (2) dispute certain other types of medical record review-related findings through the use of a documentation dispute process; and (3) appeal our RADV payment error calculation. By availing themselves of these RADV dispute and appeal processes, we noted that MA organizations would be able to reduce their RADV payment error and thereby, reduce their overall estimated MA payment error. Therefore, we proposed the following provisions under part 422:

- To revise § 422.2 to add definitions of six terms that pertain to RADV activities, and thus to our proposals for implementing a RADV dispute and appeal processes.
- A new § 422.311 describing procedures that we would implement to afford MA organizations facing a potential overpayment determination resulting from RADV audits the opportunity to have certain potential RADV payment errors addressed in advance of RADV-audit-related payment error determinations, and to have other types of confirmed payment errors overturned. At § 422.311(a) and (b), we summarized the RADV audit procedures. Beginning with § 422.311(c), we proposed implementing

a three-pronged RADV dispute and appeal procedure that MA organizations could employ to reduce their RADV payment error rate, including—

- Physician/practitioner attestation(s);
- Documentation dispute; and
- RADV payment error calculation appeal.

We noted that analysis of data originating from medical records submitted by MA organizations that have undergone RADV audit indicates that a substantial percentage of medical record-related payment error determinations are due to missing signatures or credentials on medical records. Medicare program rules dictate the necessity of physician signatures on medical records, and MA risk adjustment requirements dictate that risk adjustment diagnosis data be accepted only for health services that were provided by certain physician specialties. Therefore, RADV audit procedures require that, in addition to finding diagnosis information that would support the HCCs submitted by the MA organization for risk adjustment purposes, physician signatures, and appropriate credentials must be present on medical records. Medical records with missing signatures or credentials are scored as errors under RADV audit procedures. We estimated that if given the opportunity to do so, many physicians and other practitioners that provided the diagnosis information on RADV-reviewed medical records would in fact attest that they documented the information in these medical records, even though signatures and credentials were missing from those records. Moreover, the presence of a signature or credential attestation to accompany these medical records would in our opinion, provide justification for preventing both contract-level and national-level RADV payment errors

that would otherwise originate from medical record signature, or credential-related discrepancies.

Therefore, in proposed § 422.311(c)(1), we proposed to implement a process that would allow MA organizations to voluntarily submit CMS attestations (that is, attestations developed and pre-populated by CMS). These attestations would be signed by physicians/practitioners who would attest responsibility for providing and documenting the health services in the physician and outpatient medical record(s) that were submitted for RADV audit. We specified at proposed § 422.311(c)(1)(ii) and (iii) that MA organizations would be eligible to use attestations to address signature or credential-related discrepancies only from physician or outpatient medical records; attestations would not be allowed to address signature or credential-related discrepancies found on inpatient medical records. The proposed use of an attestation would not in any way supplant the medical record, nor would it permit attesting physicians/practitioners to alter the existing medical record. Attestations would not be acceptable to address any issues outside of the RADV-audit process.

At proposed § 422.311(c)(1)(C)(iv), we indicated that we would prospectively notify MA organizations that if the “one best” medical record used to validate an audited HCC were missing a physician/practitioner signature or credential, the MA organization would be permitted to submit a CMS–RADV attestation along with the medical record, to fulfill the requirement that medical records contain physician/practitioner signatures and credentials.

We described the proposed process that we would jointly undertake to review attestations submitted for our review at proposed § 422.311(c)(1)(iv) and (v), noting the following:

- Only CMS-generated attestations that meet certain requirements described at § 422.311(c)(1) and (d) would be eligible for consideration. Failure to meet these requirements would result in us not reviewing or accepting submitted attestations.
- CMS attestations that have been altered or amended (for example, striking out prepopulated words and replacing them with hand-written replacement words) without instruction or written concurrence from us would not be accepted.
- Attestations would need to accompany the medical record at the same time that the medical record was submitted to us for RADV audit. MA organizations would not be permitted to

submit attestations before or after submission of their RADV medical records.

- Attestations would need to originate from the physician/practitioner whose medical record accompanies and corresponds to the attestation. We would not accept attestations or medical records from any party other than the MA organization.

- Organizations would not be permitted to submit attestations during the documentation dispute or RADV reconsideration processes described at § 422.311(c)(2) and § 422.311(c)(3).

At proposed § 422.311(c)(1)(iv), we described the process that we would undertake to review attestations and notify appellant MA organizations of the results of these attestation reviews. Our attestation review determinations would be final and binding upon both parties and would not be eligible for further appeal.

We further proposed affording MA organizations the option of disputing other nonsignature or credential-types of RADV-related medical record diagnosis coding discrepancies via a proposed documentation dispute process that we described in new paragraph § 422.311(c)(2). Under our proposal, in order to be eligible for documentation dispute, MA organizations would need to submit their “one best” medical record in accordance with RADV medical record submission deadlines established by us during the RADV medical record request process.

At proposed § 422.311(c)(2)(a), we specified the types of RADV-related errors that would be eligible for the proposed documentation dispute process. The documentation dispute process would apply only to the errors that arise out of operational processing of medical records selected for RADV audits and submitted to us by established deadlines. In this context, errors that arise from operational processing mean errors that arise from the collection and processing of medical records for a RADV audit.

At § 422.311(c)(2)(ii), we proposed limitations that we would impose upon the documentation dispute process; namely that MA organizations would not be permitted to dispute any medical record coding discrepancies, nor would MA organizations be permitted to submit altogether new medical records in place of previously submitted medical records. Payment errors that resulted from missing medical records would not be eligible for documentation dispute. At proposed § 422.311(c)(2)(iii) and (iv), we indicated that we would prospectively notify MA organizations

of RADV payment errors that would be eligible for documentation dispute, describe the documentation dispute process that we would undertake, along with the process that we would undertake to notify MA organizations of the results of documentation dispute reviews. As described at proposed § 422.311(c)(2)(v), our documentation dispute review determination would be final and binding upon both parties and would not otherwise be eligible for further administrative appeal.

Proposed § 422.311(c)(3) would establish an appeals process under which RADV payment error calculations would be subject to appeal. Unlike our proposed attestation process described at § 422.311(c)(1), and proposed documentation dispute process describe at § 422.311(c)(2), which would afford MA organizations the opportunity to dispute aspects of our medical record review process, the proposed RADV payment error calculation appeal process was specifically designed to afford MA organizations the opportunity to appeal our contract-level RADV payment error calculation. Under the proposed RADV payment error calculation appeal process, we proposed establishing a three-level appeal process whereby MA organizations may—

- Seek reconsideration;
- Appeal the reconsideration decision to an independent CMS Hearing Officer; and
- Appeal the decision of the independent CMS Hearing Officer to the CMS Administrator.

Given the complexity of RADV audits in general, and the calculation of RADV-related error rates in particular, we stated our belief that it was prudent to afford appellant MA organizations multiple-layers of RADV-related payment error appeal.

At proposed § 422.311(c)(3)(ii), we also specified that MA organizations would not, under the proposed RADV payment error calculation appeal process, be permitted to appeal medical record review errors, nor would MA organizations be permitted to seek formal appeal of physician or practitioner signature or credential-related review errors. We believed that medical record review-related issues would be addressed as a result of the rigorous medical record review process, and the attestation and documentation dispute processes described earlier in the proposed regulation. In accordance with our proposed regulation at § 422.311(c)(3)(i), the RADV payment error calculation appeals process would only apply to errors identified in the RADV payment error calculation. MA organizations would not be permitted to

utilize the payment error calculation appeal process as a method for submitting any medical records for consideration in the calculation of the payment error. In order to be eligible for RADV payment error calculation appeal, MA organizations would need to adhere to established RADV audit requirements, including the submission of medical records in the manner and by the deadlines specified by CMS.

Furthermore, we noted that MA organizations would not be permitted to appeal our RADV payment error calculation methodology. Our justification for excluding methodological appeals was two-fold. First, we said the methodology that we planned to employ to calculate RADV payment errors was methodologically sound and academically defensible. We stated that we intended to ensure that all MA organizations understand the RADV payment error calculation methodology by providing annual notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. MA organizations that object to CMS' RADV payment error calculation methodology would be given an opportunity to provide comment to us under our annual notice of RADV audit methodology. Second, in addition to providing an annual notice of RADV audit methodology, we stated that we would provide an expanded explanation of methodology as part of each RADV audit report that we send to MA organizations that undergo RADV audit. Included in this expanded explanation of methodology would be RADV payment error calculation factors unique to each audited MA organization that would enable the MA organization to independently calculate its own RADV payment error.

At proposed § 422.311(c)(3)(iii) and (v), we specified that MA organizations would be notified of their RADV payment error calculation appeal rights at the time we issue a RADV audit report to that organization. MA organizations would have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. A request for reconsideration would need to specify the issues with which the MA organization disagrees, the reasons for the disagreements and explain why the organization believes the issues are eligible for reconsideration. The request for reconsideration would need to include additional documentary evidence that the MA organization considers material to the reconsideration, though MA

organizations would be prohibited from submitting medical record-related evidence such as new or previously submitted medical records or physician or practitioner attestations and from appealing any issues pertaining to the methodology applied in any part of the RADV audit. At proposed § 422.311(c)(3)(iv), we further specified that the MA organization would bear the burden of proof to demonstrate that our RADV payment error calculation was clearly incorrect.

We described our proposal regarding the conduct of a RADV payment error calculation reconsideration, the decision of the reconsideration official and the effect of the CMS reconsideration decision official at proposed § 422.311(c)(3)(e) and (f).

At proposed § 422.311(c)(3)(v) and (vi), we described the first level of RADV payment error calculation appeal, the request for reconsideration of our RADV payment error calculation. Under this process a CMS official or our contractor not otherwise involved in error-rate calculation activity would review our RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation, recalculate the payment error utilizing our RADV payment error calculation methodology (as specified in our standard operating procedures), and render a determination whether the RADV payment error calculation was accurate. This CMS official or CMS contractor not otherwise involved in RADV error-rate calculation activity would recalculate and arrive at an independent RADV payment error. Whether the official or contractor agreed with our payment error calculation, or overturned the calculation and established a new RADV payment error, this party's RADV payment error calculation determination would be issued to a CMS reconsideration official. The CMS reconsideration official would review their analysis and make a determination whether to accept or reject the findings of the CMS official or CMS contractor that recalculated the RADV payment error. In instances when the CMS official or contractor recommended overturning CMS' RADV payment error calculation and the reviewing CMS reconsideration official agreed with the newly calculated RADV payment error, we would issue a reconsideration decision which informed the appealing MA organization in writing of its reconsideration decision, in effect, notifying the MA organization of its new RADV payment error. If the reconsideration official upheld the

decision of the CMS official or contractor to sustain our initial RADV payment error calculation, the reconsideration official similarly would notify the appellant MA organization of its determination. In either instance, the decision of the reconsideration official would be final and binding, unless a request for hearing was filed by CMS or the appellant MA organization.

At proposed § 422.311(c)(4), we clarified that if CMS or an MA organization were dissatisfied with the decision of the CMS reconsideration official described at § 422.311(c)(3), CMS or the MA organization would be permitted to request a second-level RADV payment error calculation appeal, which is a hearing on the RADV payment error calculation determination. CMS or MA organization choosing to pursue a hearing would be required to file a request for hearing within 30 calendar days of the date the MA organization received the written RADV payment error calculation reconsideration decision, as described at proposed § 422.311(c)(3)(vi).

We noted that CMS or MA organizations requesting a hearing would need to do so in writing, including a copy of the CMS reconsideration official's decision to either uphold or overturn the initial RADV payment error calculation, and specify the findings or issues in that reconsideration decision that they disagreed with and why they disagreed with them. The hearing would be conducted by the CMS Office of Hearings and presided over by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration of the RADV payment error calculation. The hearing would be held on the record, unless the parties requested, subject to the Hearing Officer's discretion, a live or telephonic hearing. The Hearing Officer would also be permitted to schedule a live or telephonic hearing upon their own motion. The CMS Hearing Officer would be limited to a review of the record that was used for the initial RADV payment error calculation and the reconsidered RADV payment error calculation.

Additionally, we noted that the Hearing Officer would have full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers would include the authority to take appropriate action in response to failure of an organization to comply with such procedures.

At proposed § 422.311(c)(4)(iv), we also indicated that the CMS Hearing Officer would review and decide

whether the reconsideration official's decision was correct and to notify CMS and the MA organization in writing of his/her decision, explaining the basis for the decision, which would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.311(c)(5).

We explained that the third level of RADV payment error calculation appeal that MA organizations can request would be discretionary review by the CMS Administrator. We described this proposed process at § 422.311(c)(5). At this level of appeal, CMS or the MA organization would be permitted to appeal the decision of the CMS Hearing Officer by requesting that the CMS Administrator review the CMS Hearing Officer's determination. Parties requesting CMS Administrator review would have to request the review within 30 calendar days of receipt of the CMS Hearing Officer's determination. If the Administrator agreed to review the case, the Administrator would review the Hearing Officer's decision as well as any other information included in the record of the Hearing Officer's decision and would determine whether to uphold, reverse, or modify the CMS Hearing Officer's decision. The Administrator's determination would be final and binding.

We also noted that, based on our experience with appeals of MA and Medicare Part D program contract determinations, we have determined that it would be necessary for us to establish a "compliance date" to use as a reference point in issuing a ruling regarding RADV audit findings. Therefore, we proposed at § 422.311(b)(2), to require that the compliance date for meeting Federal regulations requiring MA organizations to submit medical records for the validation of risk adjustment data (§ 422.310(e)) also be the due date when MA organizations (or their contractor(s)) selected for RADV audit would need to submit medical records to us. We stated we would inform an MA organization in writing regarding selection for RADV audit, including the due date for submission of medical records.

We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process described in proposed § 422.311—but also the RADV audit process and underlying Medicare Advantage payment policy. These comments have resulted in changes to our above-described proposals as discussed below.

While many comments that we received relate to the underlying RADV audit process and risk adjustment methodology and may not directly address the RADV appeals process specifically, we are responding to these comments, because they appear to be relevant to the RADV appeals process that we had proposed in our Notice of Proposed Rulemaking. Certain comments were outside the scope of our proposed rule and we have not included responses to those comments.

Comment: A comment alleged that it was premature for CMS to propose rules related to the RADV appeals process because the commenter stated that the Administrative Procedure Act (APA) required that the underlying RADV audit process giving rise to the overpayments that would be appealed under our proposed regulations be subjected to notice and comment rulemaking.

Response: We disagree and believe that the RADV audit process does not establish any substantive rules within the meaning of the APA or section 1871 of the Act, but rather is a means for ensuring that payments made to MA organizations comply with substantive rules governing MA payments that are set forth in the statute, and in regulations that have been subjected to notice and comment procedures. Regulations specifying that payment amounts are subject to audit (for example, § 422.504(d)(1)(i)) have been subjected to notice and comment procedures, and provide ample notice of the fact that we have the right (and, indeed, the duty) to ensure that MA payment amounts are accurate. See also, § 422.310(e), which states that MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS, and that there may be penalties for submission of inaccurate data.

Indeed, we would point out that throughout the Medicare program, and government programs generally, audit policies and procedures intended to ensure or verify payment accuracy assist in the enforcement of rules, and are not themselves substantive rules subject to APA notice and comment procedures. Therefore, to the extent we are providing a RADV appeals process, we are providing an opportunity that does not currently exist for MA organizations to appeal audit findings that they would otherwise not have been permitted to question.

Comment: Some commenters stated that CMS did not follow proper procedures and stated that procedures

set forth in our proposed regulations, such as our "one best medical record" and other documentation requirements, established a substantive legal standard governing the payment to MA organizations, and therefore, they had to be included in the annual notice of changes to payment methods required under section 1853(b)(2) of the Act, which requires that MA organizations be afforded an opportunity to comment on changes in the methodology for determining MA payments.

Response: We disagree. The requirement in section 1853(b)(2) of the Act to provide an advance notice of methodological changes to MA organizations of proposed changes to the methodology and assumptions used to compute annual MA capitation rates pertains to the methodology for determining the proper amount of payment. All substantive changes to the risk adjustment methodology at issue in the RADV audit process have been described in the annual advance notice. The RADV audit process and appeals procedures proposed in the October 22, 2009 proposed rule do not make any substantive changes in the methodology for determining MA payment amounts. Rather, they are designed to ensure that this payment methodology has been applied correctly, and the MA organization has received the amount to which it was entitled under this methodology. The risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition. The RADV audits and appeals process are designed to ensure that the enrollee in fact has that condition, and that the MA organization is thus entitled to the amount that has been paid for that condition. The fact that audits might determine that an MA organization was not, in fact, paid correctly, is not a change in methodology or assumptions related to how the payment amount is to be determined and therefore is not subject to the advance notice requirements under section 1853(b)(2) of the Act. Nonetheless, in our October 22, 2009 proposed rule, we proposed to provide notice of RADV audit methodology to the public, as well as a summary of RADV methodology issues for each audited MA organization at the time we issue our audit finding pursuant to an actual RADV audit. We offered to provide details of our RADV audit methodology in an attempt to provide additional transparency related to the process. We anticipate providing additional notice of RADV audit methodology to the public by publishing the methodology in some

type of Medicare program document—most likely in a Medicare manual later this year (2010).

Comment: A commenter stated that CMS was not complying with requirements in section 1871(a)(2) of the Act, which states that “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, * * * shall take effect unless it is promulgated by the Secretary by regulation * * *”

Response: As discussed previously, the RADV audit process, and the appeals procedures addressed in this rulemaking, do not “establish” or “change” any “substantive legal standard governing * * * payment.” To the contrary, they are designed to ensure that the substantive legal standards for payment set forth in the statute and regulations are correctly applied. The substantive rules governing the amount of payment to which the MA organization is entitled are unchanged as governed by statute and implementing regulations.

Comment: A commenter urged that CMS suspend RADV audits until such time as CMS subjects the rules to notice and comment rulemaking.

Response: As discussed previously, we do not believe subjecting the RADV audit process to rulemaking is required or appropriate, there would be no basis for suspending the audit process.

Comment: One commenter noted that when the risk adjustment system was initially established, the Secretary was required to submit a report to Congress in accordance with section 1853(a)(3)(A) of the Act that documented the proposed method of risk adjustment of MA payment rates, and that included an evaluation of the method by an outside, independent actuary of the actuarial soundness of the proposal. The commenter believed that such an evaluation was required in the case of the RADV audit process.

Response: We disagree that RADV audits impact the risk adjustment system in any manner. As indicated earlier, RADV audits are solely to verify that the risk adjustment methodology is being correctly applied.

We also received a large number of comments from MA organizations, managed care trade associations and a law firm regarding RADV methodological-related issues. While some comments were not relevant to the rules that CMS proposed regarding the RADV appeals process, there were a number of comments that we believe

should be addressed, and as such, we do so as follows.

Comment: Many commenters recommended that CMS independently test and validate its RADV methodology before CMS implements it. The commenters indicated that CMS failed to provide any record of submitting its methodologies to an academic review and that if CMS has done so, we should have included such studies with the proposed rule so that interested parties could review and comment on any of these academic studies. The commenters recommended that CMS provide a process that permits thorough review and comment by plans of RADV audit methodology issues before undertaking further RADV audits. Several commenters further recommended that all methodological issues pertaining to RADV audits be appealable.

Response: Previously in this preamble we indicate that the process of independently reviewing medical records to validate risk adjustment data submitted by MA organizations for payment purposes has been established and operational for more than 10 years. Over the course of this timeframe, we have been advised on the RADV process by statisticians, senior analysts, expert medical record coders, physicians, managed care professionals, and other health care providers. From a medical record coding perspective, we have secured expert direction from Peer Review Organizations (PROs) (in the past) and Quality Improvement Organizations (QIOs) (currently) by incorporating them into the RADV team. From an analytic design and implementation perspective, we have in the past and continue to employ senior level expert analysts from different academic fields as independent contributors to the RADV operations team to review and validate the accuracy of the findings across the RADV process, including peer review of statistical sampling and payment error calculation methodologies. The independent expert analysis and review is similar to that conducted in an academic setting in that the participating parties are credentialed in a specific field of study, such as statistics, and possess substantial years of expertise conducting similar processes and analyses. The independent methodology review processes also involve the use of internal controls, and tests for consistency and accuracy. RADV procedures are subject to the evaluation requirements of the CMS Annual Financial Audit.

In addition, the RADV methodology that we employ in the process of reporting a component of the national Part C payment error is similar to the methodological approach that we employ in conducting contract-specific RADV audits and error calculations. This methodology has been reviewed and approved by officials at the HHS.

This notwithstanding, in considering the commenters’ questions, where necessary, we will incorporate additional independent third party review for purposes of validating RADV error-calculation methodology. As indicated in our proposed rule and cited elsewhere in the preamble to this final rule, we intend to publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary. Finally, to ensure that audited organizations understand how their RADV error rate was calculated, as indicated in our proposed rule, we further intend to describe our RADV methodology in each audited organization’s RADV audit report.

Given these efforts to ensure that the RADV process is transparent to audited MA organizations and the public, and that the methodology used under that process is reasonable, consistent, and accurate, we do not believe any further action is required.

Comment: Several commenters argued that CMS should include Medicare plan enrollees for whom no diagnosis code was submitted under the risk adjustment methodology as part of its RADV error testing samples. These commenters also recommended that CMS include “under-coding” findings in the audit error estimates in order to more accurately account for members’ health status.

Response: Our RADV audit policy does account for both underpayments and overpayments. The RADV process addresses under-coding through the application of rules for crediting a sampled enrollee with additional HCCs that are identified incidentally, during medical record review. We emphasize that these “additional” diagnoses were not originally submitted for payment for enrollees selected in the sample, and yet we provide audited organizations credit through our RADV medical record review process.

However, we have not and do not expect to sample enrollees for whom no HCCs were submitted. This is because the RADV is an audit process that is intended to validate the HCCs that were submitted by MA organizations in order to determine whether the additional payment amounts associated with these

diagnosis codes were properly made. Under our separate Risk Adjustment Data Submission Process, the data submission period for any given payment year is lengthy and extends beyond the actual payment year, providing a substantial amount of time for organizations to submit and/or correct enrollee HCC risk adjustment data for any given payment year—to reflect of enrollee health status. This is sufficient time for plans to submit data on all their enrollees, including those with no HCCs. The RADV audit process is not intended to serve as a de facto mechanism for extending the HCC data submission deadlines under which MA organizations operate.

We received a number of comments from MA organizations and a law firm regarding the financial impact of RADV audits. While these comments did not pertain directly to our proposed RADV appeals procedures, some comments nevertheless indirectly impact the RADV appeals rules. Therefore, we respond to several of these comments here.

Comment: Several commenters suggested that CMS's proposed methodology to calculate and apply error rates and payment adjustments across contract years after payments were made undermines the actuarially-based risk assumptions inherent in Plans' bid submissions.

Response: Regarding the assertion that RADV audits undermine the Part C bidding process, beginning with the introduction of the HCC risk adjustment model for CY 2004, we have published clear guidelines to be followed by MA organizations in the collection and support of diagnosis codes underlying risk scores for plan enrollees. In their preparation of a MA bid, certifying actuaries are expected to ensure that the underlying data are reasonable and appropriate for the circumstance, including the base year risk scores. If the ultimate risk scores for a plan's population are lower than initially forecast by the certifying actuary, then the plan is likely to experience lower than expected margin. Conversely, if the ultimate risk scores for a plan's population are higher than initially forecast by the certifying actuary, then the plan is likely to experience greater than expected margin. These results illustrate the nature of health plan capitation and the risk borne by MA organizations.

Comment: Commenters stated that the establishment of an audit methodology that involves retrospective contract-level payment adjustments creates the potential for unpredictable retroactive liability that MA organizations could

not have considered in developing bids for affected prior years. Commenters suggested that CMS' sampling methodology undercuts the mandate in section 1854(b)(6)(B)(iv) of the Act that MA organizations' rates reflect the revenue needs of the organization. The commenters assert that MA organizations did not develop bid submissions for calendar years 2006 through 2009 with an expectation that CMS would implement contract-wide payment adjustments based on provider documentation issues outside of the MA organizations' control. As a result, if payments effectively are reduced retroactively as the result of RADV audits, the bid submissions (and resulting payments) arguably would not adequately reflect Plans' risks, and MA organizations may be forced to dip into their reserves to repay dollars that were not anticipated to be at risk.

Response: We disagree. If plan bids are developed based on faulty data, such as inappropriate claim costs or risk score data, there is a greater likelihood of error in the bid projection. There are many factors that influence the accuracy of bid projection, and data quality is just one such factor. There is no legal authority to change a bid amount after it has been accepted regardless if additional information suggests that the bid is too high or too low.

In general, it is our belief that health plans are confusing actuarial equivalence in payment amount—which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve—with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnoses leading to such costs being incurred have a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employ to ensure accuracy under Medicare Part C actually further actuarial equivalence, rather than conflicting with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

Comment: Several commenters questioned whether CMS's RADV

medical record review coders have the qualifications and experience necessary to code RADV-related medical records. Commenters specifically questioned whether RADV coders were equipped to code accurately in situations in which clinical training may be required in order to recognize all extractable ICD-9 codes. They inquired into the certification and coding experience qualifications for the RADV coders.

Response: The coders that CMS uses to review RADV medical records are fully qualified to code RADV-related medical records. All coders are professionally certified for example, Certified Professional Coder (CPC), Certified Coding Specialist (CCS), Registered Health Information Administrator, (RHIA) and Registered Health Information Technician (RHIT), and must have prior experience coding medical records. Coders have access to physician consultation as needed. Coders also have access to our Independent Coding Consultant—a coding expert with more than 10 years of professional coding experience, which we require to be RHIA, coding certified and to have at least 5 years of experience in RADV-specific coding.

Comment: Several commenters objected to what they contend is a burden that RADV audits impose upon the physicians and physician practices who must produce medical records necessary to conduct audits. These commenters recommended that CMS take into account the potential impacts of more aggressive program integrity efforts on the medical practices that provide care to MA plan enrollees. Outside of the proposed rule, we have also received letters arguing that the burden associated with RADV audits is not limited to the CMS' audits but also extends to internal audit activity undertaken by Medicare health plans that mimics the RADV audits that we undertake for Medicare payment validation. These commenters raised concerns that Medicare health plans were misrepresenting their internal audit activity as official CMS RADV audits.

Response: Section 422.310(e) requires that providers who voluntarily enter into contracts with MA organizations submit data to CMS contractors/IVCs for RADV audits. In an effort to minimize the burden associated with this activity, we have developed best practices that we encourage health plans to employ in their efforts to gather medical records from providers and hospitals. To the extent MA organizations employ these practices, it is our belief that the impact of RADV audits on providers can be minimized.

We also understand the increasing need for providers to be able to distinguish when they are being asked for medical records in association with an MA plan's own audit or in accordance with an official Medicare program RADV audit which is subject to legislative requirements. Therefore, we issue letters on our letterhead that MA organizations must use when requesting medical records from providers when the request is specifically related to an official CMS RADV audit. Providers may rely upon these letters as an indicator that a given medical record request is for CMS' RADV, and providers may request this authorizing letter before responding to requests by the MA plan.

We received a large number of comments from MA organizations, managed care trade associations and a law firm regarding the "one best medical record" policy that CMS proposed to apply to the RADV program. By way of explanation, the "one best medical record" policy specifies that for any one sampled beneficiary—with any one HCC—the MA organization is allowed to select and submit supporting medical record documentation of a face-to-face encounter for a physician or outpatient visit (one date of service) or an inpatient stay (range of dates from admit to discharge). The face-to-face encounter would have needed to occur at some point during the data collection year (from January 1st to December 31st).

Comment: Commenters contended that the one best medical record policy forces plans to omit relevant data that could be supported through documentation that CMS does not permit—such as prescription drug data and lab results.

Response: The RADV risk adjustment model is based upon FFS claims data from specific risk adjustment provider types, and not alternative data sources, such as, prescription drug data or lab results. Therefore, the RADV audit process is based upon supporting medical record documentation from provider data sources that are used to calibrate the model. As for the one best medical record policy, while MA organizations that voluntarily submit HCCs for Medicare payment are prospectively paid based on these unaudited and unvalidated HCCs submissions, we, upon the recommendation of MA organizations, agreed to allow any one medical record from across an entire data collection period to validate an HCC incorporated into the payment to the MA organization.

Comment: Some commenters contend that if CMS is going to rely on the one

best medical record policy to the exclusion of other sources of information that might confirm an HCC, the RADV appeals process should allow for HCC medical record review findings to be appealed.

Response: To address these comments as described in § 422.311(c)(2) of this final rule, we have revised the process so that MA organizations may appeal medical record review determinations in accordance with the procedures specified in § 422.311(c)(2).

Comment: A number of commenters argued that the one best medical record policy is flawed in that it provides an insufficient basis for confirming an HCC for members with chronic diseases when a collection of several records, perhaps from various providers, considered in the aggregate might better verify a patient's condition.

Response: We disagree. In the case of a chronic disease such as congestive heart failure, all that is required is medical record documentation from one visit to a physician or a hospital, over the course of the data collection year, to validate the audited HCC.

Comment: We received several comments comparing the RADV audit and appeals process to varying program attributes of the Medicare FFS program. For example, some commenters argued that CMS' one best medical record rule conflicts with Medicare FFS standards since there is no one best medical record rule applied to Medicare payment error-rate testing for FFS providers.

Response: Payment error-testing under original Medicare is different than payment error testing under Medicare Part C. Under original Medicare, much of what comprises the error testing regimen is aimed at validating that a particular level of service was provided and therefore justifies a given level of Medicare payment. Under RADV, the payment error testing focuses on validating HCCs by examining medical records to determine whether they contain supporting diagnostic codes. This error testing is aimed at validating that a particular Medicare beneficiary indeed has the medical condition for which the MA organization has been paid for, and not whether a particular level of service (for example, level 1 office visit vs. level 2 office visits) was provided. Moreover, there is no evidence to support the notion that the Congress, in establishing the Part C payment process, ever intended the Part C payment process to mimic payment processes under Original Medicare. Indeed, they are fundamentally different.

Moreover, we believe that the one best medical record policy and the operational process associated with it are far less restrictive than Medicare FFS. MA organizations are not limited to the specified date(s) of service they reported to us with regard to selecting a medical record as supporting documentation for a specific HCC. We continue to believe that the one best medical record policy is appropriate for the Medicare Part C risk adjusted payment system which is distinct from a FFS payment system where payment is determined on a claim-by-claim basis. Under Part C, we only require that plans send one HCC for payment for an entire year; it therefore logically follows that we would only require one medical record to validate this HCC.

Comment: Some commenters stated that the one best medical record rule was inconsistent with the mandate that MA payment adjustments be actuarially equivalent to the FFS sector.

Response: It is our belief that health plans are confusing actuarial equivalence in payment amount—which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve—with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnosis leading to such costs being incurred has a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employ to ensure accuracy under Medicare Part C we believe furthers actuarial equivalence, rather than conflicts with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

Comment: A commenter noted that in Medicare Part A and B appeal contexts, supplemental information and testimony are considered, and given such weight as the fact finder determines is appropriate.

Response: Under our proposed appeals procedures that affords MA organizations the ability to appeal the Part C error calculation specified at § 422.311(c)(3), the CMS Hearing Officer

has the discretion to conduct the hearing in alternative ways beyond conducting the hearing on the record. For example, the Hearing Officer can choose to conduct the hearing by way of teleconference or in person. The CMS Hearing Officer also has the discretion to request supplemental information or to accept testimony, as he or she deems necessary. Also, under the medical record review appeal processes that we specify at § 422.311(c)(2), we afford MA organizations the ability to submit supplemental information—the attestation reviewed by the IVC—to validate the same HCC that the Initial Validation Contractor (IVC) initially determined to be in error.

Comment: Several commenters, focusing on the relationship between MA organizations and their providers, noted that errors in documentation are ultimately attributable to providers, not MA organizations. These commenters argued that, due to the nature of the MA program, while CMS makes a capitated payment to organizations that have relationships with providers, these providers may not have an incentive to document the HCCs which affect payment to the MA organization. The commenters also stated that contract-level payment adjustments penalize MA organizations, while it is providers who are responsible for maintaining adequate records. A commenter also suggested that we accept “other data” to supplement, or substitute, a medical record.

Response: Section 422.504(i)(1) clarifies for MA organizations that they are ultimately responsible for the risk adjustment information submitted to CMS. This section of the regulations states, “Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.” MA organizations are further directed in § 422.504(i)(2) that all their “first tier, downstream, and related entities are required to agree that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect * * * medical records.” Therefore, while we acknowledge the comments, we maintain that it is the responsibility of MA organizations to ensure that they submit accurate risk adjustment information, and that the providers with whom they contract are aware that we have authority to audit medical records to verify this information.

We do not require MA organizations to submit HCCs for beneficiaries; MA organizations choose whether or not to do so. For risk adjustment diagnoses that are submitted, it is the responsibility of the MA organization to obtain appropriate documentation. If MA organizations are not confident in the information they obtain from their providers, they may wish to initiate education efforts, or include provisions in their contracts that ensure providers appropriately document diagnoses and provide medical record documentation to the plan upon request.

In regards to supplemental information, we have determined, and MA plans have been informed multiple times, that the appropriate format for obtaining risk adjustment information is a medical record. For validation purposes, plans are asked to submit the one best medical record documenting the HCC. We carefully determined the one best medical record policy, after consultation and input from the industry supporting this policy. We do not believe that supplemental information would be sufficient, or add value to a record that does not support an HCC for which the plan had been paid.

Comment: Many commenters from the MA industry recommended that before CMS audit MA organizations under RADV, the agency first account for any error rates inherent in Medicare FFS data that affect MA error rates. These commenters stated that through the proposed RADV audit appeal process, CMS is imposing a set of rules regarding physician recordkeeping that were not anticipated in the ICD-9CM coding guidelines, is not consistent with standard practices and is not enforced on original Medicare claims. The result, they allege, is *de facto* MA payment adjustments based on recordkeeping discrepancies without an adjustment to original FFS Medicare risk scores for the same recordkeeping discrepancies.

Response: We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue.

Comment: A number of commenters stated that the CMS-defined attestation process was overly narrow and should be expanded to provide for more widespread use of attestations in the RADV audit process. Commenters contended that attestations should be expanded to provide MA organizations with a greater ability to correct medical record coding-related errors or deficiencies in submitted medical records. Commenters requested that CMS permit MA organizations to submit attestations that attest to the presence of

medical conditions not fully supported in the medical record submitted to CMS. The commenters further argued that CMS should permit attestations to be used to validate not only the physician signature and credentials that are missing from a medical record, but also for patient name, identifier, date of service, and other documentation inadequacies that can result in a RADV medical record coding error.

Response: Taken in the aggregate, commenters’ recommendations regarding an expanded use of attestations in the RADV audit process reflect a misunderstanding of what attestations are intended to accomplish. Many of the comments submitted suggest that we adopt a policy that in effect, allows attestations to stand in the place of the medical records that are required to validate the HCCs that have resulted in higher payments already made to MA organizations. For example, permitting physicians to use attestations to “correct” medical record coding-related deficiencies determined pursuant to medical record review; or allowing attestations to be an acceptable vehicle for the submission of new HCCs that were not otherwise already submitted to CMS for payment.

We believe that we must validate the HCCs that result in additional payment through the existence of clear, unambiguous diagnostic information in a beneficiary’s medical record. A medical record provides the written support for the diagnosis that was made and must meet certain well recognized documentation requirements. Consistent with the Medicare FFS program, medical record documentation, rather than other alternative documentation, such as attestations, is required to validate information provided to us for the purpose of making provider payments. The existence of an accompanying attestation simply provides a mechanism for the physician to validate that the medical record that is missing a signature or credential is in fact his or her patient’s medical record. That is, attestations are intended to complement medical records, not stand in the place of them.

We continue to believe that the Medicare program is best served by limiting the applicability of attestations to instances in which the original diagnosing physician submits a signed and dated attestation to validate that the medical record in question is theirs. We see no justifiable reason for CMS to expand the applicability of attestations beyond this intended purpose and therefore, we are not accepting these comments.

Comment: Several commenters objected to CMS' prohibition on using attestations for inpatient medical-record-related RADV coding errors, and noted that CMS did not provide sufficient explanation why CMS would not permit them. The commenters recommended that CMS permit attestations to be submitted with respect to inpatient records.

Response: We do not believe that permitting attestations for inpatient medical records is justifiable. The decision to permit attestations for RADV was in response to industry concerns about the lack of signatures in medical records that are generated out of physician-office settings and not hospital settings. Upon preliminary evaluation of RADV findings, our data corroborates industry concerns in that it clearly shows that the majority of RADV-identified payment errors associated with lack of provider signatures were derived from medical records submitted and reviewed under the guidelines for physician/outpatients settings. Indeed, the data further corroborates that payment errors related to the lack of signature in inpatient medical records is minuscule.

Note that, with respect to the ongoing use of attestations within the RADV audit context, we reserve the right to continue to evaluate payment error related to physician/practitioner signatures, and the impact that attestations have upon these types of errors. We further reserve the right to amend the regulations in the future regarding the use of attestations should experience under the program justify this change.

Comment: Several commenters recommended that CMS implement an administrative appeals process for reviewing attestation determinations made by CMS.

Response: We understand the commenters' concerns, but do not believe this additional appeals process is necessary. As noted in section § 422.311(c), in light of the changes we are making in this final rule to the proposed RADV appeal procedures that permit MA organizations to appeal medical record review determinations made at the RADV IVC review-level, MA organizations will be permitted to appeal medical record review-related determinations whose outcome was determined by the existence or absence of an attestation.

Comment: Some commenters recommended that CMS allow attestations to be used as acceptable vehicles for introducing new HCCs to the Medicare Part C payment process. Several commenters suggested that MA

organizations be allowed to submit a letter from a provider group or other responsible party, along with an attestation in instances where the diagnosing physician is no longer able to sign and date an attestation—for example, in instances in which the diagnosing physician has died, moved or is no longer working for the medical practice.

Response: As stated previously in our response to earlier commenters' recommendations that we expand the applicability of attestations, we do not agree that attestations are acceptable vehicles for submitting new risk adjustment data and enrollee HCCs for payment to CMS. The data submission period for any given payment year opens 12 to 18 months before the start of payment year, and closes 3 months after the actual payment year ends, providing in total, at least 27 months for MA organizations to submit or correct enrollee HCC data for any given payment year. This provides ample time for MA organizations to voluntarily submit HCCs to CMS for Medicare payment.

Furthermore, a fundamental tenet of RADV is validating the existence of diagnoses information in a medical record. Consistent with Medicare FFS, medical record documentation rather than other documentation, such as attestations, is required to validate information provided to us for the purpose of making Medicare payments. Therefore, we see no justifiable reason to abandon this principle by allowing the submission of unsubstantiated HCCs via attestations, and therefore, reject the commenters' recommendations.

Under our RADV audit policy, to the extent we discover acceptable diagnoses codes contained in the one best medical record that plans submit for purposes of HCC validation that were not earlier submitted to CMS for payment via the Risk Adjustment Payment System (RAPS) system (what are known as "additional HCCs")—we credit these diagnoses codes to the submitting MA organization. Our reason for giving health plans credit for these additional diagnoses is precisely because they existed in beneficiaries' medical record(s)—and not in other types of documentation that would not be acceptable in any Medicare venue for justifying Medicare payment.

Comment: Several commenters stated that the 12-week timeframe for submitting attestations was unreasonably short. These commenters recommended that CMS afford plans additional time to gather and submit attestations.

Response: We do not agree. We proposed that the submission timeframe for attestations line-up with the deadline for submitting medical records in order to simplify the medical record and attestation submission process for plans. Under the proposed process the medical record and associated attestation are submitted together. We strongly believe that 3 months is sufficient time for MA organizations to obtain and submit to us the medical records and attestations necessary to validate audited HCCs. To provide additional time beyond the 12 weeks afforded to MA organizations to submit the requested medical records would split-up and unnecessarily complicate the medical record and attestation submission process. Since the attestation is intended to in effect—make the medical record "whole" by way of the signature and/or credential attestation—we believe it is unreasonable to set up a submission system that separates the attestation from the submission of the medical record. Therefore, we are not accepting this recommendation and instead are finalizing the requirement that attestations be submitted to us by the medical record submission deadline.

Comment: Several commenters recommended that CMS permit health plan officials to amend the CMS attestation form through hand-written annotations or to submit MA organization or provider-developed (that is, attestation forms that were not generated by CMS) attestation forms to CMS. A more limited number of commenters recommended that CMS allow physicians not involved in the diagnostic face-to-face encounter to attest to medical records in instances where the diagnosing physician is either dead or no longer at the medical practice or facility from which the medical record originated. These commenters reasoned that in extenuating circumstances such as the death of a provider or a provider having relocated, another provider within the medical practice could be permitted to sign the attestation on behalf of the treating provider. Under this scenario, the signing provider would annotate the CMS attestation form explaining the situation—for example, "Due to the expiration of Dr. Smith on June 1, 20xx, I am signing this attestation on his behalf."

Response: We believe opening the door to allowing modifications to a CMS payment-related document raises serious program integrity-related concerns and could result in fraud to the Medicare program. The extent to which one provider can reliably and

validly attest to a medical record prepared by another provider is questionable. We consulted with other Medicare program components within CMS that are or will be utilizing attestations or similar-like documents (for example, certificates of medical necessity, attestations used in conjunction with Comprehensive Error Rate Testing (CERT)) that have some bearing on Medicare payment and confirmed that there are very limited circumstances under which we permit external modification to any payment-related documents. Given these program integrity-related concerns, we are rejecting these recommendations.

We received a large number of comments regarding our proposed RADV documentation dispute procedures.

Comment: A commenter noted that the proposed definition of “Documentation Dispute Process” in § 422.2 indicates that MA organizations can “dispute medical record discrepancies that pertain to incorrect ICD–9–CM coding * * *” and appeared to conflict with language in proposed § 422.311(c)(2)(ii)(A) stating that medical record coding discrepancies are ineligible for the documentation dispute process. Another commenter contended that the term “operational processing” as described in the regulation, was vague and needed to be further defined. One commenter recommended that CMS allow MA organizations 60 days to request documentation dispute instead of the proposed 30 days. Several commenters recommended that MA organizations be permitted to appeal documentation dispute review determinations.

Many other commenters asserted that the proposed documentation dispute process was too limited in scope, and effectively amounted to nothing more than a mechanism for rectifying clerical errors that provided no meaningful way to contest the accuracy of the auditors’ interpretation of the medical records submitted, or to supplement the record being audited.

Response: As noted in § 422.311(c) of this final rule, in light of the changes to the proposed RADV appeal procedures that we are making in this final rule that permit MA organizations to appeal medical record review determinations made at the RADV IVC review-level, we are withdrawing the proposed documentation dispute procedures described in the proposed rule. By way of this final rule, MA organizations that wish to dispute RADV medical record review determinations that arise out of operational processing of medical records selected for RADV audit (that is,

determinations that arise from the collection and processing of medical records by CMS’ RADV IVC) will now be permitted to do so via the medical record appeals process described in this final rule at § 422.311(c).

We received many comments from MA organizations and a managed care industry trade association regarding the proposed RADV appeals process at § 422.311(c)(3).

Comment: Many commenters stated that the proposed RADV appeals process was too narrow, and failed to allow for all relevant evidence to be considered as part of the appeal process. Of particular interest to many commenters was the fact that MA organizations were prohibited from appealing the substance of medical record coding determinations, as described in our proposed regulation at § 422.411(c)(3). With regard to the RADV appeals process, these commenters specifically recommended that CMS:

- Expand the scope of issues that may be raised in the appeals process to include, at minimum, challenges to medical record coding decisions and challenges to methodology—audit methodology, sampling methodology, and error-calculation methodology.
- Permit MA organizations to appeal HCC findings from the medical record review process.
- Permit MA organizations to submit coding corrections along with the additional medical records necessary to validate audited HCCs that CMS determines are in error.
- Incorporate diagnoses identified in medical records, but not previously submitted nor assigned to a member (so called “additional”) in its RADV-related payment adjustment calculations.

Response: At proposed § 422.311(c)(3)(ii) we specified that MA organizations would not be permitted to appeal medical record review because medical record review-related issues would be resolved as a result of the medical record review process and the attestation and documentation dispute processes described earlier in the proposed regulation. However, based on the public comments we received, we have reconsidered this proposed restriction, and are for purposes of this final rule, changing our policy to now allow MA organizations to appeal medical record review that occurs at the IVC level.

Therefore, under a new final § 422.311(c)(2), we are implementing a process that would allow MA organizations to appeal medical record review that occurs at the IVC level of medical record review.

In order to be eligible for RADV medical record review appeal, MA organizations must adhere to established RADV audit and RADV appeals requirements, including the submission of medical records and documents in the manner and by the deadlines specified by CMS. Failure to do so will render the MA organization ineligible for RADV medical record review appeal. At § 422.311(c)(2)(i)(1) of this final rule, we specify that in order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow our rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization’s request for appeal invalid.

At § 422.311(c)(2)(i)(2) of this final rule, we provide that the medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV IVC.

MA organizations must submit the original, IVC-audited medical record and any attestation reviewed by the IVC to CMS for consideration under the appeals process. MA organizations’ request for appeal may include the attestation reviewed by the IVC in accordance with § 422.311(c)(1) but may not include any additional documentary evidence.

At § 422.311(c)(2)(ii), we specify that MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS. We also specify that any other documentation submitted to us beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by us under the medical record review determination appeal process. MA organizations’ written requests for medical record review determination appeal must specify the audited HCC(s) that we identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal. A request for medical record review determination appeal must specify the issues with which the MA organization disagrees and the reasons for the request for appeal.

We describe the manner and timing of a request for medical record appeal at

§ 422.311(c)(2)(iii). We will issue each audited MA organization an IVC-level RADV audit report that provides details on the results of the medical record review findings. This RADV audit report will clearly specify the HCC determinations that are eligible for appeal. MA organizations will have 30 calendar days from the date of the issuance of the RADV audit report to submit a written request for medical record review determination appeal. A request for RADV medical record review appeal must specify the HCCs that we have identified as being eligible for medical record review appeal and that the MA organization wishes to appeal. The request for appeal must also include the IVC-audited one best medical record and may include an attestation form in accordance with the rules at § 422.311(c)(1), but may not include additional documentary evidence. Please note that MA organizations are not obligated to appeal HCCs that we have identified as being eligible for medical record review determination appeal.

At § 422.311(c)(2)(iv), we describe the process that we will undertake to conduct the medical record review appeal. We designate a Hearing Officer to conduct the medical record review determination appeal. The Hearing Officer need not be an ALJ. We also describe procedures for disqualifying a Hearing Officer in the event either party objects to the designation of a Hearing Officer. We provide written notice of the time and place of the hearing at least 30 calendar days before the schedule date. The hearing is conducted by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS Hearing Officer is limited to the review of the record that was before the IVC.

The CMS Hearing Officer reviews the IVC-audited one best medical record and any attestation submitted by MA organizations to determine whether it supports overturning medical record determination errors listed in the MA organization's IVC RADV audit report. As soon as practical after the hearing, the Hearing Officer issues a decision which provides written notice of the Hearing Officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS. Pursuant to the Hearing Officer's decision, we recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization.

As described at § 422.311(c)(2)(v), the decision of the CMS Hearing Officer regarding RADV medical record review

appeal will be final and binding upon the MA organization unless the MA organization requests review by the CMS Administrator. At § 422.311(c)(2)(vi), we indicate that the MA organization has 30 calendar days to request a review of the CMS Hearing Officer's determinations and that the CMS Administrator has discretionary authority whether to review the determination of the Hearing Officer. After receiving a request for review, the Administrator has the discretion to elect to review the Hearing Officer's decision or to decline to review the hearing decision. If the Administrator elects to review the hearing decision, the Administrator must review the CMS Hearing Officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified. The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the CMS Hearing Officer is final. It is important to note that notwithstanding our implementing procedures that permit MA organizations to appeal HCC determinations at the IVC level of medical record review that we have identified as being eligible for medical record review appeal and that the MA organization wishes to appeal, the ability of MA organizations to appeal these IVC-level medical record review determinations does not otherwise alter MA organizations' ability to appeal RADV payment error calculations described at § 422.311(c)(3). However, MA organizations cannot appeal RADV payment error calculations until all RADV medical record review-related appeals are finalized.

Comment: Several commenters suggested that CMS afford MA organizations a reasonable amount of time after the medical record submission deadline to submit additional documentation that corroborates an already-submitted medical record.

Response: We do not agree that the amount of time provided to MA organizations to submit medical records under existing RADV audit policy is unreasonable. We provide MA organizations 3 months to obtain and submit to CMS the medical records necessary to validate the HCCs that MA

organizations voluntarily submitted to CMS for Medicare payment. Moreover, a policy that supports submitting corroborating evidence to accompany an already-submitted medical record violates CMS' one best medical record policy. Therefore we are not accepting the commenters' suggestion.

Comment: Several commenters recommended that CMS afford MA organizations 60 days, rather than 30 days, to submit a written request for reconsideration of its RADV payment error calculation to provide sufficient time to prepare for the request.

Response: We do not agree. We continue to believe that 30 calendar days is sufficient time for any MA organization considering appealing its RADV payment error calculation to prepare and submit such a request. We are therefore, rejecting this recommendation.

Comment: Several commenters objected to the fact that all RADV-related appeals tasks are conducted by either CMS employees or agents employed by CMS. The commenters suggest that to ensure impartiality and an independent review of plan appeals, the appeals process should allow for independent reviewers outside of CMS. Plans should be allowed to choose and pay for a third party review of the error-rate calculation under reconsideration—rather than use the CMS contractor.

Response: As described in our proposed rule at § 422.311(c)(3)(v) and (vi), the CMS officials and/or contractors that will adjudicate individual appeal cases will be fully independent of the initial RADV error determinations. One important attribute in constructing an independent appeal structure for the RADV program is ensuring that the review officials or contractors called upon to perform these tasks have the necessary expertise to serve in the capacity of an independent appeal official. It would be altogether unreasonable for us to assume that plans would select appeal officials that meet our standards, not would we be able to validate this process in a timely manner. We cannot be put in the position of having to review the qualifications of plan-selected appeal officials and still be able to effectively administer the appeals process in a timely manner. As such, we are rejecting the suggestion that plans be allowed to choose and pay for their own independent review officials.

Comment: A commenter stated that the CMS' RADV appeal rules should provide for a meaningful way to appeal payment determinations.

Response: We believe that the commenter means that our ability to

adjust payments once RADV audit results are finalized should likewise be subject to appeal. We agree and for this reason, as explained in the proposed regulation, we are providing multiple avenues for MA organizations to appeal the RADV findings, including the ability to appeal mistakes in the contract specific payment error estimate as determined by our payment error estimate calculation methodology.

These opportunities to appeal provide ample recourse to MA organizations to have RADV findings fairly readdressed. As part of this process, at § 422.311(c)(3)(vi)(B) and (D), we specified that we would hire an independent RADV payment error appeals contractor to replicate and validate the payment determinations that result in our error-calculation. Therefore, MA organizations that seek to appeal their error rate calculation can rest assured that the payment determinations that result in our error calculation are reviewed by an independent contractor.

Comment: Several commenters noted that, although the proposed rule provides for the review of the RADV calculation by a neutral third party, the proposed rule did not specify the criteria that the independent third party will utilize in determining whether the error rate calculations are correct. These commenters recommend that CMS be required to accept the third-party's findings or that CMS otherwise ensure that the decision on the findings is not made by an official who has a role in the RADV payment error calculation that is under review.

Response: The independent third party will utilize the same error-calculation criteria that will be employed by us in calculating its initial error calculation. This methodology will be known to audited MA organizations. In the preamble to our proposed rule and as stated previously in this preamble, we state that we intended to ensure that all MA organizations understand the RADV payment error calculation methodology by providing notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. We anticipate publishing the RADV error calculation methodology in some type of CMS document—most likely some type of Medicare manual—and annually providing notice of any changes that will be made to this manual. In addition to providing an annual notice of RADV audit methodology, we indicated we would provide an expanded explanation of methodology as part of each RADV audit report that we send to MA organizations that undergo RADV audit.

At proposed § 422.311(c)(3)(v) and (vi), we specified that a CMS official or contractor not otherwise involved in error-rate calculation activity would review the written request for reconsideration, the RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation. We are finalizing that proposal in this rule.

Comment: A commenter believed that the level of detail proposed for the RADV appeals process was too specific. This commenter indicated that because MA organizations' and CMS' experience with data validation is relatively new, CMS should avoid putting a high level of detail into the regulation and should instead, maintain the flexibility necessary to do what makes sense in the context of the data validation.

Response: We do not agree that our experience with data validation is relatively new, since we have been performing RADV audits for over 10 years. The expertise and experience brought to the development of this function in that timeframe has enabled us to present a balanced level of detail with regard to the proposed regulation.

While we certainly appreciate the commenters' concerns regarding the level of specificity proposed—and now finalized—in the regulation, we contend that this level of detail is necessary in order for the public to fully understand how the RADV appeals process will operate. We concur with the recommendation that we remain flexible as we take further steps to implement these rules.

Comment: One commenter stated that the compliance date proposed by CMS is unduly restrictive. This commenter recommended that CMS consider additional evidence and testimony after the compliance date has passed.

Response: We disagree. Based on our experience with appeals of MA and Medicare Part D program contract determinations, it is absolutely essential for us to establish a compliance date to use as a reference point in issuing a ruling regarding RADV audit findings. In proposed § 422.311(b)(2), we specified that the compliance date be the date that MA organizations are required to submit medical records for the validation of risk adjustment data (§ 422.310(e)). By way of this final rule, we are extending the compliance date to include the date that MA organizations that choose to appeal IVC medical record review in accordance with § 422.311(c)(2) must submit medical records for review by the date we determine for the appeal process.

Without a specific date as a reference point for evaluating compliance, MA organizations could choose to assert that while they were unable to meet RADV audit requirements on the date we specified as the due date for medical record submission, they were later able to do so. Under this scenario, organizations would be free to assert the right to submit medical records in place of, or in addition to, records that were or were not, as the case may be, submitted to us by the RADV audit due date. The medical record review process could continue ad-infinity, preventing us from closing out RADV audits and collecting any identified overpayments. The notion of considering additional evidence and testimony after the compliance date has passed negates the intended purpose of establishing a compliance date in the first place, and is therefore rejected.

2. Payments to Medicare Advantage Organizations—Actuarial Valuation (§ 422.254)

We proposed amendments to § 422.254 to expressly require an actuarial certification for Part C bids. As we noted in the preamble to the proposed rule, operationally we require an actuarial certification to accompany every bid, for both Parts C and D. A qualified actuary who is a Member of the American Academy of Actuaries (MAAA) must complete the certification. The objective of obtaining an actuarial certification is to place greater responsibility on the actuary's professional judgment and to hold him/her accountable for the reasonableness of the assumptions and projections. This requirement is already set forth in the Part D regulations at § 423.265(c)(3). We noted that our change in the Part C regulation text will bring the Part C regulation at § 422.254(b)(5) in line with current operational requirements and Part D. We are adopting § 422.254(b)(5) as proposed into this final rule.

Comment: We received three comments supporting the addition of this operational requirement to regulatory text. We also received one comment asking us if this requirement would apply to 2011 Part C bids.

Response: The 2011 Part C bids are due on June 7, 2010, the first Monday of June. Regardless of whether this regulation is final by that date, we will expect MA organizations to submit Part C bids in accordance with current operational guidance, which guidance is consistent with the regulatory language we are finalizing in this rule.

EXHIBIT 19

Single Variable Model Calibration

- Total Costs =
 - Healthy beneficiaries $8 \times \$500$
 - Sick Beneficiaries $+ 2 \times \$1,500$
 - Total costs \$7,000
- Average Costs = \$700
- Risk Factors
 - Healthy: $\$500/\$700 = 0.714$ (base factor)
 - Sick: $\$1,500/\$700 = = 2.143$ total RAF
 - $\$500/\700 base factor = 0.714
 - $\$1,000/\700 disease factor = 1.429

Calibration Errors - Healthy Person Mistakenly Coded as Sick

- Calibration data set has 22 people
 - 10 healthy and coded healthy, cost of \$500 each
 - 2 healthy and coded as sick, cost of \$500 each
 - 10 sick and coded as sick, cost of \$1500 each
- Relative costs in calibration:
 - Healthy person is estimated at \$500
 - Sick person is estimated at \$1,333

Calibration Errors - Healthy Person Mistakenly Coded as Sick (continued)

- Plan must submit like FFS to be paid full costs of sick population
- Plan population exactly equivalent to FFS population
 - 12 healthy members with cost of \$500
 - 10 sick members with cost of \$1,500
- If plan submits only the 10 sick members as sick, payments for sick will average \$1,333
 - \$167 PMPM less than plan needs
 - \$1,670 total short fall for 10 members

Calibration Errors - Healthy Person Mistakenly Coded as Sick (continued)

- If plans submits the 2 mis-coded persons (assuming plan coding = FFS coding), plan receives \$1,333 for members with expected cost of \$500
 - Additional \$1,666 in payment, makes up shortfall
- RADV extrapolation recovers \$1,666
- Implicit assumption that \$1,333 is correct amount for sick members

Calibration and Sick members with Insufficient Documentation

- Calibration data set has 22 people:
 - 10 healthy people with costs of \$500
 - 10 sick people with costs of \$1,500
 - 8 are documented accurately
 - 2 are truly sick but have documentation error
 - 2 healthy people coded as sick with cost of \$500
- Relative costs in calibration:
 - Healthy person is estimated at \$500
 - Sick person is estimated at \$1,333

RADV Impact of Documentation Issues Equivalent to Calibration Issue

- RADV finds bad documentation for two sick members
- RADV finds two members who are healthy coded as sick
- RADV recovers
 - \$1,666 PM for members with bad charts
 - \$1,666 PM for members wrongly coded as sick
- In this example, recovery amounts to 16% of payment, and is 16% loss for plan

EXHIBIT 20

To: Smith, Jonathan (CMS/CPC)[Jonathan.Smith3@CMS.hhs.gov]; Kapustij, Carolyn (CMS/CPC)[Carolyn.Kapustij@CMS.hhs.gov]
From: Harlow, Jennifer A. (CMS/CPC)
Sent: Thur 8/6/2009 7:52:33 PM
Importance: Normal
Subject: FW: Model issues
Received: Thur 8/6/2009 7:52:00 PM
[Single Variable Model Calibration and RADV.ppt](#)

From jeff..... let's discuss. thanks

From:Hutchinson, Thomas E. (CMS/CDHPC)
Sent: Thursday, August 06, 2009 3:09 PM
To: Harlow, Jennifer A. (CMS/CPC)
Subject: FW: Model issues

From:Grant, Jeff [mailto:jeff.grant@healthriskpartners.com]
Sent: Thursday, August 06, 2009 10:28 AM
To: Hutchinson, Thomas E. (CMS/CDHPC)
Subject: FW: Model issues

Tom

Note from before with presentation.

Jeff Grant

Senior Vice President, Client Services

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From: Grant, Jeff
Sent: Friday, May 29, 2009 12:26 AM
To: Hutchinson, Thomas E. (CMS/CPC)
Subject: Model issues

Tom

Some select pieces of my RA for Dummies presentation. I know you can handle much more, but this is a simple world with one demographic factor and one disease factor just to keep things easy to follow. Same principles apply to more complex models obviously. I walk through the calibration and then how it pays wrong when the calibration has flaws. I go over two flaws, one of the healthy coded as sick, the other of the sick that is not adequately documented. The latter is really only a problem under RADV and hard to fix in any calibration because it is a fudge factor for bad medical records. The former could possibly be mitigated by selecting data out of the model under an encounter data collection process, but the bad documentation will not be apparent from any claims indicators and should probably be figured out and used to mitigate the RADV, i.e., adjust for bad documentation above what is found in FFS. Again, that requires the study of FFS coding and documentation that we have previously discussed and will not be able to inform your immediate issue.

Other points:

1. Plan that gets more people from FFS gets to keep revenues that other plans lose (assuming the other plans code exactly like FFS). Plan A has 50% FFS, 50% plan stayers, all coded the same and only 50% subject to RADV. Plan B has the same people year in and year out, 10% from FFS, 90% stayers but coded equivalently. Plan B has the same data as Plan A, but

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almost twice as many people subject to a RADV adjustment.

2. CMS, when asked about alternate data sources and about the appropriateness of paying using FFS data for switchers (FFS to MA), consistently responded that FFS coding represented "perfect" payment, i.e., replication of the model calibration. Trying to look for additional diagnoses results in increased coding intensity (for which CMS is now making an adjustment). Plans were told that if they stuck to how the data comes in to FFS, they would be paid correctly. Now that is doubly not true. (I have looked through QAs and searched the website for certain key phrases and find no formal documentation of this answer unfortunately).
3. PFFS, an admittedly imperfect program but one that the government sponsored, has no network and no real ability to do much else but submit what they receive on claims, which are handled by FFS rules. They ideally should have the best payment because it is most like the original model calibration. Again, extrapolation for RADV does not provide an equitable treatment for these plans and is not consistent with how the payment methodology was developed.

On enrollment:

CMS should react to the low bids this year if they result in an anticipated switch of members. CMS should immediately work to require action plans from the anticipated recipient of these enrollees, should develop its own plan for reacting to the inevitable problems caused by an unprecedented influx, and develop jointly with the plans a set of checkpoints, reports, milestones, etc., to manage any fallout from the AEP immediately rather than dancing through the IG process for several months before mutually admitting there is a huge problem to resolve. This will lower CTM and improve results for CMS and the plans. It also provides a way for CMS to evaluate if the plan is handling the transition effectively and would give the possible early warning that other measures need to be employed. It is not unreasonable to expect 10K+ disruptions, and as high as 50K would not be a surprise. Any plan should take into account the action steps and milestones required to bring various levels of potential discrepancy under control. By doing this early, by demanding that a plan demonstrate its true capacity to handle large-scale enrollments and large-scale discrepancies, CMS and the plan will be ahead of the inevitable problems. The current CVTY model on both sides should not be next year's approach.

Good as always to talk with you tonight. Next week I am in Richmond for the first time in a couple of months, but maybe we can find some time the following week to get together. I will tell you that it was great hearing you at the conference because you always have great insight and make people think. And anybody I have talked with following the conference appreciated what you had to say as well. You really have no idea how little people understand what goes on in the CMS sphere and your candor is quite helpful and appreciated. Most people just BS these guys which does not help the relationship nor their understanding of what CMS is doing and why.

Good luck talking to these guys, and if you have questions give a call.

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Jeff

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Exhibit 20 - 0343

EXHIBIT 21

February 22, 2008

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2009 for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2009. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2009 are also discussed. For 2009, CMS will announce the MA capitation rates on the first Monday in April 2008, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage component of the minimum percentage increase, which is a key factor in determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2009 for original Medicare benefits. Attachment III sets forth the changes in payment methodology for CY 2009 for Part D benefits. Attachment IV presents the preliminary CMS-HCC risk adjustment factors, and Attachment V presents the annual adjustments for 2009 to the Medicare Part D benefit parameters for the defined standard benefit.

Any changes to employer/union-only group waiver plan payment for 2009 will be issued in future guidance.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2009@cms.hhs.gov. Comments or questions also may be mailed to:

Anne Hornsby
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S3-16-16
Baltimore, Maryland 21244

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**2009 ADVANCE NOTICE
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Section E. Adjustment for MA Coding Intensity

Background

As promulgated by the Deficit Reduction Act (DRA), Section 1853(k)(2)(B)(iv)(III) requires CMS to reflect in its risk adjustment for Part C payment “differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences.” The DRA further instructs that results of the analysis will be “incorporated into the risk scores only for 2008, 2009, and 2010.” In order to comply with this section of the DRA, CMS has studied the changes in MA and FFS risk scores, the differences between those changes, and the coding patterns behind these changes.

From our research for the 2008 payment year, CMS found that MA risk scores increased approximately twice as much as FFS risk scores did for our study population between 2004 and 2006. There are a number of key reasons why risk scores in the MA and FFS sectors may rise at different rates. The composition of enrollment in each sector can have an effect on the change in the average risk score. Initially, some MA plans may have had difficulty gathering and reporting diagnosis codes as completely as FFS, so part of the differential risk score growth could be due to “catching up” to FFS. MA plans may be finding and diagnosing disease at a higher rate than FFS providers. Or, it is possible that beneficiaries enrolled in MA plans may be getting sicker faster than beneficiaries in FFS.

Our preliminary research on coding patterns, which was conducted prior to the release of the 2008 Rate Announcement, was unable to clarify enough about the coding pattern differences that result in MA and FFS risk score differences. Therefore, we did not make an adjustment for coding patterns differences in payment year 2008. We stated that we would continue to study this issue, with particular focus on the plans that have experienced significant increases in risk scores, in an effort to determine what the appropriate adjustment might be for 2009 and 2010.

CMS has continued its analysis of the coding patterns that result in differences in the MA and FFS risk scores. The findings below are based on diagnoses reported for payment years 2004-2006. CMS will update these figures by adding the (currently unavailable) 2007 risk scores to the analysis, prior to the publication of the Announcement on April 7, 2008.

Study Results

Composition effects: In order to analyze the gross difference between the change in FFS and MA risk scores, we examined the change in risk scores for three categories of enrollees: stayers, leavers, and joiners. **Stayers** were those enrollees who remained in the same sector (either FFS or MA) over the study period, **leavers** were those who left either the MA or FFS sector, either to go to the other sector or who died, and **joiners** were those who came into FFS or MA, either from the other sector or who were newly eligible to Medicare. We found that indeed some of the difference in the change in risk scores between MA and FFS was due to composition effects. Specifically, we found that:

- A significant portion of the beneficiaries who join MA are beneficiaries who are switching from FFS. In FFS, the vast majority of beneficiaries who join are newly-eligible to Medicare. The risk scores of beneficiaries who are newly eligible to Medicare

tend to be very low and these low risk scores depress FFS risk score growth relative to MA.

- Of the leavers, decedents (who have high risk scores) are a slightly larger fraction of FFS beneficiaries than of MA enrollees and, thus, the exit of high-risk score decedents restrains the year-to-year growth of average FFS risk scores by slightly more than it does MA scores.

Because most new enrollees in FFS are newly-eligible to Medicare and FFS is losing higher risk beneficiaries, overall average MA risk scores are pushed up at a faster rate than risk scores in FFS. Over the two-year period, approximately 50% of the difference between the MA and FFS sectors in the growth of risk scores is due to enrollment patterns and approximately 50% is due to the more rapid growth in risk scores for beneficiaries who stay in the same sector in consecutive years.

Focus on “stayers.” Focusing on the stayers allows us to examine differences in risk score changes that are not due to the changing composition of the enrolled population. In our analyses of the impact of coding patterns on stayers’ risk scores, we did the following:

- We focused on two cohorts of stayers: those who were stayers in 2004-2005, and those who were stayers in 2005-2006. We weren’t able to add the 2006-2007 cohort to the analysis prior to the release of the Advance Notice, but will do so before the release of the Announcement in April 2008.
- For each cohort, we defined MA stayers as those enrollees who were in the same contract in the July of each cohort year, as well as in each data collection year. For example, for the 2004-2005 stayer cohort, we include enrollees who were in the same contract in July 2004 and July 2005, and in all of 2003 and 2004. This criterion resulted in the exclusion of enrollees who would have been new enrollees in the data collection years, as well as those enrollees who switched contracts.
- We found that the overall risk scores of MA stayers increased by 0.032 more than those of FFS stayers over the two-year study period. As discussed below, we then broke down the change in aggregate risk scores into the changes in the disease component of the CMS-HCC risk score (the “disease score”) versus the demographic component.

Focus on the disease score of stayers: The disease score is the HCC component of the risk score that plans (and FFS providers) affect by their reporting of diagnosis codes. Among stayers, we found that MA disease scores increased more quickly than FFS disease scores and that change in the disease component of the risk score accounted for approximately 90% of the difference in the change in MA versus FFS risk scores.

We found that, on average, disease scores for stayers in MA plans increased 20% faster than stayers in FFS over the two years in the study period. Specifically, FFS disease scores for stayers increased by 0.145 over the two-year period between 2004 and 2006, while the average disease score among beneficiaries who remained enrolled in a single MA contract for at least two data collection years increased by 0.174 over the same time period for a two-year difference of 0.029.

Dynamics behind changes in disease scores: CMS also analyzed the reasons why the change in MA and FFS disease scores differed among stayers. A significant portion of the difference in

disease score changes is attributable to the reporting of 26 HCCs (of the 70 HCCs in the model) that fall into one of seven hierarchies: diabetes (5 HCCs), cardiovascular disease (4 HCCs), coronary artery disease (3 HCCs), cancer (4 HCCs), quadriplegia and other central nervous system disease (4 HCCs), liver disease (3 HCCs), and dialysis/renal disease (3 HCCs). Approximately one-third of the difference in disease score change is due to increases in severity within these hierarchies, particularly within the diabetes hierarchy. The remaining difference results primarily from greater retention of reported diagnosis codes within certain hierarchies from one year to the next, especially the coronary artery disease, liver, diabetes, and renal hierarchies.

Variation among contracts: CMS research has also revealed a large amount of variation among MA contracts in the disease score change among stayers, and in the dynamics behind contracts' changing disease scores. As described above, on average, disease scores for MA stayers increased by 0.174 over the 2004-2006 study period, or 0.029 greater than the average increase of 0.145 for FFS stayers. We found that approximately 40% of the contracts in our study – those operating continuously during the 2004, 2005, and 2006 payment years – had changes in stayer disease scores that were less than the changes in FFS stayers' disease scores. Looking at enrollees, we found that 25% of the MA stayers in our analysis were enrolled in contracts where the difference between the two-year increase in stayers' disease scores and the FFS increase was at least twice the industry average.

Catch-up to FFS levels of coding: Although CMS cannot definitely determine whether “catch up” to FFS coding occurred or not, CMS recognizes that plans may have experienced some catch up, particularly during initial years of operation. In order to take any such catch up into account in our adjustment, we are proposing to:

- Adjust for MA coding only in 2009 and later (not adjust for previous year's coding patterns differences).
- Make an adjustment for contracts that have existed since at least 2005.
- Adjust risk scores for enrollees in contracts that have significant coding pattern differences from FFS.
- We are proposing to weight the impact of coding differences on disease scores in more recent years (when plans would have caught up to FFS) differently than coding patterns differences in earlier years.

More complete coding: We do not assume that the coding pattern differences that we found in our study are the result of improper coding. As discussed above, CMS understands that MA plans have made efforts to identify enrollees' conditions and may be coding more completely than FFS. However, because MA coding patterns differ from FFS coding patterns, the normalization factor (which is calculated based on FFS coding) does not currently adjust for these different coding patterns.

Impact of health status on risk score changes: As noted above, it is possible that beneficiaries enrolled in MA plans may be getting sicker faster than beneficiaries in FFS and this could be driving faster risk score growth for MA enrollees. Given the care coordination and disease management activities of MA plans, however, we do not find it reasonable to assume that MA stayers' underlying health status is getting worse at a faster rate than stayers in FFS. CMS analysis has found that MA mortality rates during the study period do not explain rising risk

EXHIBIT 22



PUBLIC LAW 109–171—FEB. 8, 2006

DEFICIT REDUCTION ACT OF 2005

“(A) IN GENERAL.—The Secretary may not make any adjustment to the percent determined under paragraph (2)(B) for any year.

“(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary to make adjustments to the applicable amounts determined under paragraph (1) as appropriate for purposes of updating data or for purposes of adopting an improved risk adjustment methodology.”.

(b) REFINEMENTS TO HEALTH STATUS ADJUSTMENT.—Section 1853(a)(1)(C) of such Act (42 U.S.C. 1395w–23) is amended—

(1) by designating the matter after the heading as a clause (i) with the following heading: “IN GENERAL.—” and indenting appropriately; and

(2) by adding at the end the following:

“(ii) APPLICATION DURING PHASE-OUT OF BUDGET NEUTRALITY FACTOR.—For 2006 through 2010:

“(I) In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences.

“(II) In order to ensure payment accuracy, the Secretary shall conduct an analysis of the differences described in subclause (I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis are incorporated into the risk scores only for 2008, 2009, and 2010. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available.”.

SEC. 5302. RURAL PACE PROVIDER GRANT PROGRAM.

42 USC 1395eee note.

(a) DEFINITIONS.—In this section:

(1) CMS.—The term “CMS” means the Centers for Medicare & Medicaid Services.

(2) PACE PROGRAM.—The term “PACE program” has the meaning given that term in sections 1894(a)(2) and 1934(a)(2) of the Social Security Act (42 U.S.C. 1395eee(a)(2); 1396u–4(a)(2)).

(3) PACE PROVIDER.—The term “PACE provider” has the meaning given that term in section 1894(a)(3) or 1934(a)(3) of the Social Security Act (42 U.S.C. 1395eee(a)(3); 1396u–4(a)(3)).

(4) RURAL AREA.—The term “rural area” has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D)).

(5) RURAL PACE PILOT SITE.—The term “rural PACE pilot site” means a PACE provider that has been approved to provide services in a geographic service area that is, in whole or in part, a rural area, and that has received a site development grant under this section.

EXHIBIT 23

April 1, 2013

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2014 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2014 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html> under Ratebooks and Supporting Data. The statutory component of the regional benchmarks, transitional phase-in periods for the Affordable Care Act rates, qualifying counties, and each county's applicable percentage are also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentage for 2014 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2014. These growth rates will be used to calculate the 2014 capitation rates. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 2.96 percent, and the final estimate of the increase in the FFS Growth Percentage is 3.53 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentage.

The basis for the Growth Percentage for 2014 has been changed to incorporate an assumption that Congress will act to prevent the scheduled 25-percent reduction in Medicare physician payment rates from occurring. The Office of the Actuary has been directed by the Secretary to use this assumption, on the grounds that it is a more reasonable expectation than the reduction required under the statutory "sustainable growth rate" (SGR) formula. Although the Office of the Actuary agrees that Congress is very likely to override the physician fee reduction, the assumption conflicts with the Office's professional judgment that, as in all past years, the determination should be based on current law, not an assumed alternative.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2011 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2014 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice). Attachment IV contains the changes in the payment methodology for Medicare Part D for CY 2014. Attachment V contains tables with the Part D benefit parameters; Attachment VI

risk assessments can be valuable, they may sometimes be used as a vehicle to maximize MA revenue without follow-up care or treatment being provided to the beneficiary by the plan.

Comment: From a data perspective, a few commenters contended that submitting a subsequent encounter would be costly and administratively burdensome. Some commenters requested additional guidance on how CMS is planning to operationally “flag” diagnosis codes in the risk adjustment data submitted to CMS. A few commenters raised concerns with requiring a flag for diagnoses with 2013 dates of service, stating it would be burdensome to do so soon and requested a delay.

Response: As noted above, CMS is delaying the collection of “flags” for these assessments until 2014 dates of service to provide more lead time and allow for more planning. At this time it should be noted that, CMS is only asking that plans flag the encounters for 2014 dates of service, and is not requiring data filtering. CMS will release operational guidance as to how these assessments will be flagged prior to the start date.

Comment: A few commenters shared CMS’ concern that data obtained from MA Enrollee Risk Assessments should not be used for the sole purpose of collecting diagnoses for risk adjustment. They agree it should be used to identify the needs of the patient and ensure appropriate treatment or intervention is provided.

Response: CMS appreciates the support.

Section F. Adjustment for MA Coding Pattern Differences

Comment: A number of commenters argued that the changes to the risk adjustment model to address coding intensity are duplicative of the MA coding adjustment factor.

Response: We understand that different model versions may affect the coding difference trend differently and, when CMS determines the MA coding adjustment factor, we take into account the version of the model that will be in use during the payment year. Because we make determinations regarding the appropriate level of the MA coding adjustment by taking into account the impact on coding of the risk model, the model adjustments made to address coding does not duplicate the MA coding adjustment factor applied to the risk scores.

Comment: One commenter believed that the coding adjustment factor applied to PACE organizations is inconsistent with PACE coding over time. This commenter stated that coding for beneficiaries staying in the PACE program increased by approximately the same increase as in the FFS program and significantly less than the increase in the MA program. The application of a coding adjustment factor to PACE, based on coding changes in the MA program, results in a reduction in risk scores, and consequently payment, that this commenter did not believe would be supported by PACE’s coding experience over time.

Response: CMS applies the MA coding adjustment by developing a uniform adjustment factor. Similar in approach to the normalization factor, the goal is to set the average risk score to the correct level by adjusting for trends in the overall market.

Comment: One commenter questioned the appropriateness of modifying new member risk scores by the MA coding adjustment factor because these members have no MA coding that would differ from FFS coding that would necessitate an adjustment.

Response: MA coding adjustment is a methodological adjustment to risk scores to ensure payment accuracy given differential coding patterns in MA and FFS. The coding adjustment factor is calculated using data collected over a defined set of consecutive years from a cohort of beneficiaries continuously enrolled in MA or continuously enrolled in FFS over the entire collection period, otherwise known as the ‘stayer cohort’. The coding adjustment factor also accounts for varying lengths in enrollment in MA. For operational purposes, we apply the coding adjustment factor to all MA risk scores, but adjust the factor by the percentage of stayers in the year prior to the payment year. By making this downward adjustment to the factor, we take into account that MA plans cannot affect the coding of these new members.

Section G. Normalization Factors

G1. Normalization for the CMS-HCC Model (aged/disabled beneficiaries enrolled in MA plans)

For 2014, CMS is blending the risk scores from the 2013 CMS-HCC model with the risk scores from the 2014 CMS-HCC model to calculate the risk scores used for payment. Therefore, two normalization factors, *i.e.*, one normalization factor for the 2013 CMS-HCC model and one normalization factor for the 2014 CMS-HCC model, will be calculated to adjust the risk scores using each respective model. The normalized risk scores will then be blended for payment purposes with the risk scores from the 2014 model weighted at 75 percent and the risk scores from the 2013 model weighted at 25 percent.

The final normalization factor for the 2013 CMS-HCC model is 1.041 and for the 2014 CMS-HCC model is 1.026.

- The Part C normalization factor is used to normalize the following risk scores: Aged/disabled community, aged/disabled institutional, aged/disabled new enrollee, and C-SNP new enrollee.
- Population used to calculate annual trend: FFS beneficiaries.

CMS estimates an annual trend using a linear function applied to the following years’ risk scores:

EXHIBIT 24

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Attorneys for United Defendants

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

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-MWF(SSx)

**DECLARATION OF MARY
MURLEY IN SUPPORT OF
UNITED'S OPPOSITION TO
PLAINTIFFS' MOTION FOR
PARTIAL SUMMARY
JUDGMENT**

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

DECLARATION OF MARY MURLEY

I, Mary Murley, hereby declare as follows:

1. I am a Vice President and Chief Actuary at UnitedHealthcare, Medicare & Retirement (“United”). I make this declaration in support of United’s Opposition to the Plaintiffs’ Motion for Partial Summary Judgment in this matter.

2. I have personal knowledge, information, or belief of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

3. I have over 28 years of actuarial health experience and have been involved with Medicare-related work since 1992. I am an Associate of the Society of Actuaries and a Member of the American Academy of Actuaries.

4. I have held my current position of Vice President and Chief Actuary at United for approximately 11 years. I have prepared hundreds of bids for Medicare Advantage and Prescription Drug Plan organizations, and I am familiar with the various benefit design and bidding strategies. I oversee the annual bid submission process to CMS, and I work closely with my team on the underlying analysis, assumption setting, and supporting documentation as required by CMS.

5. Prior to that role, I served as Managing Principal at OptumInsight (formerly Ingenix), where my responsibilities included consulting with external payors and providers regarding strategic, financial, and actuarial issues. My work included consulting engagements for Medicare, Medicaid, and commercial stakeholders.

6. I have significant experience with, and extensive involvement in and knowledge of, United’s process for developing and submitting its bids and supporting documentation to the Centers for Medicare & Medicaid (“CMS”) under the Medicare Advantage (“MA”) program and pursuant to 42 U.S.C. § 1395w-24(a).

7. In my role at United, I am very familiar with how United calculates its annual bids under the MA program, including how United takes into account

1 the potential revenue impact of the MA coding adjustment factor that CMS is
2 required to apply to MA plans pursuant to 42 U.S.C. § 1395w-23(a)(1)(C)(ii).

3 8. CMS's instructions for the 2017 bid process state that "[t]he CY2017
4 MA coding adjustment is 5.66 percent. Accordingly, the projected CY2017
5 normalized risk scores must be multiplied by 0.9434 (which is $1 - 0.0566$)."
6 *CMS Instructions for Completing the Medicare Advantage Bid Pricing Tools For*
7 *Contract Year 2017* at 43 (Apr. 8, 2016), [https://www.cms.gov/Medicare/Health-](https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-Items/BPT2017.html)
8 [Plans/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-](https://www.cms.gov/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-Items/BPT2017.html)
9 [Items/BPT2017.html](https://www.cms.gov/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-Items/BPT2017.html).

10 9. United calculates that the revenue impact of applying the MA coding
11 intensity adjustment factor to United for the 2017 payment year is approximately
12 \$2.9 billion.

13
14 I declare under penalty of perjury that the foregoing is true and correct.

15 Executed on July 23, 2018, in Minnetonka, Minnesota.

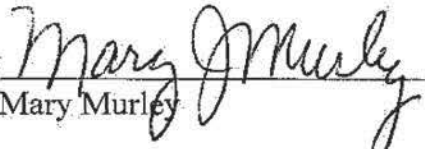
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17 By 
18 Mary Murley
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EXHIBIT 25

April 2, 2012

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2013 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2013 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html> under Ratebooks and Supporting Data. The statutory component of the regional benchmarks, transitional phase-in periods for the Affordable Care Act rates, qualifying counties, and each county's applicable percentage are also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2013 and the national Medicare fee-for-service growth percentage. These growth rates will be used to update the 2013 rates. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 2.80 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2010 are being posted on the above website.

Information on deductibles for MSA plans is included below.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2013 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). Attachment VII presents the final Call Letter. We received 114 submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 17, 2012. Eight of the comments were from advocacy groups, 22 were from associations, 5 were from members of the public, 1 was from a State, 1 was from a Congressman, 1 was from a Congressional Advisory Committee, 68 were from health plans and 8 were from consultants.

HCPCS codes, along with requirements relating to the type and number of encounters. The CMS-HCC model uses diagnoses as part of a model developed to predict Medicare costs. As such, we use diagnoses taken directly from claims or from MA reported data.

Section E. Adjustment for MA Coding Pattern Differences

Comment: One commenter suggested that CMS examine the General Accountability Office's (GAO) findings, published in the January 2012 report entitled "CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practice" and account for coding differences between Fee-for-Service Medicare and Medicare Advantage that may result in inaccurate risk score adjustments and overpayments to plans.

Response: CMS uses a different methodology than was used in GAO's analysis and, while we found their method informative, we believe that our methodology results in an accurate measure of the coding differential between FFS and MA. CMS continually develops its understanding of coding trends and makes an assessment for each payment year regarding the appropriate adjustment based on specific considerations of both coding trends and other market changes.

Comment: One commenter expressed support for CMS's decision to maintain the level of the 2012 adjustment for 2013, stating that doing so mitigates the significant adverse and disproportionate impact that the ACA is having on Puerto Rico MA plan funding.

Response: We acknowledge the commenter's support for maintaining the current coding pattern adjustment.

Section F. New Enrollee Risk Scores for Chronic SNPs

Comment: A few commenters suggested that the new enrollee factor for chronic care Special Needs Plans (C-SNPs) should apply to all existing Medicare beneficiaries who are newly enrolling in a C-SNP instead of being applied only to those who are new to Medicare, while other commenters requested that a new enrollee factor be calculated for beneficiaries new to all SNPs and PACE organizations as well, not just C-SNPs.

Response: CMS interprets the current statutory requirement to only require the application of the C-SNP risk adjustment model to new Medicare beneficiaries. CMS is not planning to develop a set of risk scores for continuing Medicare enrollees who are new to C-SNPs. Under CMS's risk adjustment methodology, risk scores reflect prior year diagnoses and, given the strict rules about documenting reported diagnoses, CMS does not consider it appropriate that we impute prior year diagnoses for beneficiaries not new to Medicare. Many beneficiaries who are enrolled in MA plans develop conditions in the payment year that they did not have previously, and the risk model is designed to accurately predict risk across subgroups of beneficiaries, including groups

EXHIBIT 26

February 24, 2012

**Notice of Final Payment Error Calculation Methodology for
Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits**

Introduction

On December 21, 2010 the Centers for Medicare and Medicaid Services (CMS) posted on its website the “Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment”. CMS invited public comment on the proposed methodology, with such comments to be submitted in writing by Friday, January 21, 2011.

CMS carefully reviewed the more than 500 comments received on the draft methodology. This Notice responds to the analytic concerns raised relating to extrapolation and payment recovery and presents the final methodology for the RADV payment error calculation.

Following the background section, this Notice provides a general walkthrough of the RADV payment error calculation methodology in two sections: (A) sampling; and (B) payment error calculation.

This methodology will be applied to the next round of RADV contract-level audits, which will be conducted on payment year 2011. Payment year 2011 is the first year for which payment recovery based on extrapolated estimates will be conducted for Medicare Advantage (MA). Note that sampling for RADV audits will occur after the close of final reconciliation for the payment year being audited.

CMS’ RADV audit initiative is the Agency’s primary strategy to address the national payment error rate for the MA program, which is currently estimated to be 11 percent for FY 2011. In addition to recovery of overpayments through RADV audits, CMS also expects that these contract-level audits will have a sentinel effect on the quality of risk adjustment data submitted for payment by MA organizations.

Background

Section 1853(a)(3) of the Social Security Act requires that CMS risk adjust payments to Medicare Advantage (MA) organizations. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification guidelines (ICD-9-CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes submitted by MA organizations are used to determine beneficiary risk scores, which in turn determine the risk-adjusted reimbursement.

RADV audits determine whether the diagnosis codes submitted by MA organizations can be validated by supporting medical record documentation. This medical record documentation must meet certain criteria and standards specified in RADV materials that CMS provides to audited contracts. Diagnoses that cannot be validated contribute to a payment error rate. This document describes the sampling

methodology that CMS will use for RADV audits and the methodology for calculating the payment error for each audited Medicare Advantage contract.

A. Sampling

To conduct these audits, CMS selects a set of MA contracts for each RADV audit cycle. Enrollees are sampled from each selected MA contract for the purpose of estimating payment error related to risk adjustment.

Sampling Frame

First, CMS identifies all beneficiaries under each MA contract who are “RADV-eligible” because they meet the following criteria:

1. Enrolled in an MA contract (H-number, E-number, or R-number) in January of the payment year— based on CMS' monthly member enrollment files;
2. Continuously enrolled in the same MA contract (as identified in step (1) above) from January of the data collection year through January of the payment year;
3. Non-End Stage Renal Disease (non-ESRD) status from January of the data collection year through January of the payment year;
4. Non-hospice status from January of the data collection year through January of the payment year;
5. Enrolled in Medicare Part B coverage for all 12 months during the data collection year (i.e., defined as full risk enrollees for risk adjusted payment); and
6. Had at least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection year that led to at least one CMS-Hierarchical Condition Category (HCC) assignment for the payment year.

Sample Size and Strata

Next, CMS selects a sample of beneficiaries from each contract's cohort of RADV-eligible enrollees. Enrollee-based stratification will be used in the process of sampling enrollees. In order to derive the strata, the RADV-eligible enrollees in each contract will be ranked from lowest to highest based on their community risk score. The enrollees will then be divided into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle stratum.

CMS will select up to 201 enrollees for medical record review from each contract selected for a contract-level audit. For smaller contracts, i.e., those with fewer than 1,000 RADV-eligible enrollees, CMS will individually adjust their sample sizes by using the finite population correction factor. The sample sizes for these smaller contracts will be 201 or fewer enrollees.

To achieve a sample size of 201 enrollees per contract, sixty-seven (67) enrollees will be randomly sampled from each group or stratum. The corresponding stratum-based enrollee weights will be computed as the number of RADV-eligible enrollees in the population grouping (or stratum) divided by the number of enrollees selected from that grouping for the sample, i.e., N_h/n_h , where h represents the corresponding stratum.

For example, if a contract has 3,000 RADV-eligible enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be randomly selected from each group. The weight for each sampled enrollee will equal 14.925 (i.e., $1,000/67$).

For small contracts with fewer than 1,000 RADV-eligible enrollees, the same enrollee-based stratification process will be applied; however, a proportionally smaller number of enrollees will be randomly sampled from each group or stratum.

The enrollee sampling weights will be used as multipliers to scale-up (or extrapolate) the sample payment error findings to the population it represents.

Once enrollees have been selected, the MA contract will be required to submit medical records to support all CMS-HCCs represented in the sampled beneficiaries' risk scores for the payment year.

Effective with the CY 2011 RADV audit, CMS will allow audited MA contracts to submit multiple medical records for each CMS-HCC being validated. All diagnoses will be abstracted from the first medical record that validates the CMS-HCC under review. The one best medical record policy will continue to apply to the RADV audit dispute and appeal processes outlined in 42 CFR §422.311. CMS will provide more detailed information in the RADV audit procedures that will be distributed to audited MA contracts.

B. Payment Error Calculation

Enrollee-level Payment Error Calculation

CMS will calculate each contract's payment error based on the validation results. For each sampled enrollee, the RADV-corrected risk score and corrected payment will be calculated based on the CMSHCCs that are supported by RADV medical record review findings for the enrollee. Enrollee-level payment errors will be defined as the difference between the original payment and the RADV-corrected payment (per member per month). The payment error for each enrollee will be either positive (representing a net overpayment), or negative (representing a net underpayment). An annual payment error amount will be calculated for each sampled enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year.

Payment Error Extrapolation Calculation

To derive the payment error estimate for each MA contract, the annual payment error for each sampled enrollee will be multiplied by the enrollee's sampling weight (computed for each stratum [h] during the sampling phase as N_h/n_h , where N represents the number of enrollees in the RADV-eligible population and n is the number of enrollees sampled). The weighted enrollee annual payment error will be summed across all enrollees in the sample to determine an estimated payment error for the MA contract (the "point estimate"). A 99 percent confidence interval (CI) will then be calculated for the estimated payment error for each audited MA contract.

The following formulas illustrate computation of a 99 percent CI around the payment error estimate for one contract, assuming a sample size of 201, with 67 enrollees selected from each of three strata groupings.

The lower bound of the 99 percent CI is computed as the estimated payment error for the contract (PE) minus (2.575 multiplied by the standard error), or $(PE - (2.575 * SE))$. The standard error (SE) can be calculated as follows:

1. Derive the variance, v_h , (standard deviation squared) of the unweighted enrollee payment errors across the sample enrollees within each of the three strata (h).
2. Calculate the variance of the estimated total (V_{T^*}) payment error, where N represents the number of enrollees in the RADV-eligible population of the h^{th} (1st, 2nd, 3rd) stratum:

$$= \sum_h \frac{N_h^2}{67} V_{T^*} v_h$$

3. The standard error is $SE_{T^*} = \sqrt{V_{T^*}}$

Payment Recovery Amount and the Fee-For-Service Adjuster

If the CI for the point estimate includes zero or is below zero, the contract will have the payment recovery amount constrained to zero.

If the CI for the point estimate is above zero, the payment recovery amount for the contract will be determined as follows. First, a preliminary payment recovery amount will be set at the lower bound of the 99 percent CI for the contract's point estimate. Second, to determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero.

The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard

used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

EXHIBIT 27

PUBLIC SUBMISSION

As of: July 05, 2017
Received: December 08, 2009
Status: Posted
Posted: December 15, 2009
Category: Health Plan or Association - HP010
Tracking No. 80a66f15
Comments Due: December 08, 2009
Submission Type: Web

Docket: CMS-2009-0088

Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Comment On: CMS-2009-0088-0002

Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Document: CMS-2009-0088-0058

Aetna Inc.--CT

Submitter Information

Name: Christina Martel

Address:

Hartford, CT, 06156

Organization: Aetna Inc.

General Comment

Attached are Aetna's comments for review.

Attachments

CT

12. Clarify Novation Agreements Under Part D (§423.551)		In general we support this change to match Medicare Advantage. We do recommend CMS allow special circumstances that may necessitate the need for novations of the Medicare PDP line of business.
Section H. Changes to Implement Corrections and Other Technical Changes	FR Page #	Comments
3. Revision to Definition of Gross Covered Prescription Drug Costs (§423.308)	54700	Related to proposal to change definition of gross covered prescription drug costs at an OON pharmacy: We recommend expanding the definition of gross covered prescription drug costs to reference covered Part D vaccines and their associated vaccine administration fees that can be obtained from non-pharmacy, out-of-network providers such as physicians and clinics. And while the "U&C" price is defined per § 423.124(a) as that which is charged by a pharmacy/provider to patients without insurance coverage, it is more appropriate to pay a vaccine administration fee subject to a scheduled amount, similar to how this would be handled for Part B vaccine administration fees. We believe that additional flexibility is needed in the definition of gross covered prescription drug costs to account for a scheduled vaccine administration fee rather than an implication of it being subject to U&C to guard against permitting coverage for an excessive amount charged by a provider under a percent copay cost sharing tier.

**Comments on Proposed Risk Adjustment Data Validation Appeals Procedures
(§§ 422.2 and 422.311)**

We welcome the opportunity to submit comments on the proposed rules governing administrative appeals for Risk Adjustment Data Validation ("RADV") audits that appeared in the October 22, 2009 Federal Register.¹ While we share CMS's recognition of the need for a dispute and appeal process for audit, it is concerned that the proposed rules are too narrow and do not provide for meaningful appeals beyond correcting clerical errors. Moreover, the proposed appeals procedures will effectively implement substantive requirements, such as the "One Best Medical Record" rule, that are contrary to Title XVIII of the Social Security Act (the "Medicare Act"), unsupported by the administrative record, and inconsistent with CMS's contractual obligations. These subsumed

¹ 74 Fed. Reg. 54634, II.D.1., at pp. 54673-678, 54716, 54719-720(October 22, 2009).

rules and limits on appeals may result in RADV audits that distort, not facilitate, the accuracy of payments to Medicare Advantage ("MA") organizations.

The proposed appeals rules raise four major concerns. Specifically, the proposed rule: (1) creates a contract-level rate adjustment process for MA organizations that is contrary to the statutory mandate that their rates be comparable to fee-for-service rates and is actuarially unsound; (2) imposes requirements regarding acceptable documentation for data validation and provider recordkeeping rules under the "One Best Medical Record" rule without proper rulemaking or an administrative record supporting such rules; (3) provides no substantive appeal rights and allows only for the correction of clerical errors; and (4) conflicts with current MA contracts.

As explained more fully below, these issues can best be addressed by withdrawing the proposed rules and instituting new rulemaking to determine the appropriate documentation needed to verify the health status of members, the statistical analyses to be used, and a full and fair appeals process for RADV audits.

1. Proposed Appeals Rules Need to be Consistent with the Medicare Act

We are concerned that the underlying premise of CMS's proposed appeals rules is inconsistent with the Medicare Act. MA payments are based upon the Medicare payments made to the fee-for-service ("FFS") providers under Medicare Part A and B. The payments for the average FFS Medicare beneficiary provide the baseline for determining payments to MA organizations. The Medicare members of a MA organization may incur higher or lower medical costs than the average FFS beneficiary depending on the

members' health status.² As a result, the Medicare Act requires that the payments to the MA organizations be adjusted for the healthcare status of its members, "that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs."³

To identify the healthcare status of Medicare beneficiaries, CMS developed a hierarchical condition category ("HCC" or "risk score") based on "such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate"⁴ HCCs reflect diagnosis codes that are clinically related and have similar cost implications.⁵ The HCCs are based on ICD-9-CM guidelines. The ICD-9 is a complex system that identifies thousands of diagnoses.

There may not be a single ICD-9 that covers a specific chronic condition. There may be a combination ICD-9 code that identifies the full diagnosis, while other times multiple ICD-9 diagnosis codes will be needed. For example, an individual with diabetes will have a diagnosis of diabetes, but may also have other chronic conditions such as neurological or ophthalmic manifestations that also must be coded. The combinations of the ICD-9 codes are used to create the HCCs and reflect the cost of treatment for the diagnoses. All diagnosis will not necessarily be identified by the treating physician if a diagnosis will not impact the treatment to be provided.

² *Id.* at 54673.

³ *Id.*

⁴ *Id.*; see also 42 C.F.R. § 42.308(c)(1).

⁵ 74 Fed. Reg. at 54674.

The adjustments to MA payments based on HCCs also have "to ensure actuarial equivalence" to the FFS payments.⁶ The Medicare Act mandates that the payments be adjusted to:

ensure that such adjustment reflects changes in treatment encoding practices in the fee-for-service sector and reflects differences in the coding patterns between Medicare advantage plans and providers under Part A and B to the extent that the Secretary identifies such differences."⁷

To ensure the "actuarial equivalence" that is mandated by the Medicare Act, each "MA enrollee's HCCs are assigned based on risk adjustment diagnoses from FFS claims and ... an enrollee's risk score ... is used to adjust a base payment rate" to the MA organization.⁸ As CMS has recognized:

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustment to be valid. This means that MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.⁹

⁶ 42 U.S.C. § 1395w-23(a)(1)(C)(i).

⁷ *Id.* at §1395w-23(a)(1)(C)(ii)(I).

⁸ *Id.*

⁹ CY 2010 Rate Notice, April 6, 2009, at 20

Concomitantly, payments are accurate when the HCCs for MA organizations are adjusted to be comparable to the HCCs for the FFS sector. Thus, if an MA organization's Medicare members have lower HCC scores than the baseline FFS member, the MA organization is paid less, and if its Medicare members have higher HCC scores, the payment is higher.¹⁰

CMS's proposed administrative appeals regulations are inconsistent with the statute. Through the proposed RADV audit appeal process, CMS will impose a set of rules regarding physician record keeping that was not anticipated in the ICD-9 coding guidelines, not consistent with standard practices and not enforced on FFS claims. The result will be MA payment adjustments based on recordkeeping discrepancies without an adjustment to FFS risk scores for the same recordkeeping discrepancies.

Auditing only the MA organizations may determine how accurate MA organizations code, but without determining how MA risk scores compare to FFS coding, the audit will lack the appropriate baseline to determine if any payment adjustments should be made for the MA organizations. Even if the audits resulted in 100% accurate coding for the MA organizations, they still may be over- or underpaid. For example, if the FFS sector under-codes Medicare beneficiaries by 10%, then MA organizations that code 100% accurately would be overpaid by 10%. The converse would also be true, that is, if FFS providers over-code by 10% and an MA organization is coding 100% accurately, the MA organization would be underpaid by 10%.

Congress recognized that using the FFS payments as a baseline would hinge on the equivalency of the two sectors, and therefore provided that "[i]n order to ensure payment accuracy, the secretary shall conduct an analysis of the differences" between MA

¹⁰ 74 Fed. Reg. at 54674.

organizations and FFS coding practices.”¹¹ Congress understood that the MA payments are based upon the actual dollars paid to the FFS sector. Absent such an analysis, no meaningful adjustment to MA payments based on an audit of their HCCs can be undertaken. To require 100% accurate HCCs for the MA organizations when it is not required for the FFS sector will result in inaccurate payment adjustments. Yet the audit and appeals process proposed by CMS does not allow for any evaluation of or proper comparison with the FFS sector. The proposed appeals regulations fail to consider the other half of the equation—the risk coding accuracy of the FFS payments. Moreover, appeals under Medicare Part A and Part B, and PRRB determinations, allow the submission of additional evidence and testimony.

To justify auditing only MA organizations, CMS assert that “there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment.”¹² Yet, MA organizations do not control the medical documentation. Rather, they rely on physicians and practitioners who may have no stake in payments to MA organizations and therefore have no “incentive ... [to] over-report diagnoses”¹³ Even assuming this contention to be true, by failing to assess any “over-report[ing]” by the FFS sector, the MA payments must still be actuarially equivalent to the FFS payments. That cannot be achieved without also auditing the FFS sectors’ compliance with the recordkeeping rules.¹⁴ Moreover, there is no evidence that physicians providing

¹¹ 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(II).

¹² 74 Fed. Reg. at 54674.

¹³ *Id.*

¹⁴ The Department of Health and Human Services has recognized in a recent report required by the Improper Payments Information Act that FFS providers do not consistently code diagnoses. “*Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT, and RAC,*” Centers for Medicare and Medicaid

services to MA organizations' members document diagnoses differently for their FFS patients. If providers document the diagnoses for all their patients the same, then there is no over-reporting for MA organizations' members as compared to FFS patients.

In addition, the sampling methodology used by CMS may be inconsistent with the Medicare Act. Although CMS has yet to announce its sampling or extrapolation methodologies, the sampling methodology it used in the 2007 pilot audits undercuts the Medicare Act's mandate that the MA organization rates reflect the actual expectations of losses and benefits to be paid by each organization.¹⁵ In its 2007 pilot RADV audit, we understand that CMS sampled only enrollees with certain HCCs. Random errors in assigning HCCs, however, are likely to result in both overstating and understating the risk factors. By excluding from the sample all the Medicare members to whom MA organizations did not assign a high risk factor, the audit will overlook any errors resulting in the understatement of enrollees' health status.

Moreover, the proposed rule expressly prohibits MA organizations from introducing "new" HCCs in the course of the audit and appeal process if the HCCs were not previously assigned to enrollees.¹⁶ Since random errors can result in either under- or over-coding, a fair audit would allow for correction of all coding errors. By precluding assigning a new HCC based on the medical records, CMS's audit will not determine whether correct HCCs were assigned to Medicare members. Rather, the audits will eliminate HCCs that are not supported by the One Best Medical Record, but not allow new HCCs that are supported by the

Services, ICN # 006973 (Oct. 2008) The Department indicated that it plans to work with FFS practitioners to improve medical record documentation practices. *Id.* Yet, MA organizations will be required to comply with the recordkeeping rules when the FFS providers will not be held to the same standard.

¹⁵ 42 U.S.C. § 1395w-23(a)(1)(C).

¹⁶ 74 Fed. Reg. at 54676.

medical records. This will not lead to accurate coding, but under-coding. As a result, the appeals process is inconsistent with the statutory mandate that the MA rates accurately reflect expected losses and benefits paid and be comparable to the FFS payments. In addition to being inconsistent with the Medicare Act, an audit that only allows a downward adjustment is "unconscionable"¹⁷ and will not achieve the "actuarial equivalence" mandated by the Medicare Act.¹⁸

II. The Administrative Appeals Rules Regarding the "One Best Medical Record" Create New Substantive Regulations

The proposed administrative appeals process incorporates certain underlying requirements that have not been subject to proper rulemaking. Specifically, MA organizations will be limited to submitting One Best Medical Record to validate the HCCs of the beneficiaries in the RADV audit sample. Incorporated within the One Best Medical Record rule are requirements on how physicians and providers must keep records, code conditions, and care for their patients. These rules have yet to be subject to rulemaking and, therefore, there is no administrative record that supports these requirements or provides the courts with a meaningful record to review the requirement. Indeed, in an appropriate rule-making process, we would be able to provide record evidence that the One Best

¹⁷ *C.f. GloPak Corp v. United States*, 851 F.2d 334, 338 (Fed. Cir. 1998) (a market price adjustment clause must be a "a two-way, not one-way street," allowing for both "an increase in the contract price,"); *also see. United States v. Delta Dental Plan*, 943 F. Supp. 172, 190 (D. R.I. 1996); *accord* Consent to Judgment at *United States v. Delta Dental Plan*, 1997 U.S. Dist. LEXIS 11239 at *3 (D. R.I. July 27, 1997); *United States by and through Woods v. Delta Dental Plan*, 1995 U.S. Dist LEXIS 9752 at *3-4 (D. AZ May 19, 1995).

¹⁸ It is worth noting that CMS's proposed extrapolation of the RADV is inconsistent with the intent of the Medicare Act. Medicare contractors are allowed to extrapolation "to determine overpayment amounts" only in extraordinary circumstances where "there is a sustained or high level of payment error; or ... documented educational intervention has failed to correct the payment error. 42 U.S.C. § 1395ddd(f)(3).

EXHIBIT 28

**America's Health
Insurance Plans**

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org



December 8, 2009

Centers for Medicare & Medicaid Services
Hubert Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: CMS-4085-P

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) to comment on the notice of proposed rulemaking titled, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on October 22, 2009 (74 FR 54633). AHIP is the national association representing 1,300 member companies providing health coverage to more than 200 million Americans. These regulations have a direct impact on AHIP's member organizations many of which participate in the Medicare Advantage, Medicare Part D prescription drug benefit (Part D), and Medicare Cost Plan programs.

Specific Comments

A. Changes to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers

1. Require Notice of Intent to Apply Under Part C and D Within application Requirements (§422.501 & §423.502; Preamble, p. 54640)

Under §422.501(b) and §423.502(b), CMS is proposing to require a Notice of Intent to Apply by the date specified annually by CMS as a condition for a new or existing MA or Part D contractor to be permitted to submit an MA or a Part D application. We believe that the proposed codification of the requirement for submission of a Notice of Intent to Apply raises several concerns, because it eliminates flexibility currently exercised by CMS to respond to circumstances that may merit permitting submission after the established deadline, which in recent years has been three months prior to the due date for applications.

On pages 54640 and 54641 of the preamble, CMS identifies the stated purpose for the Notice of Intent as allowing CMS to assign a pending contract number and complete CMS User ID connectivity. Because applications are only submitted electronically, AHIP understands the need for the applicant to establish connectivity as a condition of

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CMS is proposing an appeals process (§422.311) for RADV audits and the addition of related definitions to §422.2. CMS' proposal would make three avenues available to MA organizations as possible remedies for findings that result in payment errors. These are: an attestation process, a documentation dispute process, and a RADV payment error calculation appeals process. The preamble includes a discussion of the history of the CMS HCC risk adjustment methodology and CMS' risk adjustment data validation initiatives, as well as CMS' rationale underlying the proposed elements of the appeals process.

AHIP has consistently supported CMS' efforts to ensure that the MA risk adjustment methodology is designed to pay MA organizations appropriately based upon the health status of their members and the resources needed to treat the conditions that they experience. We understand that CMS has a responsibility to ensure payments are calculated accurately under this methodology and that MA organizations are accountable on audit for demonstrating the integrity of the data they submit. However, we have a number of serious concerns about the initial design of the current RADV audits and about the appeals process proposed for inclusion in the regulation. These issues and our related recommendations are discussed in detail below. We are interested in working with CMS as the elements of the risk adjustment data validation audit process continue to evolve.

b. Risk Adjustment Validation Initiatives (Preamble, p. 54674)

Under this subheading in the preamble, CMS explains that risk adjustment diagnoses from FFS claims and from MA organization risk adjustment data submitted to CMS are used to assign a risk score to each MA enrollee and that these risk scores are used in the enrollee-level MA payment calculation. The agency audits the MA diagnosis data a few years after submission to ensure they are supported by medical record documentation. CMS indicates that this documentation is the key to accurate payment and successful data validation. While in some past years data discrepancies resulted in payment adjustments on an enrollee-specific basis, the current audit design calls for contract-level payment adjustments and has been initiated for the 2007 payment year because it is the first year in which 100 percent of MA payment amounts were risk adjusted.

We recognize the importance of MA organization submission of reliable diagnosis data for the purpose of risk adjustment and understand that the preamble is intended to provide only a high level description of the MA risk adjustment audit initiative. However, we believe that the emphasis on medical record documentation for MA diagnosis data as "the key to payment accuracy" fails to acknowledge that a comparable evaluation of FFS medical record documentation error rates is critical to

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assessing payment accuracy, because of the role data from both sources play in the risk adjustment methodology. We urge CMS to conduct such an evaluation.

In addition, we have serious concerns that establishment of an audit methodology that involves retrospective contract-level payment adjustments creates the potential for unpredictable retroactive liability that MA organizations could not have considered in developing bids for affected prior years. We recommend that CMS take this critical issue into consideration as further decisions are made about the RADV audit methodology.

The uncertainty associated with the unknown extent of potential multi-year retroactive adjustments has been exacerbated by CMS' decision to move forward with the first group of 2007 audits prior to finalizing the audit design, including the methodology for determining any payment adjustments as well as the proposed appeals process. We recommend that CMS ensure that organizations selected for the pilots or the first group of audits are not disadvantaged in comparison to other MA organizations audited for the same payment year in the event that CMS makes improvements to the audit design in response to comments on the proposed rule or as a result of decisions reflected in subregulatory guidance.

d. Proposed Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures (§422.311; Preamble, p. 54674-54678)

As a result of CMS' experience to date in conducting MA RADV audits, which has included MA organization requests for an appeals remedy, the agency is proposing establishment of formal dispute and appeal rights for MA organizations undergoing RADV audits. We commend CMS for taking this important step, and we support establishment of a RADV audit appeals process. However, while the CMS proposal focuses on three key avenues for MA organizations to seek relief from potentially erroneous determinations, we believe that the scope of issues that may be raised in each case is too narrow, so that the proposal either fails to provide an opportunity to pursue the issues that are likely to be of greatest importance to organizations experiencing RADV audits or is otherwise unduly limited. We believe that substantial changes are essential in each area to provide meaningful appeal rights for MA organizations and that it is critical for CMS to provide an appeal right for all issues that could be subject to error or other material, unintended defects at each step of the audit process and payment error calculation. Our comments below address each of the avenues of appeal CMS has proposed and provide our recommendations.

EXHIBIT 29

December 20, 2010

**Medicare Advantage Risk Adjustment Data Validation (RADV)
Notice of Payment Error Calculation Methodology for Part C Organizations
Selected for Contract-Level RADV Audits
Request for Comment**

Introduction

Section 1853(a)(3) of the Social Security Act requires that the Centers for Medicare & Medicaid Services (CMS) risk adjust payments to Medicare Advantage (MA) organizations. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification guidelines (ICD-9-CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes are used to determine beneficiary risk scores, which in turn determine the risk adjusted reimbursement. MA enrollee risk scores are based on risk adjustment diagnoses that were present on Medicare Fee for Service (FFS) claims and/or submitted to CMS by MA organizations.

CMS annually selects MA organizations for RADV audits. Contract-specific MA organization RADV audits measure individual MA organization-level payment error-rates related to risk adjustment data for payment recovery. RADV audits confirm the presence of risk adjustment conditions based on supporting medical record documentation. As stated in the preamble of the new regulation on Risk Adjustment Data Validation –Dispute and Appeal Procedures at 42 CFR 422.311, CMS intends to provide an annual notice of the RADV payment error calculation methodology with the opportunity for MA organizations to comment on the methodology. This paper describes the sampling and error calculation methodology that CMS utilizes when conducting RADV audits. This sampling and error calculation methodology is used to calculate a payment error estimate and payment recovery amount for each MA contract selected for an audit.

Sampling

Once an MA contract has been selected for a RADV audit, CMS applies criteria for selecting the MA contract's enrollees.

Enrollee Selection

Enrollees are sampled from each selected MA contract for the purpose of estimating payment error related to risk adjustment. The enrollee sample for a RADV contract-level audit will be selected from the cohort of eligible Medicare beneficiaries who were enrolled in the contract (H-number, E-number, or R-number) in January of the payment year— based on monthly member enrollment files. The enrollees who are eligible for RADV sampling are those who were also:

1. Continuously enrolled in the same MA contract for all 12 months of the data collection year;
2. Non-End Stage Renal Disease (non-ESRD) status in or prior to the payment year;

3. Non-hospice between January of the data collection year and January of the payment year, and had less than 12 months of hospice during the payment year;
4. In Medicare Part B coverage for all twelve months during the data collection period (i.e., defined as full risk enrollees for risk adjusted payment); and had
5. At least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection period that led to at least one CMS-HCC assignment. These HCCs were present for risk adjusted payments, based on plan-submitted risk adjustment data, and are referred to as the validation HCCs for the sampled enrollees.

CMS will select up to 201 enrollees for medical record review from each contract selected for an audit.

Sample Stratification

Enrollee-based stratification will be used in the process of sampling enrollees. In order to derive the strata, the eligible enrollees, in each contract, will be ranked from lowest to highest based on their community risk score. The enrollees will then be divided into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle stratum. In the case of 201 sampled enrollees, sixty-seven (67) enrollees will be randomly sampled from each group or stratum. The corresponding stratum-based enrollee weights will be computed as the number of RADV-eligible enrollees in the population grouping (or stratum) divided by the number of enrollees selected from that grouping for the sample (or N_h / n_h), where h represents the corresponding stratum. For example, if a contract has 3,000 enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be selected from each group. The weight for each enrollee will equal 14.925 (i.e., $1,000/67$). The enrollee sampling weights will be used as multipliers to scale-up (or extrapolate) the sample payment error findings to the population which it represents.

Payment Error Calculation

Enrollee-level Payment Error Calculation

The risk scores for each sampled enrollee will be corrected based on the HCCs that are supported by RADV medical record review findings for the enrollee. The RADV (or corrected) risk scores and payments will be calculated for each sampled enrollee. Enrollee-level payment errors will be defined as the difference between the original payment and the corrected payment (i.e., payment error = (original payment minus corrected payment)). The payment error for each enrollee will be either positive-- representing a net overpayment, or negative-- representing a net underpayment. A payment error will be calculated for each sampled enrollee based on the number of months the person was enrolled in the MA selected contract (and was not ESRD or hospice) during the payment year.

Payment Error Extrapolation Calculation

To derive the estimated payment error for each MA contract, the total payment error for each sampled enrollee will be multiplied by the enrollee's sampling weight (computed during the sampling phase as N_h/n_h for each stratum). The weighted enrollee payment errors will be summed across all enrollees in the sample to determine an estimated payment error for the MA contract. The payment recovery amount for each audited MA contract will be determined by the lower bound of the 99% confidence interval around the payment error estimate. The following is an example formula for computing a 99% confidence interval around the payment error estimate for one contract, assuming a sampling method containing three enrollee strata groupings.

The 99% confidence interval lower bound is computed as the estimated payment error (PE) minus (2.575 multiplied by the standard error) or $(PE - (2.575 * SE))$, whereby the standard error can be reproduced as follows:

1. Derive the variance, v_h , (standard deviation squared) of the unweighted enrollee payment errors across the sample enrollees within each of the three strata (h).
2. Calculate the variance of the estimated total ($V_{\hat{T}}$), where N represents the number of enrollees in the RADV-eligible population of the h^{th} (1st, 2nd, 3rd) stratum:

$$v_{\hat{T}} = \sum_{h=1}^3 \frac{N_h^2}{67} v_h$$

3. The standard error is $se_{\hat{T}} = \sqrt{v_{\hat{T}}}$

Request for Comment

CMS is pleased to invite public comment on this document. CMS will review all timely comments and may revise or modify the RADV sampling and payment error calculation methodology based on the comments received. Once all comments have been reviewed and considered, CMS will post a final version of the RADV sampling and payment error calculation methodology at <https://www.cms.gov/HealthPlansGenInfo/>.

Comments must be submitted in writing by Friday, January 21, 2011 to the following email address:

RADV@cms.hhs.gov

Please specify "Comment on RADV sampling and error calculation methodology" in the subject line of your email.

EXHIBIT 30

**Aetna Inc.'s Comments on Proposed Payment
Error Calculation Methodology for Part C Organizations
Selected for Contract-Level RADV Audits**

January 21, 2011

Aetna Inc. welcomes the opportunity to submit comments on the proposed sampling and error calculation methodology for conducting Risk Adjustment Data Validation (“RADV”) audits that the Centers for Medicare & Medicaid Services (“CMS”) published for comments on December 20, 2010. While Aetna agrees that it is important to ensure accurate payments to Medicare Advantage (“MA”) organizations, the process proposed by CMS will reduce, not increase, the accuracy of payments. The proposed methodology is inconsistent with the Medicare Act requirement, as well as CMS’s stated purpose for its RADV audits, to ensure that payments to MA organizations are based on the “health status” of the enrollees in their plans.

Aetna is one of the nation’s leading diversified health care benefits companies, serving approximately 36.1 million people with information and resources to help them make better informed decisions about their health care. Through its affiliates and subsidiaries, Aetna offers a broad range of traditional and consumer-directed health insurance products and related services, including HMO and PPO plans for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna has offered MA plans since the early years of the program when Medicare Part C (formerly known as “Medicare+Choice”) was first established under the Balanced Budget Act of 1997. Aetna’s MA members typically receive enhanced benefits over standard Medicare fee-for-service coverage, including reduced cost-sharing for preventive care,

2. The Proposed Error Calculation Methodology Violates The Principles Of Actuarial Soundness And Equivalence.

CMS's proposed error calculation methodology also changes the actuarial assumptions of risk adjustments to MA payments in a way that is inconsistent with the Medicare Act. To calibrate its system of risk adjustments based on health status, CMS relied on FFS claims to measure the relative costs of providing benefits to Medicare beneficiaries with various medical conditions. Under a proper actuarial analysis, it is therefore impossible to know whether MA organizations are being "overpaid" based on a methodology that relies on medical records simply by reviewing the medical records supporting the HCCs assigned by MA organizations. Rather, a similar review of the medical records supporting the FFS claims that were used to calibrate the MA payments should be conducted.³⁹

As the Medicare Act emphasizes, in applying risk adjustments based on "health status," CMS is ultimately required to "ensure actuarial equivalence."⁴⁰ Because the statute does not define "actuarial equivalence," that phrase takes its ordinary meaning.⁴¹ "Actuarial equivalence" ordinarily refers to the principle that two types of payments or benefits with different nominal values may have the same real value when factors such as interest rates and risk are taken into account.⁴² Thus, the statute requires the Secretary to

³⁹ 42 U.S.C. § 1395w-23(a)(1)(C)(i)-(ii); see also April 2010 Regulations, 75 Fed. Reg. at 19,749 ("We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue [of the FFS coding].")

⁴⁰ 42 U.S.C. § 1395w-23(a)(1)(C)(i).

⁴¹ See Ransom v. FIA Card Servs., N.A., 562 U.S. ___, slip op. at 7 (2011).

⁴² See, e.g., Summers v. State St. Bank & Trust Co., 453 F.3d 404, 409 (7th Cir. 2006) ("\$10,000 certain [and] a 1 percent chance of obtaining \$1 million . . . are actuarial equivalents."); see also AMERICAN ACADEMY OF ACTUARIES, CRITICAL ISSUES IN HEALTH REFORM: ACTUARIAL EQUIVALENCE 1 (May 2009), available at http://www.actuary.org/pdf/health/equivalence_may09.pdf ("Actuarial equivalence is a general term used to describe two or more benefit plan designs that have approximately the same value.").

make adjustments based on “health status” so that the monthly payment to each MA organization accounts for the risk associated with health status.

CMS’s RADV audits are inconsistent with this statutory requirement because those audits cannot be reconciled with the agency’s own risk adjustment methodology. MA payments are based upon the Medicare payments made to FFS providers under Medicare Parts A and B.⁴³ CMS used FFS payment data to estimate the costs of providing treatment to a Medicare beneficiary with a condition falling within a given HCC.⁴⁴ Using the ICD-9 codes supplied by FFS providers on 1500 Health Insurance Claim Forms—not medical records—CMS calculated the cost incurred for FFS beneficiaries with a given condition.⁴⁵ The ICD-9 codes were then used to create an HCC and to identify a “risk factor,” or relative increase in cost, associated with that HCC.

In order to pay MA organizations accurately under CMS’s methodology, there must be consistency in coding between the FFS population (which is used to establish the risk factors) and the MA population (to which the risk factors will be applied to determine payments). Indeed, given that FFS data were used to develop the risk adjustments to MA payments, Congress recognized that it was essential to “establish[] risk scores that

⁴³ 42 U.S.C. §§ 1395w-23(a)(1)(C)(i)-(ii); 1395w-23(a)(1)(G); 1395w-23(a)(3)(A); 1395w-23(b)(i)(II); 1395w-23(b)(4); 1395w-23(k)(2)(B)(iv).

⁴⁴ See Gregory C. Pope et al., Risk Adjustment for Medicare Capitation Payments Using the CMS-HCC Model, 25 HEALTH CARE FINANCING REVIEW 119, 129 (Summer 2004), <https://www.cms.gov/HealthCareFinancingReview/Downloads/04Summerpg119.pdf>; 2009 Proposed Rule, 74 Fed. Reg. at 54,674; CTRS. FOR MEDICARE & MEDICAID SERVS., ANNOUNCEMENT OF CALENDAR YEAR (CY) 2010 MEDICARE ADVANTAGE CAPITATION RATES AND MEDICARE ADVANTAGE AND PART D PAYMENT POLICIES 20 (Apr. 6, 2009), <https://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2010.pdf> (“CY 2010 Rate Notice”); April 2010 Regulations, 75 Fed. Reg. at 19,748.

⁴⁵ CMS has contradictory definitions of what constitutes a valid basis for assigning an HCC. The diagnostic codes identified in the CMS 1500 Health Insurance Claim Forms by the treating physician in the FFS program are used to set the risk adjustment scores for HCCs used in the Medicare Advantage program. But CMS ignores those forms when auditing the HCCs assigned by MA organizations. Nowhere has CMS provided a single definition of what validates an assigned HCC.

are consistent across both fee-for-service and Medicare Advantage settings.”⁴⁶ Accordingly, the Medicare Act mandates that, in performing risk adjustments based on health status in MA payments, the Secretary must “ensure that such adjustment reflects changes in treatment coding practices in the fee-for-service sector and reflects differences in the coding patterns between Medicare advantage plans and providers under Part A and B,” and must “annually conduct an analysis of th[ose] differences.”⁴⁷ CMS has similarly recognized:

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustment to be valid. This means that MA organizations are coding “accurately” when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.⁴⁸

Because “MA organizations are coding ‘accurately’ when they are coding in a manner similar to fee-for-service coding,”⁴⁹ it is impossible to determine whether MA organizations are being overpaid by auditing only the medical records supporting MA claims. A proper actuarial analysis requires a comparison of MA and FFS documentation.

For example, assume Medicare paid FFS providers a total of \$15,000 per month above the average rate for Medicare enrollees with a certain risk condition. If the FFS

⁴⁶ 152 Cong. Rec. S438 (daily ed. Feb. 1, 2006) (statement of Sen. Charles Grassley); see also id. at H46 (statement of Rep. Joseph Barton) (similar); id. at H54 (statement of Rep. William Thomas) (similar).

⁴⁷ 42 U.S.C. §1395w-23(a)(1)(C)(ii)(I)-(II).

⁴⁸ CY 2010 Rate Notice at 20.

⁴⁹ Id.

providers identified ten beneficiaries with that condition, the average monthly cost per beneficiary associated with that condition would be \$1,500. That average cost would be used to pay an MA organization for any of its members that had the same condition. If, however, the FFS providers mistakenly included two beneficiaries who did not have that condition and thus incurred no costs associated with the condition, then the increase in monthly cost associated with the condition would be spread over eight enrollees, which would increase the average cost for the condition to \$1,875 per month. But if CMS did not audit the underlying FFS medical records, the agency would continue to pay MA organizations only \$1,500 per month per enrollee. As a result, if an MA organization assigned HCCs with 100% accuracy based on a review of medical records, the organization would be *underpaid* by \$375 for every Medicare enrollee with the condition, compared to actual costs in the FFS program. Until an audit of FFS claims is performed, therefore, the presence of invalid HCCs in MA claims does not demonstrate that MA organizations are being overpaid in the aggregate.

CMS's proposed sampling and error-calculation methodology does not take this reality into account. CMS is effectively assuming that FFS coding is 100% accurate, but the agency has no basis for that assumption. Indeed, CMS has not, and could not, demonstrate that FFS coding contains no errors (as CMS has defined "errors" in the RADV audit process). Many FFS providers also provide services to Medicare members enrolled in MA organizations. It defies logic to believe those providers would list ICD-9 codes with 100% accuracy on the 1500 Health Insurance Claim Forms sent to CMS under the FFS program, but not on the 1500 Health Insurance Claim Forms sent to MA organizations. CMS has presented no reason to believe this is the case.

The sampling and error calculation methodology proposed by CMS does not allow for any evaluation of, or proper comparison with, the FFS program.⁵⁰ Accordingly, CMS's RADV audits fail to "ensure actuarial equivalence" in adjusting payments based on "health status," and therefore violate the Medicare Act.

3. CMS's Proposed Sampling And Extrapolation Methodology Is Invalid And Statistically Flawed.

CMS's proposed methodology for calculating payment error also violates the Medicare Act and is arbitrary and capricious because it suffers from numerous statistical flaws. As an initial matter, CMS's methodology suffers from the same procedural flaw as the agency's One Best Medical Record rule—CMS failed to follow the proper notice-and-comment rulemaking procedures with respect to its payment error calculation methodology. Unlike a full notice-and-comment rulemaking under the APA, CMS's notice of its proposed methodology allows for only a brief thirty-day comment period, was not published in the Federal Register, and does not contain a discussion of economic analyses or regulatory alternatives. Because the payment error calculation methodology is a substantive rule that will impose obligations on MA organizations in the form of substantial payment adjustments, the Medicare Act and the APA require CMS to submit the methodology to full notice and comment before it is applied in CMS's RADV audits.⁵¹

⁵⁰ If CMS were to audit the medical records supporting FFS claims, the agency would need to apply the same rules in that audit as in its audits of MA organizations to allow for a meaningful comparison. It would be improper, for example, to apply the One Best Medical Record rule only with respect to the MA program.

⁵¹ See 42 U.S.C. § 1395hh(a)(2); 5 U.S.C. § 553(d); see also Exec. Order No. ___, 76 Fed. Reg. __ (Jan. 18, 2011), available at <http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order> (requiring, among other things, "a comment period that should generally be at least 60 days").

EXHIBIT 31



VIA EMAIL TO RADV@CMS.HHS.GOV AND FEDERAL EXPRESS

Ms. Cheri Rice
Acting Director, Medicare Plan Payment Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comment on RADV Sampling and Error Calculation Methodology

Dear Ms. Rice:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services's ("CMS") draft *Medicare Advantage Risk Adjustment Data Validation ("RADV") Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits*, released by CMS on December 20, 2010. Our comments incorporate the attached Exhibits, including the Actuarial Report attached as Exhibit A ("Actuarial Report").

As one of the largest sponsors of Medicare Advantage plans serving Medicare beneficiaries in the United States, Humana understands the trust that the government has placed with Medicare Advantage contractors as they serve many of the country's most vulnerable beneficiaries, and we are committed to continuing to work with CMS to ensure that Medicare Advantage organizations ("MAOs") are paid accurately. However, we have serious concerns about the draft sampling and payment error calculation methodology ("Proposed Methodology") because it will result in inaccurate payments to MAOs and also would have a real and direct impact on Medicare Advantage members and the health care benefits they receive.

The Proposed Methodology substantially deviates from the assumptions and methodology that CMS used to set payment rates and that MAOs relied on to submit bids. As a result, it improperly and retroactively changes how MAOs are reimbursed. It is mathematically certain that payments calculated using the Proposed Methodology would not accurately reflect the costs of providing benefits to Medicare Advantage members. In fact, the Proposed Methodology would fundamentally undermine the risk adjustment payment model by significantly underpaying MAOs for the risks they assume.

I. INTRODUCTION OF KEY ISSUES

The Proposed Methodology seems to reflect an assumption that MAOs are overpaid whenever a diagnosis relating to a risk adjustment payment is not supported by a medical record. Our comments below and the Actuarial Report describe in more detail why – given the existing actuarial method used to make risk adjustment payments – this assumption is incorrect and why the Proposed Methodology is fundamentally flawed:

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- **The Proposed Methodology disregards the FFS Claims Data used to establish payment rates.** RADV audits review only medical records for MA claims data received by MAOs from providers and submitted to CMS (“MA Claims Data”), but do not review medical records for FFS claims data used to develop the risk adjustment payment model (“FFS Claims Data”). These two sets of data are inextricably linked. CMS cannot adjust one set of data without considering the relationship with the other set of data when both are part of the comprehensive payment model. Using the Proposed Methodology, CMS’s payment model will be actuarially unsound for audited organizations because it would simultaneously use two very different sets of data to measure diagnoses – non-validated FFS Claims Data on the front end (the development of payment rates), and validated MA Claims Data on the back end of a risk adjustment data validation (“RADV”) audits. Unless CMS modifies the Proposed Methodology to appropriately adjust for this inconsistency, it will undermine the basic fairness of the underlying risk adjustment payment model.
- **The Proposed Methodology improperly deviates from the assumptions and methodology upon which MAOs relied in submitting bids.** MAOs correctly relied on the assumptions and methodology released by CMS to develop the risk scores used in bids, and reasonably assumed that FFS Claims Data and MA Claims Data would be consistently compared. MAOs could not have anticipated that CMS would implement the Proposed Methodology to retroactively recalculate risk scores used to set MAO payment rates by introducing different assumptions and a different methodology from what was employed during the bid process.

We understand that some may argue that the Proposed Methodology is not a change in payment methodology. This is simply not the case as the Proposed Methodology (i) has a direct and substantial impact on the actuarial calculations under the payment model, and (ii) substantially affects the risk scores and payment amounts in a manner that is different from the assumptions and methodology used prior to the bids. As such, it is a substantive change that is subject to the notice-and-comment requirements under the Social Security Act (the “Act”) and the Administrative Procedure Act (“APA”).

- **The Proposed Methodology would not withstand legal scrutiny.** The Proposed Methodology is arbitrary and capricious and inconsistent with the actuarial equivalence requirement and other requirements of the Act. In addition, implementation of the Proposed Methodology would be inconsistent with advance notice requirements of the Act, and other applicable laws governing the development and implementation of this substantive rule. CMS must respond in a reasoned manner to the legal and actuarial principles discussed herein and previously presented to CMS, and it must propose a solution subject to public comment before implementing any payment error calculation methodology.

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- **The Proposed Methodology suffers from additional defects.** The fundamental flaws noted above are compounded and exacerbated by defects in the statistical sampling and extrapolation approach, and by CMS's use of a "one best medical record" requirement to review MA Claims Data.

II. THE PROPOSED METHODOLOGY IMPROPERLY DISREGARDS THE FFS CLAIMS DATA USED TO SET MAO PAYMENT RATES

A. CMS Must Address the Data Inconsistency Issue

CMS relies on two interdependent sets of data to set payment rates for MAOs: (1) FFS Claims Data; and (2) MA Claims Data. The Proposed Methodology would review medical records for only one set of data (MA Claims Data), while not performing the same exercise on the other set (FFS Claims Data). However, because these two sets of data are inextricably linked, CMS must audit and validate *both* of them before extrapolating any potential RADV audit results. If it does not, CMS will dramatically underpay MAOs for the benefits they provided to Medicare beneficiaries.

Consider the following simplified example¹ (also set out in a chart below) that illustrates the impact of failing to validate the FFS Claims Data used on the front end:

- Suppose that in XYZ county, FFS Claims Data shows CMS spent an aggregate of \$60,000 on treating cancer ("Treatment Costs") in Year 1.
- CMS expects to spend an aggregate of \$60,000 on Treatment Costs again in Year 2. This is an anticipated based on FFS Claims Data and not tied to underlying diagnosis records.
- There are 100 people in the county enrolled in the original FFS program ("FFS Program"), and FFS Claims Data indicates that 60 of them have cancer. Assume if CMS were to audit the FFS Claims Data, which it did not, it would find that only 40 people have medical record documentation to validate those diagnoses.
- CMS nevertheless accepts the accuracy of the FFS Claims Data as submitted and calculates the increased risk for cancer patients to be \$1,000 per patient, effectively the "Unit Cost." This Unit Cost is analogous to the risk coefficient in the CMS risk adjustment payment model.
- In Year 2, 30 people with cancer in XYZ county enroll in a Medicare Advantage plan. In this scenario, CMS pays the MAO \$1,000 in extra revenue per cancer patient to cover the risk for covering the Treatment Costs for the 30 people.

¹ This example is simplified in order to illustrate the mathematical of failing to validate FFS Claims Data on the front end. The CMS risk adjustment methodology has additional complexities, and is described more fully in the Actuarial Report at § III.

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- Two years later, CMS audits the MA Claims Data used to determine the MAO's payments in Year 2 and discovers that only 20 (not 30) of the members had adequate medical record documentation to validate cancer for all periods in question.
- CMS then seeks to recoup \$10,000 from the MAO since only 20 members had a cancer diagnosis validated by a medical record. But this recoupment would result in an actuarially unsound and inaccurate payment.
- CMS should have calculated the Unit Cost to be \$1,500 per patient ($\$60,000 / 40$), not \$1,000. This is because the \$60,000 of Treatment Costs paid in Year 1 was accounted for by 40 patients whose medical records support the diagnosis, not 60 patients whose claims reflected that they had cancer. Using the corrected Unit Cost, the aggregate amount if correctly paid to the MAO for assuming the Treatment Costs would be \$30,000 ($\$1,500 \times 20$).

	Year 1		Year 2	
	FFS Claims Data (Unaudited)	FFS Claims Data (if Audited)	MAO Payments (Unaudited)	MAO Payments (Audited)
Beneficiaries with Cancer	60	40	30	20
Payments for Beneficiaries with Cancer	\$60,000	\$60,000	\$30,000	\$20,000
Unit Cost per Cancer Patient	\$1,000	\$1,500*	\$1,000	\$1,000*

* Note that \$1,000 would be the incorrect Unit Cost for audited MAO payments, which should be \$1,500 in order to make a valid comparison.

The above example illustrates that in order to ensure an actuarially sound and accurate payment, both the front end (the development of payment rates) and back end (RADV audit results) must have a mechanism for ensuring comparability. The absence of such a mechanism in the Proposed Methodology will have severe repercussions for beneficiaries, MAOs, and the Medicare Advantage program, as the payment model will not do what CMS actuaries designed it to do – pay MAOs for the benefits they administer under Medicare Advantage. This problem is referred to herein as the “Data Inconsistency Issue.” The Actuarial Report provides a more complete discussion and an actuarial analysis of this Data Inconsistency Issue, and should be reviewed as an integral part of these comments.

In other (similar) contexts, CMS has recognized the need to correct for the inconsistencies between FFS Claims Data and MA Claims Data when calculating payments to

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MAOs.² Additionally, Congress's requirement that CMS "adjust the risk scores for differences in coding patterns between Medicare Advantage plans and providers under the original Medicare fee-for-service program under parts A and B" requires the consistent use of data in determining risk adjusted payments to MAOs.³ The Proposed Methodology disregards the comparative nature of the risk adjustment payment model and the basic idea that valid comparisons cannot be made when risk scores for the FFS population are developed using unaudited FFS Claims Data, but risk scores for MAO enrollees are developed using MA Claims Data substantiated by medical records. In short, to ensure a valid comparison, the same type of data must be compared.

B. Recommendations for Adjusting for Data Inconsistency

The actuarial principles outlined above do not mean that CMS cannot implement an actuarially sound RADV methodology. We respectfully suggest, however, that if CMS intends to modify payments based on medical record review, then it must also correct for the Data Inconsistency Issue in an appropriate manner. To do so, CMS could audit FFS Claims Data and correct the risk (and demographic) coefficients used to establish payment amounts (which are analogous to the "Unit Cost" in the above illustration) using only those diagnoses substantiated in medical records, using the very same methodology that CMS has employed in the RADV audits. CMS would then apply the corrected coefficients to determine the final risk scores of audited MAO members. These corrected coefficients, as adjusted for unsubstantiated diagnoses

² Advance Notice of Methodological Changes for Calendar Year 2008 Medicare Advantage (MA) Payment Rates at 8 (Feb. 16, 2007):

Because the CMS-HCC model is calibrated on fee-for-service data and the resulting risk scores are adjusted for fee-for-service normalization, MA coding patterns that differ from patterns in fee-for-service may result in risk scores that are not equivalent to the risk scores of the FFS beneficiaries used to calculate the county rates.

Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies at 20 (Apr. 6, 2009) (emphasis added):

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, *for this comparison to be valid*, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MAOs are coding 'accurately' when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, 'differences' in coding patterns, regardless of the source, would make the MA plan coding 'inaccurate' for purposes of implementing risk adjustment.

Id. at 26 (emphasis added):

[T]he risk adjustment methodology is designed *to compare* the risk scores of MA plan enrollees to . . . beneficiaries not enrolled in MA plans.

³ See Social Security Act § 1853(k)(2)(B)(iv)(III), 42 U.S.C. § 1395w-23(k)(2)(B)(iv)(III).

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in FFS Claims Data, would be higher than those previously calculated by CMS. The post-audit risk scores for all sampled members would be recalculated using the corrected coefficients, and a statistically appropriate extrapolation methodology would then be applied. The problem with the coefficients and this potential solution are discussed further in the attached Actuarial Report at § VI.

Alternatively, CMS could apply payment adjustments following a comparison of the extent to which diagnoses are not substantiated by medical records in FFS Claims Data, and the extent to which diagnoses are not reflected in medical records in MA Claims Data. This approach would not, as has been suggested, reimburse MAOs for members whose diagnoses do not validate, or excuse a certain level of payment errors. To the contrary, it is an alternate mechanism for CMS to correctly calculate the payment impact of its audit and apply an appropriate conversion factor to account for the different sources of diagnostic data used to establish payment rates. As discussed in the Actuarial Report at § VI, this approach would be another way of achieving the same corrective result as the coefficient recalculation approach.

III. The Proposed Methodology Improperly Deviates from the Assumptions and Methodology Upon Which MAOs Relied in Submitting Bids

In addition to the actuarial issues described above, there would be other fundamental problems if CMS implemented the Proposed Methodology without appropriately addressing the Data Inconsistency Issue. In particular, the Proposed Methodology improperly deviates from the assumptions and methodology considered for calculating the risk scores that MAOs used in submitting bids and by CMS in approving those bids. The impact on the bidding process is explained in detail in the Actuarial Report at § V, which should be reviewed as an integral part of these comments but the main principles are set forth below.

A. CMS Must Publish the Methodology and Assumptions for Bids Before the Bids are Submitted, and Must Adhere to Those Assumptions and Methodology when Making Payment

The assumptions and methodology provided in advance of bid submission by CMS are critical to MAOs' bids and to the proper functioning of the Medicare Advantage program. The Act reflects the significance of these assumptions and methodology by requiring advance notice of payment rates and risk coefficients that will apply in the upcoming year. In addition to notice of payment rates and risk coefficients, the annual notice must also include an "explanation of the *assumptions and changes in* methodology used in such announcement."⁴ Any such changes may be implemented only after CMS publishes and provides an opportunity for MAOs to comment on proposed changes from the "methodology and assumptions used in the previous announcement."⁵

⁴ Social Security Act § 1853(b)(3), 42 U.S.C. § 1395w-23(b)(3) (emphasis added).

⁵ Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2).

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These provisions implement a core principle that CMS must give MAOs the assumptions and methodology needed to develop their bids *before* those bids are submitted. Furthermore, all MAOs must submit their bids using the same assumptions and methodology in order to achieve the level playing field that the Medicare Advantage competitive model requires.

B. The Proposed Methodology Deviates From the Assumptions and Methodology CMS and MAOs Relied on When Submitting and Approving Bids

The Proposed Methodology fundamentally changes the assumptions and methodology MAOs have used to develop risk scores⁶ in bids that have already been approved. CMS requires MAOs to project the overall risk score of their enrolled population, which materially affects the MAOs' bid amount. MAOs projected risk scores in their bids using the same methodology that CMS used to develop the risk coefficients. Those coefficients were based on FFS Claims Data, not diagnoses substantiated by medical record review. These coefficients also define the beneficiary with a "national average risk profile."⁷ MAOs must submit their bid amounts for providing the standard benefit package to a beneficiary with a "national average risk profile."⁸ Similarly, CMS published risk scores for the FFS population based on FFS Claims Data, not diagnoses substantiated by medical record review.⁹ MAOs applied the same methodology to project MAO risk scores and determine their bid amounts.

The Proposed Methodology recalculates the MAOs' risk score (and resulting payment) based "on the HCCs that are supported by RADV medical record review findings for the enrollee."¹⁰ This is a different methodology for calculating risk scores from the methodology MAOs properly used in submitting their bids, with substantial and material payment implications.

⁶ A risk score is a description of the health and demographic status of the enrolled population. A brief summary is as follows: CMS assigns "coefficients" (otherwise known as "risk adjustment factors") for different demographic and health-status conditions. For example, in 2007, the coefficient for a 66 year old non-institutional male enrollee was 0.330. The coefficient for non-institutional diabetes without complications was 0.181. CMS adds the coefficients together to compute a "risk score" for each member; the plan's projected risk score is the anticipated average for a plan's membership. If a plan projects a risk score of 1.05, it is in effect projecting that its enrolled population will have medical costs 5% higher than the national average for a FFS beneficiary.

⁷ CMS sets the coefficients in a statistical manner so that a FFS beneficiary with a "national average risk profile," Social Security Act § 1854(a)(6)(A)(i), 42 U.S.C. § 1395w-24(a)(6)(A)(i), is 1.0.

⁸ The "bid" amount is "the monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements . . . in the payment area for an enrollee with a national average risk profile for the factors described in section 1853(a)(1)(C) (as specified by the Secretary)." Social Security Act § 1854(a)(6)(i), 42 U.S.C. § 1395w-24(a)(6)(i).

⁹ CMS is required to publish the "average risk factor" [another term for "risk score"] for the FFS program covered population based on diagnoses reported for inpatient and other sites of services. Social Security Act § 1853(b)(4)(D), 42 U.S.C. § 1395w-23(b)(4)(D). In doing so, CMS is required to use "the same methodology as is expected to be applied in making payments" to MAOs. *Id.*

¹⁰ Proposed Methodology, at 2.

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We understand that CMS may have questioned why actuaries did not anticipate that medical record reviews might be conducted or that some MA Claims Data is not accurate. However, even if MAOs and certifying actuaries could have anticipated that CMS would conduct RADV audits, they had no reason to believe that CMS would not address the Data Inconsistency Issue as part of its calculation of any extrapolated payment errors. Indeed, even today it is uncertain how CMS will determine payment error from the RADV audits. In its final rule published in the Federal Register April 15, 2010 regarding RADV, CMS indicated, CMS indicated it is reviewing public comments on the Data Inconsistency Issue, but the Proposed Methodology does not address it.¹¹ As a result, the ultimate effect of RADV extrapolation on MAO risk scores remains unknown. Actuaries could not reasonably have known of or accounted for the Proposed Methodology in preparing bids. Indeed this challenge persists today, as CMS has not issued any notice seeking comments on a proposed change to the methodology for projecting risk scores for future contract years.

C. Actuaries Would Not Have Certified the Actuarial Soundness of MAO Bids, and CMS Should Not Have Accepted the Soundness of Those Bids, Using the Proposed Methodology's Approach to Calculating Risk Scores

MAOs calculated bid amounts using projected risk scores based on the methodology discussed above. MAOs and their actuaries certified that those bid amounts were actuarially sound, meaning that the required revenue stated in the bid was reasonable in relation to the benefits to be provided. If risk scores were instead based on the approach resulting from the Proposed Methodology, those same bids would not have provided the required revenue. As such, the bids would not have been actuarially sound, and actuaries would not have certified them. Instead, bid amounts would have been substantially higher, resulting in higher member premiums and or fewer supplemental benefits offered to members.

By accepting MAOs' bids, CMS verified the assumptions and methodology the MAOs used. This is because CMS

may only accept such a bid amount . . . if the Secretary determines that such amount . . . [is] supported by the actuarial bases provided . . . and reasonably and equitably reflects the revenue requirements . . . of benefits provided under that plan.¹²

If the MAOs' assumptions and methodology for projecting risk scores were incorrect, CMS could not lawfully have accepted the bids.

¹¹ Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,745 (Apr. 15, 2010).

¹² Social Security Act § 1854(a)(6)(B)(iii), 42 U.S.C. § 1395w-24(a)(6)(B)(iii); *see also* 42 C.F.R. § 422.258(b).

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IV. THE PROPOSED METHODOLOGY WOULD NOT WITHSTAND LEGAL SCRUTINY

A. The Proposed Methodology Effects an Impermissible Retroactive Change to the Assumptions and Methodologies in the Bids and is Contrary to the Contract

If applied to contract years for which bids have already been submitted, the Proposed Methodology would violate the Act. As noted above in Section III, the Act requires the Secretary to provide, in advance, the assumptions and methodology to be used in each annual announcement. The Act further requires the Secretary to provide advance notice of, and an opportunity to comment on, “proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement” in the prior contract year.¹³ Similarly, CMS committed itself not to “implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute.”¹⁴

Also as described in Section III, CMS obtained bids from MAOs (and approved the soundness of those bids) based on the published methodology for projecting risk scores and estimating bid amounts. The Proposed Methodology would make payments using wholly different methodology. MAOs performed their end of the contract and provided healthcare benefits to their enrollees. The Proposed Methodology changes the assumptions on which the CMS pricing was established based on the MAO bids.

By changing a critical assumption and introducing a new methodology, the Proposed Methodology violates the advance notice requirements in the Act, and breaches the contract between MAOs and CMS. CMS did not provide (and has not otherwise provided)¹⁵ advance notice of this change in assumptions and methodology.¹⁶

B. The Proposed Methodology Must Be Promulgated Through Notice-and-Comment Rulemaking

In addition to the specific advance notice requirements discussed in Section IV.A above, the Proposed Methodology may not be applied retroactively because it “takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or

¹³ Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2); *see also* Social Security Act § 1853(b)(3), 42 U.S.C. § 1395w-23(b)(3) (requiring an explanation of assumptions and changes in methodology).

¹⁴ 42 C.F.R. § 422.521.

¹⁵ The Proposed Methodology does not satisfy the notice-and-comment requirement for changes in assumptions and methodology for future contract years, as set forth in the Act. Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2). Rather, the Proposed Methodology is framed as an audit tool with respect to contracts already entered into. We believe that CMS must carefully consider and provide clear indications if it wishes to change the assumptions and methodology for projecting risk scores and other aspects of the bid process for CY 2012.

¹⁶ Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2).

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attaches a new disability in respect to transactions or considerations already past.”¹⁷ The Proposed Methodology would alter the legal landscape that existed when MAOs submitted bids, as described above in Sections II and III, and in Section V below. Most notably, MAOs had no notice that CMS would attempt to implement the Proposed Methodology, which had not been used or announced. Nor would the Proposed Methodology be, as CMS has asserted, just “a means for ensuring that payments made to MA organizations comply with substantive rules governing MA payments that are set forth in the statute.”¹⁸ RADV audits that rely on medical record validation alter the risk adjustment payment model because payment rates that were developed using Medicare FFS Claims Data would be retroactively adjusted using a different methodology – MA Claims Data supported by a medical record.

Moreover, the Act requires that any:

rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . [shall be] promulgated by the Secretary by regulation.¹⁹

The APA similarly requires notice-and-comment rulemaking before the Proposed Methodology is implemented because it is a substantive “rule” within the meaning of the APA.²⁰ As it has not proceeded through this process, it is invalid and void.²¹

Although Humana appreciates that CMS has provided this opportunity for comment on the Proposed Methodology, this procedure would not satisfy the requirements of notice-and-comment rulemaking even for prospective application. CMS itself has already identified the Data Inconsistency Issue as a significant issue requiring further study, but has not yet proposed how it intends to address it. As part of the formal rulemaking process that established appeals rights for RADV audits in April 2010, commenters raised the Data Inconsistency Issue and, as CMS described it, argued that CMS must “account for any error rates inherent in [FFS Claims Data] that affect MA error rates” before CMS can extrapolate alleged overpayments resulting

¹⁷ *Nat’l Mining Ass’n v. Dep’t of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002).

¹⁸ Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,745 (Apr. 15, 2010). There is no statutory provision that requires risk adjustment payments to be made based solely on validation of diagnoses in medical records. In fact, the Act requires that CMS address the Data Inconsistency issue as discussed elsewhere in these comments.

¹⁹ Social Security Act § 1871(a)(2), 42 U.S.C. § 1395hh(a)(2); H.R. REP. NO. 100-391, at 430 (1987) (“Policies meeting the definition [of covered policies] that were not issued in compliance with those procedures would be invalid.”).

²⁰ 5 U.S.C. § 551(4); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 102627 (D.C. Cir. 2000) (recognizing that test methods for compliance are substantive rule because “changing the method of measuring compliance with an emission limitation can affect the stringency of the limitation itself”).

²¹ *Heartland Reg’l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (holding that lack of notice and comment is “fundamental flaw that ‘normally’ requires vacatur of the rule”).

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from an RADV audit.²² CMS acknowledged the importance of the Data Inconsistency Issue, stating: “We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue.”²³ However, CMS has not proposed any mechanism for resolving the issue. CMS must “respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments, and to show how that resolution led the agency to the ultimate rule.”²⁴ CMS must therefore address the Data Inconsistency Issue detailed in the Actuarial Report before implementing the Proposed Methodology, or any other methodology that computes extrapolated payment error amounts based on RADV audit findings. As a result, we respectfully submit that CMS may not simply “post a final version of the RADV sampling and payment error calculation methodology” on its website, as CMS indicated it intends to do.²⁵ Rather, CMS must address the substance of the public comments on the Data Inconsistency Issue that have already been presented and that have been further presented here. It must publish its analysis and proposed resolution, with a statement of the basis for the proposed resolution. That must be published for public comment prior to implementation.

The United States Court of Appeals for the District of Columbia Circuit earlier this month reemphasized the need for the Department of Health and Human Services to follow the relevant rulemaking procedures, and consider and provide a reasoned response to comments submitted to the Agency arguing that the Agency’s mathematical computations for implementing payment rates to hospitals were incorrect.²⁶ Additionally, the President’s recent Executive Order instructs agencies that the public has the right to comment on “all pertinent parts” of rulemaking, including “relevant . . . technical findings,” before they are implemented.²⁷ Here, CMS has already acknowledged the potential merit of refining the error rate calculation, highlighting the procedural flaw if CMS does not publish an analysis and propose a solution for comment.

Simply asserting that the Proposed Methodology is designed to assure proper payments²⁸ does not suffice to meet the substance of the public comments or address the Data Inconsistency. Nor are these simple assertions a legally sufficient response to the detailed analyses and arguments presented in this letter and the attached Exhibits, which are incorporated by reference.

²² Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,749 (Apr. 15, 2010).

²³ *Id.*

²⁴ *Action on Smoking & Health v. C.A.B.*, 699 F.2d 1209, 1216 (D.C. Cir. 1983) (quoting *Rodway v. U.S. Dep’t of Agriculture*, 514 F.2d 809, 817 (D.C. Cir. 1975)).

²⁵ Proposed Methodology, at 3.

²⁶ *Cape Cod Hosp. v. Sebelius*, No. 1:08-cv-1751, slip op. (D.C. Cir. Jan. 14, 2011).

²⁷ Exec. Order No. 13,563, 76 Fed. Reg. 3,821, 3,822 (Jan. 21, 2011).

²⁸ *See, e.g.*, Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,746–47 (“[T]he RADV is an audit process that is intended to validate the HCCs that were submitted by MAOs in order to determine whether the additional payment amounts associated with these diagnosis codes were properly made.”).

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CMS's failure to conduct an analysis of and to address public comments, and publish for public comment a proposed resolution of, the Data Inconsistency Issue would render invalid any extrapolated overpayment amounts calculated through the Proposed Methodology.

C. Arbitrary and Capricious and Contrary to Law

By failing to address the Data Inconsistency Issue and other issues identified in these comments, the Proposed Methodology is so internally inconsistent and illogical as to be arbitrary and capricious under the APA.²⁹ That is, it fails to consider and address important factors,³⁰ and lacks a "rational connection between the facts found and the choice made."³¹

The Proposed Methodology is also "not in accordance with law,"³² because it fails to implement various statutory provisions governing the Medicare Advantage program. In addition to the important provisions discussed above in Sections III and IV.A relating to the bid process and advance notice requirements, the Proposed Methodology fails to implement the statutory provisions relating to risk adjustment. Congress required CMS to adjust Medicare Advantage payments for health status "so as to ensure actuarial equivalence,"³³ and to ensure that risk adjusted payments reflect "differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences."³⁴ Congress further required that CMS's method "account for variations in per capita costs based on health status."³⁵ By failing to address the Data Inconsistency Issue, the Proposed Methodology would violate these provisions governing risk adjustment. As discussed in these comments, by failing to address the Data Inconsistency Issue, risk adjustment payments will no longer be comparative with FFS, and would not properly compensate MAOs for the health status of their membership.

²⁹ 5 U.S.C. § 706(2)(a); *see also* *ABF Freight Sys., Inc. v. NLRB*, 510 U.S. 317, 324 (1994).

³⁰ *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) ("court must consider whether the decision was based on a consideration of the relevant factors"); *Woods Petroleum Corp. v. Dep't of Interior*, 47 F.3d 1032, 1037 (10th Cir. 1995).

³¹ *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974); *see also* *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins.*, 463 U.S. 29, 42–43 (1983).

³² 5 U.S.C. § 706(2)(A).

³³ Social Security Act § 1853(a)(1)(C)(i); 42 U.S.C. § 1395w-23(a)(1)(C)(i). Adoption of the Proposed Methodology would also place CMS in conflict with various other provisions of the Act, including various aspects of the bid process including assuring the actuarial soundness of bids based on the cost of providing benefits to an enrollee with a "national average risk profile" (as defined by the Secretary). Social Security Act § 1854(a)(6)(A)(i); 42 Social Security Act § 1854(a)(6)(A)(i); 42 U.S.C. § 1395w-24(a)(6)(A)(i).

³⁴ Social Security Act § 1853(a)(1)(C)(ii)(I); 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I).

³⁵ Social Security Act § 1853(a)(3); 42 U.S.C. § 1395w-23(a)(3).

EXHIBIT 32



January 21, 2011

Cheri Rice
Acting Director
Medicare Plan Payment Group
Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Response to CMS's Request for Comment on RADV sampling and error
calculation methodology

Dear Ms. Rice:

UnitedHealthcare Medicare & Retirement, on behalf of UnitedHealth Group and its affiliates ("United"), submits to the Centers for Medicare & Medicaid Services ("CMS") the following comments in response to CMS's Request for Comments on its Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits released on December 20, 2010 (the "Proposed Methodology").

United is one of the largest providers of Medicare Advantage ("MA") plans in the United States and has participated in the Medicare Part C program since its inception. United works with CMS on the development of many policies related to the MA program and strives to be a valued business partner with the government to ensure the success of the entire Medicare program. Together with CMS, physicians and other health care providers, United works to ensure that payments to our MA plans are accurate.

As explained in detail below, United believes that the Proposed Methodology represents a radical and unjustified change in the MA payment methodology that will leave MA plans no choice but to reduce coverage, cut benefits, or raise premiums for potentially millions of beneficiaries, or in some cases even exit the market. Further, the Proposed Methodology would subject Medicare Advantage Organizations ("MAOs") to a payment methodology that did not exist when MAOs submitted their actuarially certified MA bids and signed their MA contracts to assume the risk of providing coverage for their MA members. Even on a prospective basis, the Proposed Methodology will significantly impact the actuarial assumptions used in the bid process and consequently negatively impact coverage and benefits. United believes, and is



plans the impact may be so acute that a decrease in ancillary benefits is not enough to absorb the impact and the MAO also may need to impose an increase in premium or significantly higher cost sharing for some of the most utilized benefits by seniors such as physician office visits and prescription drugs. This would be very disruptive to MA members, is not in their best interests and undercuts the entire purpose of the MA program.

The effect of the Proposed Methodology will likely be felt most acutely by some of the most vulnerable members. MAOs that offer special needs plans to low-income beneficiaries eligible for both Medicare and Medicaid (dual eligibles) effectively have less flexibility with respect to reductions in benefits or increases in member premiums. This is because many dual eligible plans file FFS benefit cost sharing levels in their bids. There may not be an ability to reduce benefits to adjust for the impact of the Proposed Methodology since the plan benefits cannot go below FFS benefit levels. In addition, while an MAO could increase its premiums for dual eligible products, this would be illogical because it makes no sense to offer a product with a member premium to a population that cannot afford to pay a premium. MAOs that serve these dual-eligible populations may be forced to stop offering such products because they would be unable to formulate a bid that was actuarially sound and meet CMS's bid instructions for a product that makes sense for that population.

Finally, the inability to offer certain plans because of the impact of the Proposed Methodology could significantly reduce competition among plans, as MAOs cut back their plan offerings or withdraw from MA altogether. Additionally, if the Proposed Methodology is applied retroactively to plan years for which MAOs are unable to account for the adjustment in their bids, many MAOs will be forced out of business because they will be unable to pay to CMS the requested amounts, and will not see any ability to certify bids that achieve necessary margins going forward.

IV. THE PROPOSED METHODOLOGY FAILS TO ACCOUNT FOR DOCUMENTED ISSUES WITH THE MEDICARE PAYMENT SYSTEM.

A fundamental premise of the Proposed Methodology is that the underlying risk adjustment system is a sound basis to support an extrapolation and can result in accurate contract-level adjustments. This premise is incorrect. MAOs are not paid to treat members for



specific conditions. Rather MAOs are paid risk-adjusted payments that are determined based on a model that attempts to predict, relying on available data, the health risks that may be present in populations of members.

Members are assigned risk scores that reflect their health status as determined from data submitted for the previous calendar year dates of service. These risk scores and MA's risk adjustment system relies on member diagnoses to prospectively adjust capitation payments for a given member. The diagnosis codes relied upon are those submitted by treating providers to MAOs, generally as submitted on claims forms. As described above, these codes form the basis of the risk adjustment system.

The CMS-HCC Model is a statistical risk adjustment payment model that attempts to predict members' medical cost based on health risks, which is in turn used to determine MA capitation payments. The Model statistically estimates coefficients for HCCs, as well as gender, age, Medicaid/disabled indicators and interaction terms.^{17/} CMS uses the functional form and coefficients from the statistical estimation process to compute a capitation payment for each member. CMS then uses the RADV audit process to evaluate whether these individual risk-adjusted payments to MAOs are accurate, and now proposes to use these results to determine whether the contract-level payments are accurate. As shown below, the Model is not equipped to accurately make these adjustments.

a. The Proposed Methodology fails to consider the purpose and application of the CMS-HCC Model and its recognized lack of precision.

The CMS-HCC Model, which was developed and used by CMS to assign HCCs and predict costs, is a useful predictor of results for large populations but was not designed to predict results for individual members.^{18/} There is substantial unexplained cost variation among individual members with the same HCC for which the model cannot account. The Proposed Methodology fails to account for the Model's inability to accurately predict costs for individual beneficiaries.

^{17/} See Pope et al., at 119-141, Summer 2004.

^{18/} See *id.*



Inferences about the nature of specific elements of a population based solely upon aggregate statistics collected for the group to which those individuals belong is commonly known as an *ecological fallacy*. This fallacy assumes that individual members of a group have the *average* characteristics of the group at large. For example, a particular category of people are measured to have higher cholesterol than the general population. It is an error to assume that *all* members of that group have higher cholesterol than the general population. For any given individual from that group, there is no way to know if that person has lower cholesterol, average cholesterol, or higher cholesterol compared to the general population. In the same way, predictions made utilizing the accepted CMS-HCC Model should only be applied to large populations of members to ensure that random but significant differences in diagnoses among members which are not captured by diagnosis codes do not produce capitation payments that deviate dramatically from actual values (or costs). In fact, even when the comparisons of predictive accuracy are made for large subcategories of members, the Model can under or over predict values by as much as 30 percent for some subgroups in the model.^{19/}

The Proposed Methodology is flawed because it purports to use a statistical model designed to predict costs across a large group of members to adjust MA payments at the contract-level based on conclusions made on an individual basis. The CMS-HCC Model was not developed or intended to be used to predict individual costs and risks. Instead, to produce accurate contract-level error calculations the Proposed Methodology must be altered to take into account the accepted limitations and uncertainty of the existing model.

b. The Proposed Methodology relies on codes supported by the medical records while the payment system relies on codes supported by claims data.

In conducting a RADV audit, CMS determines whether each HCC is supported or not supported by the limited “one best medical record” (OBMR). Thus, the fundamental premise of the RADV audit process is that (i) HCCs derived from medical records should be equal to HCCs derived from claims submitted by treating providers, (ii) that differences between HCCs derived from medical records and HCCs derived from claims are “payment errors,” and therefore (iii) that any “overpayment” resulting from “payment errors” must be refunded to CMS. This premise is fundamentally flawed because (i) information contained in diagnosis codes reported in

^{19/} See Pope et al., Tables ES-3 through ES-4.



claims is not equal to information contained in medical records and (ii) the process used to develop HCCs from medical records is different from the process used to determine HCCs from claims. Stated differently, the discrepancies between HCCs derived from medical records and those derived from claims data are the result of comparing two different inputs, medical records and claims data. Thus, it is anomalous to use an audit of HCCs from medical records to calculate “corrected” risk scores that are based on HCCs from claims data. While this lack of congruity might be an acceptable compromise process to confirm that specific health conditions claimed for a member are present, this model cannot be used to predict the accuracy of complex health conditions for thousands of members across an entire contract.

Studies have shown that the diagnoses described in medical records and diagnoses identified in claims are, in practice, inconsistent due to the difference in purpose and ability to provide detail in each.^{20/} A provider, when choosing a diagnosis code, may look for a key phrase that most closely approximates a condition. But when completing the medical record, the physician is describing in his or her own words the conditions and symptoms presented, and no key phrases are required. This inconsistency, that is, the discrepancy between HCCs derived from claims data and HCCs derived from medical records, exists not only in the MA program, but in original FFS Medicare as well.

Claims and medical records contain different information. Reasons for the differences include:

- Only one diagnosis is needed in support of most claims submitted by physicians;
- Lack of documentation or shorthand in either claims or medical records;
- Ambiguities or uncertainties in coding specific conditions;
- Errors in coding or medical record errors; and/or
- Differences in interpretation of medical notes, including laboratory results.

Discrepancies and errors in diagnosis codes supported by medical records and those contained in claims data are well documented by many parties, including CMS. CMS conducts regular coding audits and reports coding discrepancies and errors.^{21/} Authors of the CMS-HCC

^{20/} See e.g., Measuring Diagnoses: ICD Code Accuracy, Health Service Research 2005 October; 40 (5 Pt 2): 1620–1639). This article can be obtained at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361216/>.

^{21/} See http://www.cms.gov/apps/er_report.



Model acknowledged the presence of judgment in coding and coding errors: “Concern about the quality of diagnostic reporting is the greatest in physician offices, where the diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals.”^{22/} Although efforts to reduce coding discrepancies are important, they are unlikely to ever be completely eliminated as long as coding includes human interpretation, judgment, and data entry.

The process of identifying HCCs from claims data also is very different than the RADV audit process conducted by CMS. HCCs from claims are derived by mapping diagnosis codes through diagnosis groups and condition categories, and applying hierarchies to arrive at HCCs. Diagnoses derived from medical records are determined through auditing by verification contractors and a rule-based reconciliation process. These are very different methods. The first uses programs established to map a diagnosis code ultimately into an HCC, and the second relies on human analysis of the information and terminology in medical records. Thus, a coder may be attempting to validate an HCC searching for wording or criteria that was not considered by the physician when determining the diagnosis code that then mapped to an HCC. Further, the two coders who are reviewing the medical records may themselves use different judgment when determining whether an adequate description exists in the medical record to validate the HCC. These process differences are likely to account for some inconsistencies in HCCs. These inconsistencies result in some HCCs not validating simply because a coder does not recognize a key phrase or word in a medical record that he or she believes should exist. This uncertainty is not accounted for anywhere in the Proposed Methodology.

The statistical model developed to determine risk-adjusted payments to MAOs was based on HCCs identified from diagnosis codes found in claims. In statistical terms, the data generation process for HCCs derived from claims data is very different from the data generation process for HCCs derived from medical records. As a result, it is inappropriate to use one HCC methodology in a model developed for the other. Furthermore, there is no assurance that forecasted expenditures, as the Proposed Methodology contemplates, are accurate or even unbiased. Diagnosis code errors and coding patterns due to ambiguities and judgment are implicit and accepted in the model where HCCs are derived from claims data. If CMS wishes to

^{22/} See Pope et al., at 129, Summer 2004.



determine payments based on a statistical model where HCCs are derived from medical records, then a statistical model utilizing this framework should be developed from the ground up. This would require developing a sample of Medicare FFS data using verification contractors and the reconciliation process to obtain HCCs from medical records. Estimation of a statistical model that uses HCCs derived from medical records as independent variables and medical expenditures as the dependent variable would be required. The functional form, including statistically significant HCCs, and the estimated coefficients would be different in such a model than what is currently in place.

c. The Proposed Methodology fails to account for the data disparity present in the Medicare FFS payment system on which Medicare risk-adjusted payments are based.

The discrepancies between claims data and medical records data are not unique to the MA risk adjustment system. Such discrepancies exist and have been identified in the Medicare FFS system. In fact, the MA risk adjustment system was developed using Medicare FFS claims data for the purpose of establishing “comparable” payments to MAOs and was intended to represent an actuarial estimate of the risk present in MAO plan membership relative to that of the Medicare FFS population. Given the grounding of the risk adjustment system in FFS claims data, the Proposed Methodology must take into account the circumstances of the underlying FFS data used to develop the model. Specifically, the model must account for the recognized and accepted potential disparity between the diagnoses reported by providers on claims and those documented in medical records, or existing in a population.

It is well established, although not entirely understood, that in any given year, providers significantly underreport the existence of medical conditions and especially chronic disease.^{23/} For example, a MedPAC study demonstrated that when comparing a diagnosis of congestive heart failure from one year to the next, only 61 percent of the beneficiaries diagnosed with the disease in year one were diagnosed with the disease the following year (even adjusting for death or other factors). In the case of chronic obstructive pulmonary disease it was 62 percent and was 59 percent for quadriplegia/paraplegia. The conclusion was that the true prevalence rate of a

^{23/} W. Pete Welch, Ph.D., *Outpatient Encounter Data for Risk Adjustment: Strategic Issues for Medicare and Medicaid*, J. of Ambulatory Care Management, July 2002, p. 4.



disease could be 1.4 times the observed rate.^{24/} When taking into account geographic variations in reporting patterns, and other factors such as consistency with medical records and consistency over time, the variation could be as much as 50 percent.^{25/}

To determine whether an MAO's payments accurately reflect what would be paid to treat a FFS population based on the claims data submitted for the FFS population, CMS needs to analyze the FFS data disparities and the impact of translating the disparities into the HCCs. CMS has reported that it has examined the disparity between FFS claims and FFS medical records and calculated a FFS error rate.^{26/} "CMS [has] reported four categories of errors: incorrect coding, medically unnecessary services, documentation errors, and other errors,"^{27/} but the Proposed Methodology does not take into account the FFS error rate and its impact on the underlying risk adjustment system.

CMS has previously recognized that it is necessary to "refine the error rate calculation" to account for any data discrepancy inherent in the Medicare FFS data so that they do not improperly affect MA error rates.^{28/} And CMS has acknowledged that "MA organizations are coding 'accurately' when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared."^{29/} Unfortunately the Proposed Methodology does not reflect this comparison. Instead, the Proposed Methodology seeks to adjust MA payments at the contract-level based solely upon alleged coding errors in member medical records without any adjustment for the extent to which these alleged "errors" or discrepancies are reflective of similar differences found in Medicare FFS data on which the entire risk adjustment system and CMS-HCC Model is based.

Based on the established data regarding the FFS error rate, it is possible that if an audit shows no or few errors, then the MA plan is actually being underpaid relative to the Medicare

^{24/} *Id.* at 4.

^{25/} *Id.* at 6.

^{26/} Dept. of Health and Human Services, Office of Inspector General, *Centers for Medicare & Medicaid Services' Use of Medicare Fee-for-Service Error Rate Data to Identify and Focus on Error-Prone Providers*, October 2010, available at: <http://oig.hhs.gov/oas/reports/region5/50800080.pdf>.

^{27/} *See id.*

^{28/} *See* 75 Fed. Reg. 19678, 19749 (April 15, 2010).

^{29/} Centers for Medicare & Medicaid Services, *Announcement of Contract Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies* at 20, (April 6, 2009) (hereinafter "Announcement of CY 2010 MA Capitation Rates") available at: <https://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2010.pdf>.



FFS system. Therefore, the FFS error rate must be incorporated into any methodology, through an actual adjustment or through consideration in the underlying CMS-HCC Model (for example through adjustment of coefficients) to ensure MAOs are not unfairly penalized for shortcomings of the Medicare coding payment system generally.

V. THE PROPOSED METHODOLOGY SHOULD NOT BE APPLIED RETROACTIVELY.
a. MAOs' Bids Have Not Been Formulated or Prepared Based on the Proposed Methodology.

Making changes to payment methodology retroactively undermines the actuarial soundness of the bids. Retroactive changes to the risk factors resulting from the RADV extrapolation after bids already have been submitted would invalidate the process used by the MA plan's actuaries to develop bids.

Each year, entities interested in offering an MA plan product to Medicare beneficiaries must submit a bid to CMS. The bid must: (1) present the estimated revenue requirements of the plan; (2) be standardized with respect to risk; (3) document methods of assumptions in compliance with (i) applicable actuarial standards of practice, (ii) CMS's bid instructions and guidance, and (iii) applicable laws and rules; and (4) be certified by a qualified actuary.^{30/}

In order to project costs and formulate a bid, an MAO and its actuaries must make assumptions based on the payment methodology that CMS has announced in advance, and these assumptions must be based in fact using all relevant data and information available at the time the bids are prepared. CMS did not announce its intention to extrapolate error rates at the contract-level until April 2008.^{31/} Even then, CMS did not provide any information regarding the method it planned to employ. Because CMS did not provide MAOs with information regarding how it planned to calculate contract-level error rates until December 2010, there was no information available to the actuaries and MAOs have been unable to formulate or adjust the assumptions related to projected risk scores of its members to account for the changes that will occur as a result of the Proposed Methodology. MAOs and their actuaries also have been unable to make any actuarially sound assumptions about what the methodology might look like in order

^{30/} See CMS Office of the Actuary; *Actuarial Bid Training, Introduction to Bidding*, April 2010, available at: <https://webinar.cms.hhs.gov/p64225010/>.

^{31/} See Announcement of CY 2009 MA Capitation Rates at 22.

EXHIBIT 33



AMERICAN ACADEMY *of* ACTUARIES

January 21, 2011

Ms. Cheri Rice
Acting Director, Medicare Plan Payment Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comment on RADV Sampling and Error Calculation Methodology

Dear Ms. Rice:

On behalf of the American Academy of Actuaries'¹ Health Practice Council, I appreciate this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to its recent request for comments on the Medicare Advantage (MA) risk adjustment data validation (RADV) payment error calculation methodology. We are concerned that the audit process as currently proposed would apply the risk-adjustment model in a way that is inconsistent with the way it was developed. This letter outlines our concerns.

The Importance of Risk Adjustment

In general, risk adjustment is intended to capture differences in morbidity from one cohort of individuals to another. As such, the CMS hierarchical condition categories (HCC) risk adjustment system is an important component of the MA program. Risk-adjusting plan payments can reduce incentives for plans to avoid high-cost enrollees and can help ensure that plan payments are adequate.

Throughout the development and refinement of the MA risk-adjustment model, CMS has sought to ensure that the risk-adjustment system properly reflects the differences in the risk profile of enrollees in a consistent manner. In addition, CMS has sought to recognize appropriate changes in fee-for-service (FFS) coding over time and differences in coding across programs.

Periodically auditing the data is appropriate to ensure that conditions are coded correctly and that risk scores and the resulting risk-adjusted payments properly reflect the underlying health status of MA enrollees. Because improper coding can result in inaccurate payments to MA plans, RADV audits can help improve plan payment accuracy.

Concerns with Proposed Audit Process

Our primary concern with the proposed audit process is that it creates an inconsistency between how the risk-adjustment factors were developed and how they now would be applied. An underlying principle of risk-adjustment systems is that there needs to be consistency in the way the model was developed and how it is used. The CMS-HCC risk-adjustment factors were developed with FFS data that, to the best of our knowledge, were not validated or audited for accuracy. The proposed audit process, however,

¹ The American Academy of Actuaries is a 17,000-member professional association whose mission is to serve the public on behalf of the U.S. actuarial profession. The Academy assists public policymakers on all levels by providing leadership, objective expertise, and actuarial advice on risk and financial security issues. The Academy also sets qualification, practice, and professionalism standards for actuaries in the United States.

effectively would apply those factors only to MA data that are validated. In other words, the data used in the RADV audit to determine a plan's payment error are fundamentally and materially different from the data used to develop the risk-adjustment model.

If, as a result of the RADV audit, for example, certain lower-cost enrollees no longer are considered diabetic but would have been considered diabetic in the FFS data used to develop the risk scores, then the payment for diabetic members in the payment year could be inadequate. In this example, the risk score factor associated with diabetes would be understated relative to the factor that would have resulted from using only substantiated diagnoses, because the lower-cost patients would have lowered the average spending amounts among those identified as diabetics in the FFS data. When that factor is applied to similarly non-validated data, the total payments for those with diabetes would be adequate. When that same factor is applied only to those with substantiated data, however, the total payments could be too low.

This type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities. In addition, the uncertainty related to a plan's ultimate post-audit risk score could make it difficult for actuaries to estimate the plan's risk score and certify the plan bid.

Extrapolating RADV payment-error calculations to adjust premium payments to MA plans represents a significant change in the risk-adjustment methodology. The Health Practice Council is concerned that the resulting modified payment methodology may not appropriately reflect the relative risk profile of enrollees in the affected MA plans.

As you may be aware, per a request from CMS (then the Health Care Financing Administration), the Academy reviewed the risk-adjustment methodology that was developed in response to requirements in the Balanced Budget Act of 1997.² We welcome the opportunity to serve as a similar resource to CMS. We would be happy to study more closely the current risk-adjustment and proposed audit processes and to consider potential options for addressing the above concerns. If you have any questions or would like to discuss these comments further, please contact Heather Jerbi, the Academy's senior health policy analyst (202.785.7869; Jerbi@actuary.org).

Sincerely,

Thomas F. Wildsmith, MAAA, FSA
Vice President, Health Practice Council
American Academy of Actuaries

cc: Richard Foster, Chief Actuary, Centers for Medicare & Medicaid Services (CMS)
Paul Spitalnic, Director, Parts C and D Actuarial Group, CMS
Timothy Hill, Deputy Director, Center for Medicare, CMS
Jennifer Harlow, Director, Division of Payment Validation, Medicare Plan Payment Group, CMS

² American Academy of Actuaries' Risk Adjustor Work Group, *Actuarial Review of the Health Status Risk Adjustor Methodology*, Jan. 14, 1999: <http://www.actuary.org/pdf/medicare/hcfariskadj.pdf>.

EXHIBIT 34

Humana Inc.
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Humana

March 7, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS-4159-P, Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Programs

Dear Ms. Tavenner:

This letter is in response to the Centers for Medicare and Medicaid Services' ("CMS" or the "Agency") request for comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule dated January 10, 2014 (the "Proposed Rule").

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. Humana serves approximately 12 million total medical members receiving medical services across the country. As one of the nation's top providers of Medicare Advantage and Medicare Part D benefits with approximately 5.8 million members, we are distinguished by our near 30-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. Humana is also a member of America's Health Insurance Plans ("AHIP"), the principal national trade association representing health insurance plans that provide coverage to more than 200 million Americans as well as a member of the Pharmaceutical Care Management Association ("PCMA"), the principal trade association for pharmacy benefit managers. We have provided extensive input into the development of AHIP's and PCMA's comments on the proposed rule and concur with and endorse their recommendations submitted under separate cover. The following comments are intended to supplement those provided by these two organizations.

Humana appreciates the Agency's ongoing efforts to refine elements of the Medicare Parts C and D Programs and values the opportunity to work collaboratively toward this end. We applaud the agency for its proposal to permit Medicare Advantage (MA) organizations to offer expanded health-driven rewards and incentives programs. We believe this proposal will enable Humana to more effectively encourage and support our members in their journey toward health and well-being.

Activity	Rationale
	limitations in the completion of rewards-eligible activities
Volunteerism	- Promotes social interaction and well-being - Reduces likelihood of depression and other mental health conditions associated with isolation
Memory Fitness Activities	Improves or maintains beneficiary cognitive functions

III.B.1. Implementing Overpayment Provisions of Section 1128(d) of the Social Security Act (§ 422.326 and § 423.360) and III.B.6 Risk Adjustment Data Requirements (§ 423.310)

CMS proposes to amend 42 C.F.R. § 422.310 on risk adjustment data requirements and to implement Section 1128(d) of the Social Security Act, as mandated by the Affordable Care Act, which requires the HHS Secretary to establish a process for MAOs and Part D Sponsors to report and return an identified overpayment to the Medicare program.

Comment: With respect to reporting and returning overpayments under proposed § 422.326, we agree that the annual final deadline for risk adjustment data is an appropriate standard for determining when “applicable reconciliation” has occurred under the MA program. As CMS has acknowledged, setting an earlier “applicable reconciliation” date would cause an administrative burden on MA organizations and CMS because risk adjustment data submitted by providers and others often require correction in the normal course before the annual final deadline for such data.

We request, however, that CMS clarify in the final rule what constitutes an “overpayment” after the final deadline for risk adjustment data has passed for MA organizations. According to CMS’s proposed rule, an “[o]verpayment means any funds . . . to which the MA organization, after applicable reconciliation, is not entitled”¹⁰ **As explained in further detail below, this Proposed Rule would benefit from a clarification that an overpayment cannot exist for an MA organization’s particular contract unless CMS’s payments to the contract as a whole are inaccurate in light of an appropriate Fee-for-Service Adjuster that is applied to the entire contract.**

CMS has stated clearly in the MA Risk Adjustment Data Validation (RADV) context that before it is possible to determine whether an MA organization has been overpaid based on the results of a RADV audit of a particular contract’s diagnosis code data submissions, CMS must first apply a Fee-for-Service Adjuster (FFS Adjuster) amount to account for differences between the manner in which CMS develops MA organization premium payments (based on diagnoses in Medicare FFS claims) and the manner in which CMS determines RADV payment errors (based on diagnoses documented in medical records).¹¹ The FFS Adjuster amount is applied because, as CMS has stated, MA organizations are expected to code diagnoses in the same manner as

¹⁰ 79 Fed. Reg. at 2055.

¹¹ *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, available at <http://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/PaymentValidation.html>. As of March 7, 2014, CMS has not announced its determination of the FFS Adjuster amount.

providers under Medicare Parts A and B, and MA plans are coding “accurately” when they do so.¹²

This same principle applies with equal force to potential overpayments under proposed § 422.326. **Applying the principles adopted by CMS in the RADV audit context means that an overpayment cannot exist for a particular contract unless CMS’s payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract. Potential overpayments can be determined, therefore, based only on processes such as CMS’s RADV audits, which are designed to measure whether contract-level payments to an MA organization are accurate when compared to an appropriate FFS Adjuster. To the extent an MA organization develops processes intended to measure payment accuracy at the contract-level, the MA organization would be required to report and repay inaccuracies calculated after applying CMS’s FFS Adjuster. Indeed, consistent with prior CMS guidance, this is the sole instance in which an “overpayment” can be determined for purposes of proposed § 422.326.** Clarification of proposed § 422.326 in this regard will assist other agencies and stakeholders that may attempt to interpret the final rule but that may not be as familiar with the payment model established by Part C and the regulatory history thereunder.

This concept similarly applies to the Proposed Rule at § 422.310(e)(1) regarding medical record reviews. Under the Proposed Rule, CMS would require that “any medical record reviews conducted by an MA organization . . . be designed to determine the accuracy of diagnoses submitted” to the Medicare Advantage (Part C) program for reimbursement purposes.¹³ When the “medical record reviews” conducted by an MA organization include an effort to measure the accuracy of payments received from CMS on a contract-wide basis applying an appropriate FFS Adjuster, the MA organization is necessarily in compliance with the proposed requirement that its “medical record reviews . . . be designed to determine the accuracy of diagnoses submitted.” CMS should clarify that this is true regardless of the nature or purpose of any other medical record review activities undertaken by an MA organization because a determination of “accuracy” requires application of a FFS Adjuster at the contract-level. Indeed, this is the only mathematically appropriate way to determine whether diagnoses submitted by an MA organization for a particular contract as a whole are “accurate.” **Thus, the review of any particular medical record for any reason by an MA organization can only be relevant for determining the “accuracy of diagnoses submitted” to the extent the review of the record is part of a process intended to measure payment accuracy at the contract-level in view of an appropriate FFS Adjuster amount.** Such clarification is necessary for MA organizations and other stakeholders and agencies alike. If the final rule were interpreted to mean that every review of any particular medical record for any purpose could impact payment accuracy, MA organizations would be placed in an untenable position of attempting to reconcile individual medical records to submitted diagnoses in a manner that would be fundamentally at odds with the MA payment model, which is based on diagnoses in Medicare FFS claims rather than medical records.

¹² *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (April 6 2009)*, available at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2010.pdf>.

¹³ 79 Fed. Reg. at 2000.

EXHIBIT 35

UNITEDHEALTH GROUP®

March 7, 2014

Ms. Marilyn Tavenner
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Ms. Liz Richter
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Submitted via Federal eRulemaking portal: <http://www.regulations.gov>

RE: Request for Comments on Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Programs; Proposed Rule: File code CMS-4159-P

Dear Administrator Tavenner and Director Richter:

UnitedHealth Group and its affiliates (United) is pleased to provide the Centers for Medicare & Medicaid Services (CMS or the Agency) comments regarding the Notice of Proposed Rulemaking (NPRM) published in the Federal Register, 79 Fed. Reg. 1918 (Jan. 10, 2014): Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs [CMS-4159-P]. We welcome the opportunity for a constructive dialogue regarding the changes proposed in this NPRM and their impact on (1) the health care system, (2) Medicare beneficiaries, and (3) the Federal government.

United's workforce of 165,000 people is working to modernize the health care system to: enhance the consumer experience, improve access drive quality outcomes, and reduce health care costs. UnitedHealthcare Medicare & Retirement serves more than 10.1 million Medicare beneficiaries - including nearly one-in-five Medicare beneficiaries - across all major senior health benefits product categories, is the market leader in Medicare Advantage health benefit products, and is the largest Medicare Part D prescription drug plan provider. Through OptumRx, part of the United family, we contract with over 66,000 pharmacies to serve beneficiaries participating in Medicare Part D prescription drug plans.

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B.6. Risk Adjustment Data Requirements (§ 422.310)

1. Requirements Relating to Medical Record Review

The Proposed Rule would require that “[a]ny medical record reviews conducted by a MAO . . . be designed to determine the accuracy of diagnoses submitted under § 422.308(c) and § 422.310(g).”¹³ We support CMS’ decision to require MAOs to design medical record reviews to determine the accuracy of diagnoses submitted by providers on claims data.

At the same time, the Proposed Rule must, if adopted, adhere to the statutory mandate that MAOs be paid appropriately for the health status of their members relative to costs incurred in Fee-For-Service (“FFS”) for similar beneficiaries. The risk scores of MA and FFS beneficiaries are comparable only if CMS measures their health status using equivalent methodologies and data. Under the Proposed Rule, MAOs will be undercompensated for the relative risk of their membership if they delete diagnosis codes from claims that are unsupported in a medical record and CMS does not simultaneously account for the equivalent diagnoses in FFS data. Put another way, if MAOs are required to delete provider-submitted diagnosis codes that are unsupported by a review of the corresponding medical chart, while CMS determines the health status of FFS beneficiaries based on diagnosis data derived from claims and not adjusted by a review of medical charts, the result will be to make MAO members appear artificially healthier than otherwise identical FFS beneficiaries. This would systemically skew the resulting payment calculation in violation of statutory requirements. CMS should take steps to offset this systemic effect.

Recommendation: As a necessary corollary of the proposal, CMS should offset the impact of diagnoses submitted in provider claims but not found to exist in medical record reviews to account for equivalent diagnoses in FFS data. Specifically, CMS should give MAOs a credit for diagnoses submitted in provider claims but deleted following medical record reviews up to the rate identified by CMS as the applicable FFS Adjustor in the RADV program.

- A. MA payments are based on a relative reimbursement methodology that compares MAO’s members’ risk scores to those of FFS beneficiaries, and require that CMS and MAO’s calculate risk scores in the same way.

MA payments are set by a relative reimbursement methodology that compares MAOs members’ anticipated healthcare expenses (measured by risk scores) to those of FFS beneficiaries. CMS pays MAOs a capitated, per-member-per month amount for coverage of original FFS benefits.¹⁴ To eliminate incentives for favorable risk selection, CMS adjusts monthly payments to MAOs to reflect, in part, the health status of their beneficiaries.¹⁵ It does so by applying a risk adjustment multiplier (or “risk score”) that reflects a member’s anticipated healthcare expenditures based on their health status compared to the average FFS beneficiary as determined using FFS claims

¹³ 79 Fed. Reg. 1918, 2053 (Jan. 10, 2014).

¹⁴ 42 U.S.C. § 1395w-23(a)(1); 42 C.F.R. § 422.304(a)(“CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.”).

¹⁵ 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. § 422.308(c) (“CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence.”).

data.¹⁶ A MA beneficiary with a risk score of one (1) is equivalent to a FFS beneficiary with average costs.¹⁷

In order to work properly and consistently with the statute and regulations, risk adjustment requires that FFS and the MAOs calculate the severity of a member's health condition in the same way.¹⁸ CMS regulations set forth a payment methodology that is dependent upon actuarially equivalent data and requires MAOs to "submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data."¹⁹ Diagnosis codes submitted by providers through claims data are one of the primary mechanisms CMS uses to determine the level of risk associated with a particular beneficiary.²⁰ The GAO has recognized that the risk scores for MA and FFS beneficiaries of identical health will be comparable only if "MAOs and FFS providers code medical diagnoses with the same level of reliability and completeness."²¹

B. Unless CMS accounts for corresponding errors in its FFS data, the Proposed Rule will introduce inconsistent standards of accuracy between FFS and MA data and systematically undercompensate MAOs.

We understand the Proposed Rule to require that MAOs audit and correct, during medical record reviews they undertake, codes previously submitted by providers. Under this proposal, MA and FFS data would be held to inconsistent standards of accuracy unless CMS similarly adjusts FFS

¹⁶ See Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Chapter 7, "Risk Adjustment," Section 70 –70.1 ("The CMS-HCC risk adjustment models are used to calculate risk scores, which predict individual beneficiaries' health care expenditures, relative to the average beneficiary. . . . When CMS recalibrates the CMS-HCC risk adjustment model, it uses data from fee-for-service (FFS) claims, using one year's diagnoses to predict the following year's expenditures. . . . [R]isk scores for individual beneficiaries . . . will average 1.0 in the denominator year for the FFS population."); U.S. Gov't Accountability Office, Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices, 1 (2012) ("To risk adjust payments, CMS calculates a risk score for every Medicare beneficiary, including those in MAOs and the FFS program. A beneficiary's risk score is the ratio of expected health care expenditures for that beneficiary under Medicare FFS relative to the average health care expenditures for all Medicare FFS beneficiaries.").

¹⁷ Paulette C. Morgan, Congressional Research Service, Medicare Advantage Risk Adjustment and Risk Adjustment Data Validation Audits 7 (2012) ("The results derived from the model can be standardized such that an individual with a risk score of 1 equates to a Medicare fee-for-service beneficiary with average costs . . .").

¹⁸ United States v. Scan Health Plan, No. CV 09-5013-JFW (JEMx), 2013 U.S. Dist. LEXIS 129656, at *8 (C.D. Cal. Jul. 30, 2013) ("Because MAOs are compensated on a relative system, the contracts fundamentally presume that both the MAOs and Medicare will filter and treat diagnostic information the same way.").

¹⁹ 42 C.F.R. § 422.310(d) ("MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-services data, when appropriate, and to all relevant national standards.") (emphasis added); see also 42 C.F.R. § 422.308(c) ("CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.") (emphasis added).

²⁰ See U.S. Gov't Accountability Office, GAO-1-206, Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments, 6-7 (2013) ("For most MA beneficiaries, CMS uses its CMS-Hierarchical Condition Categories (CMS-HCC) model to risk-adjust payments to MAOs. . . . The CMS-HCC risk adjustment model uses enrollment and claims data from Medicare FFS. The model uses beneficiary characteristic and diagnostic data from a base year to calculate the expected health care expenditures under Medicare FFS for the following year.").

²¹ U.S. Gov't Accountability Office, Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices, 2 (2012).

data to account for diagnoses reported in claim that are not documented in the medical record. One consequence of this asymmetry is that MAOs will be systematically undercompensated because MA beneficiaries will not be accurately compared to FFS beneficiaries.

We acknowledge, as CMS has recognized, that diagnosis codes submitted by providers contain inaccuracies because physicians, who are usually compensated on a per service basis (based on procedure codes), are generally “not as familiar with diagnosis codes and their associated documentation guidelines as they are with procedure coding rules.”²² As CMS has recognized in the RADV context, however, both MA and FFS data contain such errors.²³ To the best of our knowledge, CMS does not obtain medical charts for FFS beneficiaries and use them to determine the accuracy of diagnosis codes in the FFS data used to calibrate MA risk adjustment coefficients.²⁴ Based on the information CMS has made available, we believe CMS’ automated filtering methodology is focused mainly on procedural issues related to Medicare claims, such as inconsistencies in documentation, proper information contained in the claims, and proper timeframes.²⁵ Unless modified to account for the FFS error rate, the Proposed Rule would unfairly undercompensate Plans.

In the RADV context, CMS has recognized that it would be inappropriate (and inconsistent with the MA reimbursement methodology) to adjust payments to MAOs based on a review of medical records, while at the same time setting the Part C rate based on FFS estimates that look exclusively at claims data. CMS has recognized that FFS claims data also contain provider coding errors. On February 24, 2012, it announced that it would offset a MAO’s payment error rate by a FFS Adjustment amount to determine its final recovery amount:

²² See Centers for Medicare & Medicaid Services, 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide, 6-2. This often results in the coding of diagnosis codes within providers’ offices not being as complete and accurate as it might be if it were directly linked to reimbursement for providers. See MedPAC, Report to Congress: Medicare and the Health Care Delivery System, 96 (2012), available at http://www.medpac.gov/chapters/Jun12_Ch04.pdf (finding providers do not consistently code conditions from year to year).

²³ Centers for Medicare & Medicaid Services, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) (introducing a FFS Adjustment to account “for the fact that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)”).

²⁴ See, e.g., Centers for Medicare & Medicaid Services, Recovery Auditing in the Medicare and Medicaid Programs for Fiscal Year 2011: FY 2011 Report to Congress as Required by Section 1893(h) of the Social Security Act for Medicare and Section 6411c of the Affordable Care Act for Medicaid, 1-2 (“While all claims submitted to Medicare are screened by thousands of system edits prior to payment, claims are generally paid without requesting the supporting medical records. As a result, some claims may be paid inappropriately, resulting in improper payments. . . . Most improper payments can only be identified through review of the medical record. Given the volume of claims submitted to CMS on a daily basis, CMS is not able to perform 100 percent medical review prior to payment, commonly referred to as pre-payment review. CMS must rely on conducting medical record review after payment commonly referred to as post-payment review.”).

²⁵ See, e.g., Centers for Medicare and Medicaid Services, Processing of Claims for Part A and Part B: Enterprise Architecture, 2-18 (2006) (“Automated edits check for completeness, valid submittals, valid values, and data consistency. The edits also apply rules and guidelines, check for duplicates and suspensions, and validate provider and beneficiary eligibility. If suspensions are generated or further investigation is required, the claim/adjustment may undergo further manual processing.”).

The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.²⁶

The logic behind the FFS Adjustment in the RADV context applies with equal force in the context of medical record reviews. We see no reason to require that both MA and FFS data be scrutinized for error rates when determining retroactive payment adjustments, while not engaging in a similar adjustment process when paying plans prospectively.

Recommendation: CMS should amend the Final Rule to ensure an accurate comparison of MA and FFS beneficiaries' risk adjustment scores. We believe that the easiest fix to implement, although other solutions may have a similar net effect, would be for CMS to give MAOs credit for any diagnoses identified as submitted in provider claims data but not supported in a medical record up to the rate identified by CMS as the applicable FFS Adjustment identified through the RADV program, beginning with the 2014 final payment reconciliation in August 2015. For example, if CMS were to determine that X% of the diagnoses submitted through FFS claims data were not supported by a medical record, MAOs would get credit for up to X% of the diagnoses that were submitted to them in claims data but not supported by a medical record.

In promulgating the Proposed Rule, CMS does not suggest, let alone point to evidence, that the codes added by Plans through medical record reviews are inaccurate. The requirement that MAOs look for errors in provider-submitted codes is not premised on any such finding and in any event is not logically designed to address any such inaccuracies.

If CMS is concerned that MAOs engage in medical record reviews, whereas it does not, the Secretary is statutorily required to address any resulting differential through the Coding Intensity Adjustment—the mechanism that Congress created to address this precise issue. Congress requires the Secretary to examine and fully adjust for coding activity differences between MAOs and FFS providers that may alter the baseline comparison between MA and FFS beneficiaries. Congress amended the Medicare statute to provide that “the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage Plans and providers under part A and B to the extent that the Secretary has identified such differences.”²⁷

We believe that the coding intensity adjustment currently in place is fully adequate and requires no upward adjustment. Should CMS disagree, and have a sufficient factual basis to do so, the

²⁶ Centers for Medicare & Medicaid Services, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012).

²⁷ 42 U.S.C. § 1395w-23 (a)(1)(C)(ii)(I); CENTERS FOR MEDICARE & MEDICAID SERVICES, MEDICARE MANAGED CARE MANUAL, Chapter 7, “Risk Adjustment,” Section 100 (“Beginning in 2010, CMS instituted a separate adjustment to the Part C risk scores to account for differential coding patterns between MA and FFS. The adjustment for 2010 of 3.41% was based on our estimate of how much lower Plans’ 2010 risk scores would have been if the disease scores (the portion of the risk score attributable to diagnostic coding) for MA enrollees who stayed in an MAO during the period 2007 to 2010 (‘MA stayers’) had grown at the same rate as FFS beneficiaries’ risk scores during this period.”).

answer is to fine tune the Coding Intensity Adjuster. Requiring MAOs to audit and delete provider submitted codes is neither a logical nor direct response to the practice of medical record review by MAOs. Indeed, if MAOs were to discontinue medical record review activities, they would still be undercompensated, unless the coding intensity adjuster were substantially reduced.

2. Removal of January 31 Deadline

CMS proposes to remove the regulatory provision for a sweeps deadline of January 31st following the payment year. Instead, CMS would have discretion to select a deadline annually. We understand that CMS intends to announce a similar deadline annually, which is in keeping with current practice. We do not believe that CMS should remove the regulatory certainty of the January 31st deadline, as MAOs Plan their processes around this deadline. It would be extremely disruptive to these processes if CMS were to announce an *earlier* deadline in any year.

Recommendation: We propose that CMS amend the current regulation to provide that CMS may *extend* the existing deadline annually.

3. Submission of Diagnoses After Deadline

CMS proposes to amend the regulation to clarify that after the sweeps deadline, an MAO “can submit data to correct overpayments but cannot submit diagnoses for additional payments.” This revision is consistent with current practices. MAOs often have circumstances where they want to delete one diagnosis code and would replace it with another diagnosis. For example, an MAO may want to delete diabetes with acute complications and replace it with diabetes without complications so that it loses only some of the payment. Such a delete and replacement would result in a more accurate payment. This would also be consistent with how CMS treats such discrepancies in RADV.

Recommendation: After the sweeps deadline for the submission of diagnoses for additional payment, MAOs should be able to submit additional diagnoses with deletes as long as they are not seeking additional payments.

B.7. RADV Appeals

Background

In February 2012, CMS announced that it would use a FFS Adjuster as part of the RADV error calculation methodology. At the time, CMS provided no information regarding how the FFS Adjuster would be calculated. Two years have passed and CMS has initiated the first round of RADV audits that will utilize the 2012 methodology, but CMS has still not explained publicly how it will calculate the FFS Adjuster.

Recommendation: There are likely several alternative ways to measure the FFS Adjuster. We recommend that CMS publish a proposed methodology and seek public comments. Further, we recommend that CMS publish and finalize this methodology before CMS completes the current audits that have recently begun.

CMS’ proposed changes to the RADV appeals process rules are premised on CMS’ authority to make contract level extrapolated overpayment assessments. United has previously filed comments in opposition to CMS’ proposed RADV methodology. See letter dated January 21,

EXHIBIT 36



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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, *et al.*

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 417, 422, 423, and 424****[CMS-4159-F]****RIN 0938-AR37****Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.**SUMMARY:** The final rule will revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug

benefit program (Part D) regulations to implement statutory requirements; improve program efficiencies; and clarify program requirements. The final rule also includes several provisions designed to improve payment accuracy.

DATES: *Effective Dates:* These regulations are effective on July 22, 2014 except for the amendment in instruction 27 to § 423.100, the amendment in instruction 30 to § 423.501, and the amendment in instruction 34 to § 423.505, which are effective on January 1, 2016.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT:

Christopher McClintick, (410) 786-4682, Part C issues.

Marie Manteuffel, (410) 786-3447, Part D issues.

Kristy Nishimoto, (206) 615-2367, Part C and D enrollment and appeals issues.

Whitney Johnson, (410) 786-0490, Part C and D payment issues.

Joselyn Lissone, (410) 786-5116, Part C and D compliance issues.

Frank Whelan, (410) 786 1302, Part D improper prescribing issues.

SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of this final rule. The applicability dates are discussed in the preamble for each of these items.

TABLE 1—APPLICABILITY DATE OF KEY PROVISIONS OTHER THAN 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE

Preamble section	Section title	Applicability date
III.A.4	Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)).	01/01/2016
III.A.7	Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)	01/01/2015
III.A.20	Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(6))	06/01/2015
III.A.24	Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460(b)(2)(i), 417.460(f)(1)(i)(A) through (C), 422.74(d)(4)(i)(A), 422.74(d)(4)(v), 423.44(d)(5)(iii) and (iv)).	01/01/2015

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(§§ 422.752, 423.752, 422.760 and 423.760)

3. Contract Termination Notification Requirements and Contract Termination Basis (§§ 422.510 and 423.509)**4. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C))****5. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§§ 422.756 and 423.756)****6. Timely Access to Mail Order Services (§ 423.120)****7. Agent/Broker Requirements, Particularly Compensation (§§ 422.2274 and 423.2274)****8. Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(v))****9. Medication Therapy Management Program (MTMP) under Part D (§ 423.153(d))****a. Multiple Chronic Diseases****b. Multiple Part D Drugs****c. Annual Cost Threshold****10. Requirement for Applicants or their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b))****11. Requirement for Applicants for Stand Alone Part D Plan Sponsor Contracts to Be Actively Engaged in the Business of the Administration of Health Insurance Benefits (§ 423.504(b)(9))****12. Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract Per PDP Region (§ 423.503)****13. Limit Stand-Alone Prescription Drug Plan Sponsors to Offering No More Than Two Plans Per PDP Region (§ 423.265)****14. Applicable Cost-Sharing for Transition Supplies: Transition Process Under Part D (§ 423.120(b)(3))****15. Interpreting the Non Interference Provision (§ 423.10)****16. Pharmacy Price Concessions in Negotiated Prices (§ 423.100)****17. Preferred Cost Sharing (§§ 423.100 and 423.120)****18. Prescription Drug Pricing Standards and Maximum Allowable Cost (§ 423.505(b)(21))****19. Any Willing Pharmacy Standard Terms & Conditions (§ 423.120(a)(8))****20. Enrollment Requirements for Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))****21. Improper Prescribing Practices (§§ 424.530 and 424.535)****a. Background and Program Integrity Concerns****b. Drug Enforcement Administration (DEA) Certification of Registration****c. Patterns or Practices of Prescribing****22. Broadening the Release of Part D Data (§ 423.505)****23. Establish Authority to Directly Request Information From First Tier, Downstream, and Related Entities (§§ 422.504(i)(2)(i) and 423.505(i)(2)(i))**

diagnoses for Part D by the final risk adjustment data submission deadline.

In summary, we proposed an approach to defining applicable reconciliation that establishes dates that differ for Part C and Part D. We asked for comment on this approach.

We noted that payment errors identified as a result of any corrections to risk adjustment data submitted by MA organizations (and other organizations required to submit risk adjustment data to CMS) on or before the annual final risk adjustment data submission deadline are handled as part of the current annual process of risk adjustment payment reconciliation. Because these payment errors are prior to the date defined in this final rule as “applicable reconciliation”, we stated that we do not consider these errors to be overpayments for the purpose of §§ 422.326 and 423.360. That is, any deletions of risk adjustment data in the file submitted on or before the final risk adjustment data submission deadline for a payment year, would result in payment errors that are addressed with processes that have been in place prior to our codification of section 1128J(d) of the Act in proposed §§ 422.326 and 423.360.

Likewise, for Part D, any payment errors identified as a result of any corrections to PDE or DIR data submitted on or before the later of the annual deadline for submitted PDE and DIR data are handled as part of the current Part D reconciliation process, and we do not consider these errors to be overpayments for the purpose of § 423.360.

Finally, we stated our expectation that MA organizations and Part D sponsors must be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS for a payment year, whether during or after that payment year, and whether before or after applicable reconciliation dates. This expectation is based on existing requirements at §§ 422.310, 422.504(l), 423.329(b)(3)(ii), and 423.505(k), and proposed amendments that clarify and strengthen these requirements.

We did not receive any comments on the proposed definitions of the terms “funds” or “overpayment.” (See the next section for comments and responses on the provision regarding “identified overpayment.”) We received the following comment on the term “applicable reconciliation”, and our response follows.

Comment: Some commenters supported CMS’ proposal to have separate applicable reconciliation dates for the Part C and Part D programs,

noting that this approach is simpler and more practical than the alternative CMS described (where there would be 2 applicable reconciliation dates for the Part D program—one for risk adjustment and another for PDE and DIR data).

Response: We appreciate the support. We will finalize our proposal that the Part C applicable reconciliation date will be the same as the final risk adjustment data submission deadline, and the Part D applicable reconciliation date will be the later of: The annual deadline for submitting prescription drug event (PDE) data for the annual Part D payment reconciliation referred to in § 423.343(c) and (d) or the annual deadline for submitting DIR data.

We would like to note that the final risk adjustment data submission deadline will still apply to diagnosis data for both Part C and Part D risk scores for beneficiaries in MA–PD plans.

After consideration of the public comments received, we are finalizing the provisions at §§ 422.326(a) and 423.360(a) as proposed.

b. General Rules for Overpayments (§ 422.326(b) Through (c); § 423.360(b) through (c))

We proposed at §§ 422.326(b) and 423.360(b) that if an MA organization or Part D sponsor has identified that it has received an overpayment, the MA organization or Part D sponsor must report and return that overpayment in the form and manner set forth in the section. In paragraphs §§ 422.326(c) and 423.360(c), we proposed that the MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. We noted that the terms “reckless disregard” and “deliberate ignorance” are part of the definitions of “knowing” and “knowingly” in section 1128J of the Act, which provides that the terms “knowing” and “knowingly” have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). We stated that without such a proposal to include “reckless disregard” and “deliberate ignorance”, some MA organizations and Part D sponsors might avoid performing activities to determine whether an overpayment exists. We also provided that if an MA organization or Part D sponsor has received information that an overpayment may exist, the organization must exercise reasonable diligence to determine the accuracy of this information, that is, to determine if there is an identified overpayment.

Finally, in paragraphs §§ 422.326(d) and 423.360(d), we proposed the

requirements for reporting and returning an identified overpayment. An MA organization or Part D sponsor must report and return any identified overpayment it received no later than 60 days after the date on which it identified it received an overpayment. The statute provides an alternative deadline: The date any corresponding cost report is due, if applicable. We proposed that this alternative deadline is not applicable to the Parts C or D programs because, in general, MA organizations and Part D sponsors are paid based on their bids, and not based on their actual incurred costs.

The MA organization or Part D sponsor must notify CMS, using a notification process determined by CMS, of the amount and reason for the overpayment. Also within this 60-day time period, the organization must return identified overpayments to CMS in a manner specified by CMS, including the amount and reason for the overpayment. We proposed to codify at paragraph (3) the statutory requirement that any overpayment retained by an MA organization or Part D sponsor after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

We also emphasized that an MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment. We will recover the returned overpayment through routine processing according to the systems schedule established in the annual operations budget. That is, payments are recovered through the established payment adjustment process, not on the 60-day schedule that applies to each MA organization or Part D sponsor that has identified an overpayment. Rerunning reconciliation each time an entity identifies an overpayment that triggers its 60-day clock is simply not feasible for CMS.

Finally, we proposed that there will be circumstances when we may ask the MA organization or Part D sponsor to provide an auditable estimate of the overpayment amount, reason for overpayment, and make a payment to CMS. This may occur, for example, when an overpayment is identified after the final Part D reopening for a contract year has occurred but prior to the end of the look-back period or if an MA organization or Part D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be

detailed in forthcoming operational guidance.

We received the following comments on general rules for overpayments and our responses follow.

Comment: Several commenters requested that CMS clarify when the 60-day period begins. Specifically, does the period begin once the MA organization or Part D sponsor has identified that there is an overpayment or once the organization has determined the exact amount of the overpayment? A commenter expressed concern that the proposed rule does not appear to acknowledge that the amount of an overpayment must be quantified before it is “identified.” Another commenter requested that CMS address the situation where an MA organization or Part D sponsor becomes aware of an issue or error that may have resulted in one or more overpayments, but could not determine, with reasonable certainty, the amount of the overpayment(s) within a 60-day period.

Response: It is important to understand the distinctions among identifying, reporting, and returning an overpayment in this rulemaking for the purposes of the MA and Part D programs. Once an organization has identified that it has received an overpayment, the 60-day period for reporting and returning the overpayment begins. Because of the nature of the Part C and Part D programs, we did not propose that “identified” includes completion of the act of quantification of an overpayment amount. Rather, we proposed that identification of an overpayment means knowing that the MA organization or Part D sponsor has submitted erroneous data to CMS that caused CMS to overpay the organization.

An organization can identify or assess that there is a problem with data submitted to CMS, and determine that it is incorrect data, prior to actually calculating what the payment impact is of that erroneous data. For the MA and Part D programs, the relevant factor is identifying that the data is incorrect and will result in an overpayment. For example, a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment. Under this provision, the day after the date on which the organization has confirmed an identified overpayment—because the organization knows that the diagnosis is not supported by documentation—is the first day of the 60-day period for reporting and returning the overpayment. As another example, an

MA organization may find that data used to calculate Healthcare Effectiveness Data and Information Set (HEDIS) measures that the organization submitted to CMS are found to be invalid; when the organization has confirmed that it has identified invalid data leading to an overpayment, this is the first day of the 60-day period for reporting and returning the overpayment.

Then, during the 2-month period for reporting and returning the overpayment, the organization must determine what data should be submitted to CMS to correct the identified overpayment, and then must engage in the reporting and returning process that we will describe in forthcoming guidance. This reporting and returning process will involve: (1) Notifying CMS that an overpayment exists, including notification of the reason and estimated amount for that overpayment; and (2) submitting the corrected data to CMS.

In other words, we believe that the MA organization and Part D sponsor will discover through appropriate payment evaluation procedures when a 60-day period would begin under the requirements of this provision, because “day one” of the 60-day period is the day after the date on which organization has determined that it has identified the existence of an overpayment. Once the organization “starts the clock,” it has 60 days to submit to CMS the corrected data that is the basis of the overpayment. It is the act of submitting the corrected data to CMS, along with a reason and an amount of the overpayment (which may be an estimate), that constitutes fulfillment of the requirement to report and return the overpayment.

As we stated in the January 10, 2014 proposed rule preamble (79 FR 1997), “It also is important to note that the MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment”. We will recover the returned overpayment through routine CMS payment processes. That is, payments will continue to be recovered through the established payment adjustment processes and schedules. As a result the payment recovery may not occur within the 60-day window triggered by identifying an overpayment. Rerunning payment reconciliations and conducting payment recovery within CMS payment systems each time an entity identifies an

overpayment that triggers its 60-day clock is simply not feasible for CMS.

We will release operational guidance on the process an organization will use for informing CMS that it has identified a Part C and/or Part D overpayment. This guidance will also address how an organization will be required to provide a reason for and the amount of the overpayment (which may be estimated). We seek to reduce burden and implement an efficient process for administering the reporting and return of overpayments, so we are considering making use of existing procedures for organizations to communicate payment data issues to CMS. For example, MA organizations and Part D sponsors have used the Remedy system for a number of years to inform CMS of payment issues and provide relevant information on that issue.

In the forthcoming operational guidance, we will address the question of how to report the overpayment amount, including estimation of the overpayment amount and updates under certain scenarios.

Comment: A commenter contended that, applying the principles adopted by CMS in the RADV audit context, an overpayment cannot exist for a particular MA contract unless CMS’ payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract. Potential overpayments can be determined, therefore, based only on processes such as CMS’ RADV audits, which are designed to measure whether contract-level payments to an MA organization are accurate when compared to an appropriate FFS Adjuster. The commenter further contended that to the extent an MA organization develops processes intended to measure payment accuracy at the contract-level, the MA organization would be required to report and repay inaccuracies calculated after applying CMS’s FFS Adjuster, and consistent with prior CMS guidance, this is the sole instance in which an “overpayment” can be determined for purposes of proposed § 422.326.

Response: We disagree with the commenter. Our RADV methodology does not change our existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must

be supported by medical record documentation.

However, we are clarifying the link between the § 422.326 overpayment provisions and RADV audits under § 422.311 by adding a condition to the requirement at § 422.326(d), as follows: an MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment. We are adding to paragraph (d) the provision “unless otherwise directed by CMS for the purpose of § 422.311.” Thus, when an MA organization has a contract selected for a RADV audit, during the audit the MA organization will not be allowed to report and return an overpayment under § 422.326 that is due to errors in the data used to risk-adjust payments for the audited contract for the payment year that is the subject of the RADV audit. We will notify the MA organization about the timeline for reporting and returning any overpayments for a contract under a RADV audit. This new provision protects the integrity of the RADV audit process, including the sampling frame of beneficiaries in a selected MA plan, whose diagnoses will be audited.

Comment: A commenter stated that there will be many circumstances and situations where entities receiving an overpayment will not have the ability to repay funds within the 60-day period without undue hardship.

Response: MA organizations and Part D sponsors have an obligation to pay an overpayment owed under Section 1128J(d). As noted previously, our recovery of overpayments will occur through routine payment processing cycles and schedules. In most circumstances, MA organizations and Part D sponsors will be submitting corrected data, which will be re-run by CMS and then CMS will recover the overpayment.

Comment: A commenter noted that 60 days is not a sufficient timeframe, as identifying and quantifying overpayments can be a very involved process. Another commenter stated that most overpayments are identified through analyses and studies, such as internal RADV studies; the commenter requested that the 60-day time period begin at the conclusion of the internal study, so that overpayments can be referred to CMS after all issues have been identified and confirmed.

Response: We provide that the 60-day period is the time period for reporting and returning an identified overpayment, after the organization has conducted the activities needed to identify that it has received an

overpayment. As explained previously, for the purposes of the MA and Part D programs, the MA organization or Part D sponsor must report and return the identified overpayment, which is due to incorrect data it has submitted to CMS, no later than 60 days after the date on which the organization identified it received the overpayment. Subsequently and within the 60-day period the MA organization or Part D sponsor is required to report and return the overpayment. Reporting the overpayment involves notifying CMS of the reason for and the amount of the overpayment. Returning the overpayment is deemed to have occurred through the act of correcting the erroneous data submitted to CMS, for example, by deleting incorrect PDEs or risk adjustment data. Note that if an organization identifies one set of erroneous data that has caused an overpayment, the organization must begin the 60-day clock on that date, and if subsequent overpayments are identified, the organization must begin subsequent 60-day reporting and returning periods.

Comment: A commenter questioned whether CMS will be identifying criteria for organizations to use to determine an overpayment.

Response: We have specified in this final rule the specific types of “funds” that are subject to the provisions under this section through the definition of “funds”. Funds are payments an organization has received that are based on data that the organization submitted to CMS for payment purposes. We will not provide additional criteria or a checklist.

Comment: A commenter stated that logically, an MA organization or Part D sponsor cannot return an overpayment until it has calculated the exact amount that it must return. It might take a considerable amount of time for the MA organization or Part D sponsor to audit its records to determine the amount, whether there is an issue in previous years, and whether extrapolation, or case by case analysis, is appropriate. The commenter was concerned that while a plan sponsor might be able to report to CMS that it has identified an issue within 60 days, a plan sponsor may not have enough information after identification to be able to report the exact amount. Therefore, the commenter requested that CMS clarify that the 60 days begins once the organization has identified the exact amount of the overpayment. The commenter suggested, as an alternative, that if the MA organization or Part D sponsor has notified CMS that it believes there is an overpayment, but it will take more than

60 days to determine the exact amount, CMS consider allowing a “tolling” of the 60 days so that the organization may determine the amount it must return to CMS. Under this “tolling” process, the organization would be required to notify CMS within 60 days of identifying that an overpayment likely exists, but would be provided additional time by CMS to determine the exact amount.

Response: We have not used the phrase “exact amount” in this rule-making. For the MA and Part D programs, we define overpayment in the regulation as “funds” the organization has received to which it is not entitled, and then defines “funds” as any payment based on data submitted by an MA or Part D organization. Because of the nature of the Part C and Part D programs, the key focus in implementing these statutory provisions for the MA and Part D programs is thus correcting the incorrect data that the organization submitted to CMS that resulted in an overpayment. We will then run reconciliation on its routine operational schedule to recover overpayment amounts based on the corrected data. The purpose of the 60 days is to provide the MA or Part D organization with sufficient time to correct the incorrect data submitted to CMS using established data correction processes. MA organizations and Part D sponsors are deemed to have returned the overpayment when they have taken the actions to submit the corrected data that is the source of the identified overpayment. Within the 60 days the MA organization and Part D sponsor must also report the overpayment amount (or estimated amount). If an estimated overpayment amount is reported, it may be higher or lower than the actual overpayment amount recovered because additional payment data submitted into the CMS payment system from other sources may be incorporated into the payment calculations.

Comment: A commenter stated that it is unclear what may occur post-reconciliation if both parties have been overpaid. For example, if CMS owes the Part D sponsor \$10 million due to activity post-reconciliation and a \$2 million overpayment is discovered, the commenter questioned whether we will still require that the \$2 million be refunded within 60 days or whether the sponsor will be allowed to offset amounts owed by CMS. The commenter recommended that if an overpayment would be reduced or fully covered by a reopening, that CMS allow sponsors to request a reopening and offset the reopening amount due from the

overpayment pending completion of the reopening.

Response: For both the Part C and Part D programs, the provisions regarding reporting and returning identified overpayments become effective the day after the date of applicable reconciliation. As we have stated, MA organizations and Part D sponsors are deemed to have returned the overpayment when they have submitted corrected data that is the source of the overpayment. We will recover the overpayment amount through routine processing. For Part D, that means that if an overpayment is discovered after the initial reconciliation but prior to the reopening described at § 423.346, a Part D sponsor may request a reopening and submit the corrected data to fulfill its obligation to return the overpayment. The overpayment will be reconciled through the routine reopening process.

Comment: A commenter stated that the onus on plans for the calculation of an overpayment amount creates a risk that CMS may be overpaid/underpaid in the monies returned.

Response: As explained in proposed rule (79 FR 1997), we will recover overpayments through the correction of erroneous data and established payment adjustment processes. Therefore, we believe that the risk the commenter mentions does not exist because CMS' systems will calculate the exact amount to be recovered.

Comment: A few commenters objected to the fact that the proposed rule does not address situations in which a sponsor has overpaid CMS, and requested that this regulation also set forth rules by which CMS handles an organization's overpayments to CMS.

Response: This final rule is intended to implement section 1128J(d) of the Act, which pertains only to overpayments the government made to contracting MA organizations and Part D sponsors.

Comment: A commenter requested that MA organizations and Part D sponsors be able to submit auditable estimates of an overpayment in lieu of determining which data is in error and submitting corrected data, given the fact that the administrative costs of determining a specific set of data deletes is significant relative to the size of the issue. The commenter recommended that CMS permit plans to proactively suggest the use of such tools to resolve potential overpayments.

Response: The use of auditable estimates is intended only for a limited set of circumstances. This may occur, for example, when the Part D reopening occurs prior to the end of the look-back period or if an MA organization or Part

D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be detailed in forthcoming operational guidance. Therefore, we will not allow, on a routine basis, submission of auditable estimates in lieu of submission of corrected data. By recovering overpayments based on the corrected payment data, we will be more likely to ensure that the most accurate overpayment amounts are returned to the Medicare Trust Fund.

Comment: A commenter expressed concern that this final rule could impose a boundless duty to troll medical records in search of unknown vulnerabilities, and requested that CMS make clear that Part C and Part D plans are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists.

Response: The focus of this final rule is on ensuring that MA and Part D organizations return an overpayment when it is identified. For many years organizations have been obliged to submit accurate, complete, and truthful payment-related data, as described at §§ 422.504(l) and 423.505(k). Further, CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation. Thus, we have always expected that MA organization or Part D sponsor implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment. Therefore, we do not believe that §§ 422.326 and 423.360 represent such a new requirement.

Comment: A commenter requested that CMS confirm that the data submission requirement under this section is based on enrollment data and risk adjustment scores, and thus does not apply to direct overpayments from providers.

Response: Once an overpayment is identified, the MA or Part D organization is responsible for correcting the data that caused the overpayment. This is data that is routinely submitted to CMS for payment purposes, such as, risk adjustment data.

Comment: A commenter requested that CMS clarify if changes in a beneficiary's low income subsidy (LIS) status could result in an overpayment under this provision.

Response: As we stated in the proposed rule, we believe that MA organizations and Part D sponsors cannot be held accountable for the accuracy of the data controlled and

submitted to CMS by other entities. (We emphasize here that the term "other entities" used to discuss these overpayment provisions does not include the following parties referenced in §§ 422.504(i) and 423.505(i): first tier, downstream, and related entities, contractors, or subcontractors to the MA organization or Part D sponsor.) It is the Social Security Administration and the states that notify CMS of individuals whom they have determined to be eligible for the Part D LIS. We in turn provide the subsidy information, including effective date and level of subsidy, to the Part D plan in which the beneficiary enrolls. Although, we will not consider an overpayment to have occurred strictly due to changes in a beneficiary's LIS status, Part D sponsors are required to adjust prescription drug event (PDE) data to accurately reflect the beneficiary's LIS status.

Comment: A commenter supported our proposal for when overpayments have been identified.

Response: We appreciate the commenter's support for our proposal.

Comment: A few commenters requested that CMS provide more clarity or an example of what is meant by "acts in reckless disregard or deliberate ignorance."

Response: We are revising our definition of an identified overpayment to state that an MA organization or Part D sponsor has identified an overpayment when it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization or Part D sponsor has received an overpayment.

As to the circumstances that give rise to a duty to exercise reasonable diligence, we are not able to anticipate all factual scenarios in this rulemaking. MA organizations and Part D sponsors are responsible for ensuring that payment data they submit to CMS are accurate, truthful, and complete (based on best knowledge, information, and belief), and are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments. Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments. However, conducting proactive compliance activities does not mean that the person has satisfied the reasonable diligence standard in all circumstances. In certain circumstances, for example, reasonable diligence might require an investigation conducted in good faith and in a timely manner by

qualified individuals in response to credible information of a potential overpayment.

We note that in discussing the standard term “reasonable diligence” in the preamble, we are interpreting the obligation to “report and return the overpayment” which is contained in section 1128J(d) of the Social Security Act. We are not seeking to interpret the terms “knowing” and “knowingly”, which are defined in the Civil False Claims Act and have been interpreted by a body of False Claims Act case law.

Comment: Some commenters thought that we had an overly broad interpretation of the statute and that there was no statutory basis for CMS to interpret the term “identified” in section 6402 of the Affordable Care Act to include “reckless disregard or deliberate ignorance of the existence of the overpayment.” A commenter stated that the term “knowing” is not actually used in the overpayment standard set forth in section 6402(d) of the Affordable Care Act, so the mere existence of an errant reference to the False Claims Act definition of “knowing” does not give CMS sufficient basis to apply the expansive False Claims Act knowledge standard to the definition of “identified” under section 6402. This commenter noted that in an earlier version of the Affordable Care Act, H.R. 3962, used the False Claims Act knowledge standard in the section on reporting and returning of overpayments. The commenter also stated that the final version of the Affordable Care Act enacted by the Congress used the term “identified,” and not the word “knowledge.” This commenter believed that the Congress’s explicit rejection of the False Claims Act knowledge standard, and use of the term “identified” in the final legislative language weighs against incorporating the False Claims Act knowledge standard into the regulatory provision.

Response: We disagree with the commenters’ arguments. While we acknowledge that the terms “knowing” and “knowingly” are defined but not otherwise used in section 1128J(d), we believe that the Congress intended for section 1128J(d) to apply broadly. If the requirement to report and return overpayments applied only to situations where the MA organization or Part D sponsor has actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated. Thus, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: Several commenters recommended that CMS remove the language relating to “reasonable diligence” from the proposed regulation. These commenters believed that an identified overpayment should be limited to actual knowledge of an overpayment.

Response: For the reasons discussed previously, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: A few commenters were concerned that by adding a reasonable diligence requirement, CMS appears to be suggesting that a much lower level of sponsor behavior—a failure to act reasonably—could trigger potential False Claims Act liability. One commenter stated that the phrase “reasonable diligence” is not a recognized or defined standard and is overly vague as to the obligations of plans to follow through on information received regarding a potential overpayment. The commenters have serious concerns about the implication of such a standard.

Response: We understand the commenters’ concerns. However, we do not believe that it is inappropriate to expect that MA organizations and Part D sponsors act reasonably. We note that it is the statute that establishes liability under the False Claims Act for failure to report and return identified overpayments, pursuant to section 1128J(d)(3).

c. Look-Back Period for Reporting and Returning Overpayments

We proposed at §§ 422.326(e) and 423.360(e) to codify a look-back period for MA organizations and Part D sponsors. MA organizations and Part D sponsors would be required to report and return any overpayment that they identify within the 6 most recent completed payment years. The statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. CMS proposed 6 years as the look-back period because we believe this best balances government’s interest in having overpayments returned with entities’ interest in finality. Six years also is consistent with the CMP provisions, and maintenance of records requirements under the contracts. We also proposed that overpayments resulting from fraud would not be subject to this limitation of a look-back period.

We received the following comments on the look-back period, and our responses follow.

Comment: We received a few comments recommending that we shorten the 6-year look-back period. A commenter noted that permitting greater finality in overpayment reporting and recovery will decrease administrative costs and free up resources to focus on benefits. This commenter also stated that an organization would have to retain a significant amount of documentation to fully support and justify payments, more than what they would retain under CMS’s 10-year record retention requirement. Several commenters recommended that the look-back period be 3 years to align with the RAC look-back period. A commenter noted that the 3-year period would also be consistent with the federal government’s treatment of government contractors that are subject to the Federal Acquisition Regulation. A couple of commenters recommended that we implement a 4-year look-back period to align with the 4-year period that Medicare Administrative Contractors can reopen Medicare fee-for-service payment determinations.

Response: We disagree with the commenters’ recommendations to shorten the look-back period. We note that section 1128J(d) of the Act has no time limit to the obligation to report and return overpayments received by a provider or supplier. However, as we stated in the preamble to our proposed rule and again in this preamble to our final rule, we proposed 6 years as the look-back period because we believe this best balances government’s interest in having overpayments returned with entities’ interest in finality. Six years is consistent with the CMP provisions, and maintenance of records requirements under the contracts. It is also consistent with the False Claims Act in that the statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. We believe that our final rule does not create additional recordkeeping burden or cost. Under § 422.504(d) and § 423.505(d), MA organizations and Part D sponsors are required to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices related to costs, financial statements, cash flow, etc.

Comment: A commenter requested that CMS clarify the parameters of the 6-year look-back provision.

Response: As we stated in the preamble to the proposed rule and this

final rule and again in §§ 422.326(e) and 423.360(e), MA organizations and Part D sponsors are required to report and return any overpayment that they identify within the 6 most recent completed payment years. That would mean, for example, after the initial reconciliation that takes place for Part D payments (that is, the determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) for contract year 2015 (which will take place at the end of 2016), Part D sponsors are obligated to report and return overpayments under § 423.360 for contract years 2010 through 2015.

Comment: A few commenters recommended that CMS impose the same limitation on the look-back period for all overpayments, even those relating to fraud. A commenter noted that under the statutory scheme set forth in section 6402 of the Affordable Care Act, the existence of an overpayment does not depend on, or otherwise reflect, the existence of fraud. Commenters also requested clarification from CMS whether MA organizations and Part D sponsors that become aware of an overpayment prior to the look-back period have an obligation to investigate and determine whether that overpayment resulted from fraud. These commenters were concerned that MA organizations and Part D sponsors would have to investigate potential overpayments indefinitely, no matter how far in the past they may have occurred, because these organizations would have to determine whether there was any fraud in connection with the potential overpayment in order to determine whether a reporting obligation exists.

Response: Upon further review, we agree with the commenters' suggestion that CMS impose the same limitation on the look-back period for all overpayments. Six years is consistent with the more commonly applicable FCA statute of limitations as well as the statute of limitations under section 1128A of the Act. Therefore, we have elected to establish a 6-year look-back period regardless of the nature of the overpayment, and we have amended the regulation text at §§ 422.326(e) and 423.360(e) accordingly. We note that the government may have other avenues for pursuing the return of overpayments due to false and fraudulent claims outside of these provisions.

Finally, we note that an MA organization's and Part D sponsor's

obligation to investigate and identify false and fraudulent claims is outside the scope of this final rule.

After consideration of the public comments received on the overpayment provisions, we are finalizing as proposed the following provisions: §§ 422.1, 422.300, 422.504(l), 423.1, and 423.505(k). We are finalizing the provisions at § 422.326, with the following modifications. First, we add at the end of paragraph (d) the phrase "unless otherwise directed by CMS for the purpose of § 422.311." Second, we strike the following sentence in the proposed paragraph on the six-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period." To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say "Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) above."

Finally, we are finalizing the provisions at § 423.360 with the following modifications. We strike the following sentence in the proposed paragraph on the six-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period." To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say "Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d)."

2. Risk Adjustment Data Requirements (§ 422.310)

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of risk adjustment data. We proposed to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under

§§ 422.308(c)(1) and 422.310(g)(2). Under our proposal, medical record reviews conducted by an MA organization could not be designed *only* to identify diagnoses that would trigger additional payments by CMS to the MA organization; medical record review methodologies would have to be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.

We also proposed to amend § 422.310(g) regarding deadlines for submission of risk adjustment data; our proposal was to restructure and revise subparagraph (g)(2) and add subparagraph (g)(3). Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. Thus, we proposed, at § 422.310(g)(2)(ii) to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment so that the regulation text would be consistent with our procedures.

Finally, we proposed to make two additional changes in paragraph (g). First, we proposed the deletion of the January 31 deadline in paragraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. We noted that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, also discussed in this final rule. Second, we proposed adding paragraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

In response to the January 10, 2014 proposed rule, we received approximately 25 pieces of correspondence from organizations and individuals regarding these proposals. We received the following public comments and our responses follow.

Comment: Many commenters expressed concern about the vagueness and overly broad statement of CMS' proposal to amend § 422.310(e) to require that medical record reviews conducted by MA organizations be designed to determine the accuracy of diagnoses they submitted to CMS. Some commenters thought this implied a requirement to verify every diagnosis

submitted by every provider, while others thought this implied a restriction on the ability of plans to identify what medical records to review. Other commenters believed the proposed amendment limited plans' ability to review medical records for operational purposes other than risk-adjusted payment, such as focusing on only a portion of a medical record for a subset of beneficiaries in order to enhance HEDIS scores, conduct contract compliance reviews, and validate claims processing and billing.

Finally, a few commenters argued that CMS should offset the payment impact of diagnoses an MA organization submitted to CMS that were later found through medical record reviews to not be supported by medical record documentation by adjusting the amount of CMS' overpayment to the MA organization for the level of error in equivalent diagnoses in FFS claims data. Specifically, the commenters argued that CMS should give MA organizations a credit for erroneous diagnoses they submitted from their providers' claims up to the rate identified by CMS as the applicable FFS Adjustor in the RADV program. The commenters also argued that there is no reason to require that both MA and FFS diagnosis data be scrutinized for error rates when determining retroactive payment adjustments, while not engaging in a similar adjustment process when paying plans prospectively.

Response: We thank the commenters for their input. We are not finalizing the proposed amendment to § 410.322(e).

However, we emphasize that our decision to not finalize this regulatory proposal does not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.

Comment: A few commenters supported CMS' proposal to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually, with the proviso that CMS' timing of this annual deadline always allows sufficient opportunity for organizations to make final data submissions. Several other commenters stated their concern about this proposed change in deadline, including a concern

that CMS might announce a deadline earlier than January 31 in some years. These commenters requested that CMS clarify that the annual deadline would never be before January 31, and a few commenters suggested that the regulation state that the deadline is January 31 but may be extended. Finally, a few commenters requested that CMS not change the January 31 date to a floating date, in order to allow operational stability.

Response: We are not finalizing this proposal at this time.

Comment: Many commenters disagreed with CMS' proposal under § 410.322(g)(2) that, after the final risk adjustment data submission deadline, CMS would permit submission of data to correct overpayments but not permit late submission of diagnosis data that would result in additional payment, asserting that this asymmetrical approach does not promote CMS' stated goal of improving payment accuracy. The commenters maintained that an MA organization should be allowed to submit additional diagnoses after the final risk adjustment data submission deadline to correct not only an overpayment to the MA organization, but also an underpayment. A commenter recommended that, after the final deadline, MA organizations should be able to submit paired deletions-additions of diagnoses as long as the result is not an increased payment to the organization but a smaller reduction in payment than would otherwise occur if only the deletion were submitted; for example, an MA organization may want to delete the diagnosis code for diabetes with acute complications and replace it with the code for diabetes without complications so that it loses only some of the payment. Finally, a commenter requested that CMS allow exceptions to the general rule that no new diagnoses may be submitted after the final risk adjustment data submission deadline for special circumstances such as system failures, file formatting issues, and other technical problems.

Response: For a given payment year (which is a calendar year), CMS applies diagnoses from the previous year (the data collection year) to calculate beneficiary risk scores used to risk-adjust payments to MA organizations in the payment year. MA organizations must finalize any corrections and new submissions of diagnosis data for a data collection year by January 31 of the year after the payment year. That is, we allow 13 months after the end of the diagnosis year for MA organizations to identify errors in data they have submitted (that is, deleting diagnoses from CMS' systems) and to identify and

submit additional diagnoses that were not submitted during the diagnosis year. We believe that is a very reasonable period of time to finalize risk adjustment data for a diagnosis year.

These risk adjustment processes have been in place for many years, and we believe it is the responsibility of MA organizations to have internal audit processes in place allowing them to finalize their risk adjustment data for a payment year by the conclusion of this 13-month period. Therefore, we are finalizing, as proposed, the provision codified at § 422.310(g)(2)(ii) that, after the final deadline, an MA organization may submit risk adjustment data to correct overpayments but not to add payments.

Comment: A commenter supported CMS' proposal to limit post-deadline modifications to deletions of incorrect diagnoses but requested that CMS offer one additional opportunity to eliminate unsupported diagnosis codes in advance of a RADV audit.

Response: When we are preparing to initiate a RADV audit cycle, all MA organizations are notified that they should eliminate unsupported diagnoses from CMS' systems by a date specified in the notice. Subsequently, we inform the contracts that have been selected for RADV.

In summary, after consideration of the public comments received, we are not finalizing the proposed amendment to § 410.322(e). Also, we are not finalizing at this time our proposal at § 422.310(g)(2)(ii) to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline. We did not receive any comments on subparagraph (g)(3) and are finalizing it as proposed.

3. RADV Appeals

a. Background

We published final Risk Adjustment Data Validation (RADV) appeals regulations in the April 15 2010 **Federal Register** (75 FR 19677). These rules were proposed and finalized under our authority to establish Medicare Advantage (MA) program standards at section 1856(b)(1) of the Act and are found at § 422.311 et seq. Since finalizing these rules in 2010, we conducted additional RADV audits and determined that some of the appeals

EXHIBIT 37

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE
COMPANY, *et al.*,

Plaintiffs,

v.

ERIC D. HARGAN, in his official capacity as
Acting Secretary of the Department of Health and
Human Services, *et al.*,

Defendants.

No. 1:16-cv-00157-RMC

UNITED’S MOTION FOR SUMMARY JUDGMENT

Plaintiffs UnitedHealthcare Insurance Company, *et al.* (“United”), respectfully move this Court to enter summary judgment in United’s favor pursuant to Federal Rule of Civil Procedure 56, for the reasons stated in the accompanying memorandum. A proposed order is attached.

October 17, 2017

Respectfully submitted,

/s/ Daniel Meron

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**UNITED STATES DISTRICT COURT
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**MEMORANDUM IN SUPPORT OF
UNITED'S MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

This Administrative Procedure Act suit challenges the validity of a 2014 rule—the “Overpayment Rule”—promulgated by the Centers for Medicare and Medicaid Services (“CMS”). The Rule relates to the Medicare Advantage (“MA”) program’s process of risk adjustment, whereby CMS is required to ensure that insurance providers who offer MA plans are paid appropriately based on the level of actuarial risk their patients present relative to an average Medicare beneficiary. If the plan’s patients present lower-than-average risk—*i.e.*, are expected to incur lower healthcare costs—the plan is paid less, and if the plan’s patients present higher-than-average risk, the plan is paid more. A patient’s risk is determined in large part by what diagnosis codes—codes meant to reflect a patient’s health conditions—have been submitted by physicians on claims forms.

In the Overpayment Rule, CMS determined that an MA plan receives an “overpayment” if even a single diagnosis code submitted by a physician to the plan and transmitted by the plan to CMS is insufficiently documented in the underlying medical charts. The Rule requires a plan to delete any such codes it has identified and return any associated payments. CMS imposed this requirement even though similarly unsupported codes are prevalent in the claims data for its own traditional Medicare beneficiaries (sometimes called “fee-for-service,” or “FFS,” beneficiaries), which CMS uses to compute the relative health status of plan beneficiaries and adjust the plan’s payments accordingly. By failing to account for the prevalence of undocumented codes in CMS’s own data, the Rule makes MA plan members appear artificially healthier and less costly to insure than FFS beneficiaries who are in fact identical and pose identical actuarial risk.

Congress designed the MA reimbursement system to prevent just such distortions. In adjusting MA plan payments based on the level of risk their patients pose, CMS is required by statute to ensure “actuarial equivalence”—*i.e.*, ensure that payments to plans are adjusted using

an apples-to-apples comparison of the risk assumed by a plan in insuring a beneficiary and the risk that CMS incurs for an identical FFS beneficiary. 42 U.S.C. § 1395w-23(a)(1)(C)(i). To accomplish that objective, Congress also requires CMS to compute the risk scores—the numerical measure of the risk of providing health insurance—for both groups using the “same methodology.” *Id.* § 1395w-23(b)(4). The Overpayment Rule violates both of those statutory requirements by measuring the health status of MA plan beneficiaries using one measure (diagnoses recorded in medical charts) and the health status of FFS beneficiaries using another (diagnosis codes in claims data), in a manner that produces different assessments of risk for identical patients based simply on the program (MA or FFS) in which they are participating.

These statutory provisions, and the apples-to-apples principle they demand, are fundamental to the entire reimbursement scheme. Congress, the Government Accountability Office, officials in the Department of Health and Human Services, outside actuarial experts consulted by Congress and CMS, and even CMS itself have long recognized that in order for the system to work as designed, beneficiaries whose demographic and health status characteristics are identical must have identical risk scores, even if one is an MA plan beneficiary and the other is a traditional Medicare beneficiary. In departing from CMS’s own past pronouncements on this issue without any reasoned explanation, the Overpayment Rule violates not only the Medicare Act’s requirements but also the APA’s fundamental prohibition on arbitrary and capricious agency action. For example, the Overpayment Rule’s interpretation of an “overpayment” cannot be reconciled with CMS’s earlier recognition, in the context of developing its methodology for calculating overpayments during agency-run audits of MA plans, that whether a plan has been overpaid depends on whether the plan’s data contains a *relatively* higher rate of unsupported codes than CMS’s own data. Having accepted that the prevalence of

unsupported codes in CMS's own data must be considered in *that* context, there is no rational basis for refusing to consider it in *this* one.

In the face of all of this, CMS justified its Rule on one primary ground: that MA plans are required to attest to the “accuracy” of the data they submit, and that codes that are not supported by medical charts are not “accurate.” That simplistic response ignores CMS's own prior recognition that because risk adjustment is based on a comparison between an MA plan's patient population and that of traditional Medicare, “MA organizations are coding ‘accurately’ when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.” 2010 Rate Announcement, AR4335. An interpretation of accuracy that resulted in plans and CMS having different coding patterns, CMS reasoned, would result in inaccurate and invalid comparisons of CMS and MA plan populations, with MA plans having risk scores that are not equivalent to those of FFS beneficiaries. *Id.* By requiring MA plans to attest that they believe their data to be accurate, CMS simply has confirmed that to the best of their knowledge MA plans' data reflects the same coding patterns (*i.e.*, the same proportion of unsupported codes) as CMS's own data. And to the extent that CMS intended the Overpayment Rule to adopt implicitly a different interpretation of the accuracy attestation, that interpretation would render the attestation *itself* unlawful: Because CMS may not directly require MA plans to delete provider-submitted diagnosis codes that lack medical record documentation without making a corresponding adjustment in its own data or accounting for the difference, neither can it indirectly accomplish that result by requiring MA plans to attest that their data contain no such unsupported codes.

Finally, the Overpayment Rule's separate interpretation of “identified” also is unlawful, because it squarely conflicts with the language Congress adopted. Congress directed that an MA

plan has an obligation to return an overpayment within 60 days of when the overpayment “was identified.” 42 U.S.C. § 1320a-7k(d)(2). But CMS construed that statutory provision to set the 60-day clock running from when the overpayment *should have been identified*—eliminating the statutory requirement that the overpayment actually “*was identified*” and substituting in its place a new regulatory negligence standard under which MA plans must exercise reasonable diligence to find overpayments at pain of treble-damages liability under the False Claims Act. *Id.* (emphasis added). There is no textual, logical, or historical support for CMS’s new standard, and it should be set aside as well.

BACKGROUND

A. Medicare Advantage And Risk Adjustment

The Medicare Act establishes a federal health insurance program for disabled and elderly individuals. Parts A and B of the Act create the traditional Medicare program. *See* 42 U.S.C. § 1395c *et seq.*; *id.* § 1395j *et seq.* Beneficiaries enrolled in traditional Medicare receive healthcare from a network of healthcare providers, including doctors, hospitals, and other medical professionals, whom CMS reimburses for each service rendered. For this reason, traditional Medicare beneficiaries are often referred to as fee-for-service (FFS) beneficiaries.

Part C of the Medicare Act creates the Medicare Advantage program.¹ *See id.* § 1395w-21 *et seq.* Medicare Advantage allows individuals eligible for traditional Medicare to receive healthcare benefits through private insurance plans instead. Under the MA program, private insurers like United are responsible for covering at least the same level of benefits that traditional Medicare offers, and for ensuring that providers are paid for their services. In return, CMS

¹ Medicare Advantage was previously known as Medicare+Choice (or M+C). United refers to it as Medicare Advantage (or MA) throughout this brief. United likewise uses CMS to include both the Centers for Medicare & Medicaid Services and its predecessor agency, the Health Care Financing Administration.

makes fixed, per-member-per-month payments to the MA plans—effectively insurance premiums. *See generally id.* § 1395w-23.

Among other benefits, Medicare Advantage allows the government to offload risk to private insurers. The healthcare needs of particular individuals cannot be perfectly predicted. A person in seemingly perfect health on Monday could be struck by a car on Tuesday or contract a debilitating disease on Wednesday, yielding enormous unforeseen medical costs. If these costs befall a traditional FFS Medicare beneficiary, the government is responsible for the full amount of those consequences. If they befall an MA beneficiary, on the other hand, the MA plan must cover that additional cost. The MA program thus lets CMS shift the risk of unpredictable costs to MA plans in exchange for a set monthly payment.

In order for the program to be viable, the monthly payments must, in the aggregate and on average, accurately reflect the relative risk a plan assumes in insuring the expected healthcare costs of its members—otherwise, private insurers would not participate. The statutory scheme is designed to ensure that this occurs by adjusting the per-member-per-month payments based on an assessment of the relative risk CMS itself would bear, in terms of expected healthcare costs, if it remained responsible for providing healthcare to those same beneficiaries. That process begins each spring, when CMS announces a “benchmark” rate for the following payment year for each county in the United States. 42 U.S.C. § 1395w-23(b)(1)(B)(i). This benchmark effectively represents the highest monthly payment that CMS will make to an MA plan the following year for providing healthcare to an *average* Medicare beneficiary. *Id.* § 1395w-23(a)(1)(B). The precise formula CMS uses to determine these benchmark rates is complex, but it is based on CMS’s actual costs for providing healthcare to an average FFS beneficiary in each county. *See* 76 Fed. Reg. 21,432, 21,484 (Apr. 15, 2011) (noting that a county’s benchmark “will be set at

some percentage of the county's average FFS expenditure"). Then, by June, MA plans submit bids that include, in relevant part, the estimated per-member monthly payment the plan would require to provide the same level of benefits offered by traditional Medicare to an identical beneficiary (*i.e.*, the average Medicare beneficiary for whom CMS has published its costs). *See* 42 U.S.C. § 1395w-24(a)(6)(A); *see also* 42 C.F.R. § 422.254(b)(1) (bid is for "beneficiary with a national average risk profile").²

Calculating an MA plan's monthly payments thus begins with a figure calibrated to the revenue needed for an *average* Medicare beneficiary's care. But, of course, not every Medicare beneficiary is an average one. Some are healthier and will wind up having below-average healthcare costs. Some are sicker and will wind up having above-average healthcare costs. If MA plans were simply paid the estimated cost for the average Medicare beneficiary, regardless of a particular member's particular risk, they would have an incentive to enroll only healthy individuals. To ensure that MA plans are willing to cover all individuals and are paid appropriately for doing so, the statute requires CMS to adjust the payment for each MA beneficiary in light of "such risk factors as age, disability status, gender, institutional status, and . . . health status . . . , so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). This process of risk adjustment—increasing or decreasing the per-member payments to MA plans to account for the differences in expected healthcare expenditures—is at the heart of this case.

² To encourage plans to be more efficient than CMS, CMS sets each MA plan's unadjusted per-member monthly payment by comparing the plan's bid with the benchmark rate. For plans whose bids are at or above the benchmark, their payments are initially set at the benchmark rate. 42 U.S.C. § 1395w-23(a)(1)(B)(ii). Any additional needed revenue must be collected from their members in the form of premiums. *Id.* § 1395w-24(b)(2)(A)(ii). For plans whose bids are under the benchmark, payments are initially set at the bid amount, plus a portion of the difference between the benchmark and the bid amount, which the plans must use to provide additional benefits or lower premiums. *Id.* § 1395w-23(a)(1)(B)(i), (a)(1)(E); *id.* § 1395w-24(b)(1)(C). More efficient plans are thus able to increase their membership by offering more attractive plans to potential members.

B. The Proxy For Predicting Future Costs: Diagnosis Codes

Because the goal of risk adjustment is “to pay [MA plans] more accurately based on a model which predicts future expenditures,” creating a successful risk adjustment methodology requires identifying data that serves as a useful proxy for future healthcare costs. 2000 Rate Announcement, AR3834. Demographic factors offer some such proxies—older individuals tend to have higher health costs than younger individuals, for example, so age serves as a rough proxy for healthcare expenditures. As explained in more detail below, however, CMS also uses diagnoses of certain medical conditions as a more accurate (though still imperfect) proxy in its risk adjustment methodology. The basic idea is that an individual diagnosed with, say, severe pneumonia is very likely to have healthcare costs in the coming year that are higher than those of an otherwise similar individual who has received no medical diagnoses—but lower than those of an otherwise similar individual diagnosed with lung cancer.

There are at least two different sets of data that can be used to identify medical diagnoses. The first is a patient’s medical chart—the record of diagnosis and treatment prepared directly by the doctor (or other healthcare provider) who treated the patient. Medical records can of course have errors—a doctor can misdiagnose a patient or misrecord a correct diagnosis on the chart. But the larger problem with using medical charts as the proxy data is the burden and cost of doing so. In a 1999 study of MA risk adjustment commissioned by Congress, the American Academy of Actuaries³ deemed it “nearly impossible” to assemble diagnostic information directly from medical charts, whose form can vary from provider to provider, noting that the “data-gathering cost” of such a model would be “prohibitive.” American Academy of Actuaries,

³ The American Academy of Actuaries is a nonprofit, nonpartisan public policy organization for actuaries of all specialties. Its expertise concerning MA risk adjustment is recognized by CMS, which both selected the Academy to undertake the 1999 study and also requires every MA plan bid to be certified by a member of the Academy. *See* 42 C.F.R. § 422.254(b)(5).

Actuarial Review of the Health Status Risk Adjustor Methodology, AR11367.

The second set of data—the set that CMS actually decided to use in MA risk adjustment—is *diagnosis codes*. See, e.g., 2010 RADV Rule, AR2824 (“The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis.”). Diagnosis codes are numerical codes used by the healthcare industry on claims and other forms to designate a particular medical diagnosis. The source of these codes is the International Classification of Diseases (ICD), a classification system whose latest edition contains over 100,000 codes. Kimberly J. O’Malley et al., *Measuring Diagnoses: ICD Code Accuracy*, 40 Health Servs. Res. 1620, 1621 (2005).

Doctors can, and sometimes do, assign these codes themselves, but often a doctor’s billing staff review a patient’s medical chart and assign the corresponding codes. Inevitably, some diagnosis codes included in claims forms do not match the diagnostic information in the medical chart. See generally *id.* at 1627-32. Even assuming that the doctor has correctly diagnosed the patient and correctly recorded that diagnosis on the patient’s medical chart, coders will sometimes omit the corresponding diagnosis code or, alternatively, include a code that is not fully substantiated by the chart.⁴ The prevalence of these diagnosis coding discrepancies varies by provider type. It is relatively low in hospitals because, under traditional Medicare, reimbursement for inpatient care has long been based in part on the nature of a patient’s diagnoses, not just the services provided, and hospitals therefore have extensive departments devoted to ensuring that their diagnosis codes and charts line up correctly. See *Transitional*

⁴ In addition, doctors sometimes fail to document existing conditions in the medical charts but include the correct (albeit unsupported) diagnosis code in the claim form. The fact that a code is unsupported, therefore, does not necessarily mean that it falsely represents a patient’s actual condition. However, for purposes of this brief, United (like CMS) assumes that medical charts represent a patient’s actual medical conditions more faithfully than do diagnosis codes.

Hosps. Corp. of La., Inc. v. Shalala, 222 F.3d 1019, 1021 (D.C. Cir. 2000); 1999 Report to Congress, AR11234 (“The implementation of prospective payment for hospitals vastly improved the diagnostic information available on hospital bills.”). By contrast, diagnostic coding discrepancies are fairly common in doctors’ offices, which have little (or no) incentive to code diagnoses completely and accurately because their payments generally are based on services provided, not diagnoses. See, e.g., Gregory C. Pope et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, AR11867 (noting that in doctors’ offices “diagnoses have not [historically] affected payment, and recording of diagnoses is less rigorously practiced than in hospitals”); Richard Kronick & W. Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Res. Rev., Vol. 4, No. 2, E1, E3 (2014), https://www.cms.gov/mmrr/Downloads/MMRR2014_004_02_a06.pdf.

C. CMS’s Risk Adjustment Methodology

Since 2004, CMS has used diagnosis codes to determine the appropriate risk adjustment for MA beneficiaries’ payments through application of the CMS Hierarchical Condition Categories (CMS-HCC) model. The CMS-HCC model is a prospective risk adjustment model designed to predict the relative incremental risk (in the form of additional expected healthcare costs) that a beneficiary with a particular condition would impose on an MA plan. It does so by calculating how much more costly an identical beneficiary would be for CMS itself to insure compared to an average CMS beneficiary.

The model identifies a range of diagnosis codes (corresponding to various health conditions) that CMS has found to be good predictors of future healthcare costs. See 2014 Advance Notice, AR4814-20 (listing the conditions). To assess the predicted added healthcare costs associated with these diagnosis codes, CMS analyzes the claims data of traditional FFS beneficiaries. CMS identifies FFS beneficiaries with the diagnosis codes in a base year,

determines those beneficiaries' actual healthcare costs the following year, and then uses regression analysis to estimate how much the various diagnoses, as well as demographic factors (such as age and sex), contribute to costs.⁵ 2004 Advance Notice, AR3895-96 & n.1. In short, it correlates diagnosis codes to incremental costs. *See generally* Pope et al., *Risk Adjustment*, AR11857-79; Evaluation of the CMS-HCC Risk Adjustment Model, AR11892-902. These estimates are converted into a numerical risk coefficient. The model is designed so that a beneficiary with average healthcare costs has a risk score of 1.0. A condition that would be expected to increase that average beneficiary's costs by, say, 20% is therefore assigned a risk coefficient of 0.20. 2004 Advance Notice, AR3896.

Having established the value of the various risk coefficients based on the FFS data, CMS then applies those same coefficients in the same way to MA beneficiaries. 2004 Advance Notice, AR3903. An MA plan submits to CMS "risk adjustment data" that includes the diagnosis codes its beneficiaries received in a given year. (CMS already has the beneficiaries' demographic information.) CMS assigns the relevant risk coefficients for each diagnosis and demographic characteristic and adds them up to arrive at total risk score for each beneficiary. Those risk scores are then used to adjust the plan's payments. An MA beneficiary with a risk score of 2.00, for instance, would trigger an MA payment that is twice the standard payment.⁶

⁵ CMS initially calibrated the model using a sample of 5% of FFS claims data from 1999 (diagnoses) and 2000 (costs). 2004 Advance Notice, AR3896. It has since recalibrated using more recent and complete FFS data. *See, e.g.*, 2014 Advance Notice, AR4768.

⁶ An example illustrates how risk adjustment under the CMS-HCC model works. *See* Evaluation of the CMS-HCC Risk Adjustment Model, AR11900-02 (using 2011 risk coefficient values). Imagine a female MA beneficiary who is 76 years old and in the prior year received diagnosis codes reflecting acute myocardial infarction (AMI), chronic renal failure, and an ankle sprain. The baseline risk coefficient for a female, age 75 to 79, is 0.457. AMI carries a risk coefficient of 0.359. Chronic renal failure adds another 0.368. The ankle sprain (a transient injury that is not predictive of future expenditures) is not one of the conditions in the model and therefore does not impact the score. Adding up the risk coefficients leads to a total risk score of 1.184. For this

D. The Impact of Diagnosis Coding Discrepancies

As noted earlier, diagnosis codes submitted with claims—including FFS claims—do not always perfectly correspond with patients’ medical charts or actual conditions. When CMS calibrates the CMS-HCC risk adjustment model, it does not attempt to correct for those discrepancies by auditing the FFS claims data to confirm that the diagnosis codes are properly supported by medical records. As a result, the authors of the CMS-HCC model acknowledged that there would be coding discrepancies in the data used to calibrate the model—*i.e.*, that the model would treat some FFS beneficiaries as having conditions (because they had the associated code) even though there was no support for those conditions in their medical charts. *See Pope et al., Risk Adjustment*, AR11867; 2010 RADV Rule, AR2826.

By design and effect, the existence of beneficiaries whose provider assigned them a particular diagnosis code but who do not actually have the associated condition is built into the model. Beneficiaries who do not actually have a condition obviously are unlikely to incur healthcare costs associated with the condition. The existence of these “zero cost” beneficiaries therefore affects the overall average, incremental risk coefficient that the model calculates for a particular condition. Consider a simplified hypothetical scenario: Suppose that when it calibrates the model, CMS identifies four FFS beneficiaries with the diagnosis code for diabetes and determines that the aggregate incremental healthcare costs for the four beneficiaries the following year were \$12,000. CMS therefore concludes that the average per-patient cost associated with diabetes is \$3,000, and it sets the diabetes risk coefficient accordingly. But suppose further that one of these diagnosis codes was a false positive; the beneficiary did not in fact have diabetes. That means that the \$12,000 was in reality attributable to just three

beneficiary, then, the MA plan would receive a payment 1.184 times the payment it would receive for someone with the characteristics of an average Medicare beneficiary (a 1.0).

beneficiaries, such that the true per-patient cost of diabetes was actually \$4,000 ($\$12,000 \div 3$ beneficiaries). By averaging the cost over the four beneficiaries with the diagnosis code, rather than just the three beneficiaries who actually have diabetes, CMS's model produces a lower average incremental cost (and associated risk coefficient) than it would have done if the diagnosis codes in the FFS data had been perfectly accurate.

The impact of no-cost beneficiaries on the risk coefficients will not necessarily make risk adjustment payments to MA plans inaccurate, however. Suppose for instance that an MA plan also has four beneficiaries with the diagnosis code for diabetes. Applying the risk coefficient derived from the FFS data, CMS would pay the plan an incremental total of \$12,000 ($\$3,000 \times 4$) for the diabetes diagnoses. If all four beneficiaries actually have diabetes, this payment will undercompensate the plan for its presumptive incremental costs, which would be \$16,000 ($\$4,000$ per beneficiary who actually has diabetes). If only two beneficiaries actually have diabetes, the payment will *overcompensate* the plan for its presumptive incremental costs (\$8,000). But if the proportion of beneficiaries among the MA plan's population who do not have the condition is the same as in the FFS population, such that three of the beneficiaries actually have diabetes, then the total payment of \$12,000 equals the plan's expected costs ($\$4,000 \times 3$). Thus, in assessing whether the MA risk adjustment system is paying plans appropriately, the *relative* accuracy of diagnostic coding in FFS and MA claims must be taken into account.

E. The Coding Intensity Adjustment and the RADV FFS Adjuster

Both Congress and CMS have acknowledged the importance of considering the *relative* accuracy of MA and FFS diagnostic coding when assessing whether MA plans have been paid appropriately. Two different aspects of the MA risk adjustment process make this clear: (1) Congress's enactment and CMS's implementation of a statutory "Coding Intensity Adjustment,"

and (2) CMS's recognition of the need for an "FFS adjuster" as part of its audit procedures.

I. The Coding Intensity Adjustment

Because the MA risk adjustment system is based on diagnosis codes, MA plans have an incentive "to find and report as many diagnoses as can be supported by the medical record"—to code with high "intensity." Kronick & Welch, *supra*, at E3-E4. For example, MA plans sometimes arrange for additional, after-the-fact reviews of their patients' medical charts to look for diagnoses documented in the charts that the provider failed to code. By contrast, as noted earlier, reimbursement under traditional FFS Medicare generally is not tied to diagnoses, so the incentive for comprehensive coding is weaker. *See id.* at E3. These divergent incentives can lead to different coding patterns that can skew risk adjustment payments.

To see why, suppose that an MA plan's beneficiaries are identical to the sample of FFS beneficiaries used to calibrate the risk adjustment model. Because the two sets of beneficiaries have the same medical conditions, they have the same expected future costs and should have the same risk scores. If, however, some documented diagnoses were not coded for the FFS beneficiaries but were coded for the MA beneficiaries, the MA beneficiaries will wind up with higher risk scores. That is, even though the MA beneficiaries' diagnosis codes are perfectly accurate in the absolute sense (*i.e.*, are supported by the medical charts), because they are more complete than those of their FFS counterparts, the MA plan will artificially appear to have taken on more risk, and will therefore be overpaid.

For this reason, Medicare experts have long recognized that "for the purposes of creating an equitable MA payment system, the relevant question is whether MA risk scores are systematically *different* than those risk scores would be in FFS, and not which set of scores is more *accurate*" in an absolute sense. *Id.* at E4 (emphasis added). And not long after the adoption of the CMS-HCC model, Congress perceived that the incentives for higher coding

intensity among MA plans had heightened the risk of such differentials. Accordingly, in the Deficit Reduction Act of 2005, Congress instructed CMS to analyze any “differences in coding patterns between Medicare Advantage plans and providers under part A and B [*i.e.*, traditional FFS Medicare].” Pub. L. No. 109-171, § 5301(b)(2), 120 Stat. 4, 51 (2006). Congress further said that, “to ensure payment accuracy,” CMS should adjust MA beneficiaries’ risk scores in light of those different coding patterns. *Id.*

After its analysis confirmed higher coding intensity among MA plans, CMS began imposing such a downward adjustment to MA plans’ risk scores in 2010, calculated to replicate the risk score-adjusted payments that would have resulted had plans not engaged in the different coding activities. 2010 Rate Announcement, AR4334. In doing so, CMS rejected commenters’ argument that a downward adjustment would be appropriate only if MA plans were submitting *unsupported* codes. CMS recognized that MA plans might simply “be coding more completely than FFS,” 2009 Advance Notice, AR4231, and was careful to say that it had not concluded that MA plans had engaged in any “improper coding,” *id.*; 2010 Rate Announcement, AR4335. But even if none of a plan’s codes were “incorrect,” the mere fact that the plan’s coding “differs from FFS” coding was sufficient to require the adjustment. 2010 Rate Announcement, AR4341. The agency observed that, because the MA risk adjustment model is calibrated on FFS data,

MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. *This means that MA organizations are coding “accurately” when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.* In this sense, “differences” in coding patterns, regardless of the source, would make the MA plan coding “inaccurate” for purposes of implementing risk adjustment.

Id., AR4335 (emphasis added). CMS noted that several members of Congress had expressly recognized this relative notion of accuracy. Senator Grassley, for instance, had explained that the intensity adjustment provision was intended to address “coding that is inaccurate or

incomplete for the purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings, *even if such coding is accurate or complete for other purposes.*” *Id.*, AR4336 (emphasis added) (quoting 152 Cong. Rec. 511 (2006)).

As is now required by statute, CMS has applied the Coding Intensity Adjustment in every payment year since 2010. 42 U.S.C. § 1395w-23(a)(1)(C)(ii). CMS has never found that higher coding intensity in MA plans reflects the inclusion of codes that are inaccurate in an absolute sense (*i.e.*, unsupported by medical records); to the contrary, it has said the data “fail[] to show a systematic correlation between coding pattern differences and errors in the reporting of documented coding.” 2010 Rate Announcement, AR4337. But CMS continues to recognize that “to ensure payment accuracy,” it must account for “*differential* coding patterns in MA and FFS.” 2014 Rate Announcement, AR4865 (emphasis added).

2. *The RADV FFS Adjuster*

CMS also has acknowledged that payment accuracy requires accounting for FFS coding errors in the context of determining whether an MA plan has been overpaid through “risk adjustment data validation” (RADV) audits. CMS began conducting these audits of selected MA plans shortly after adopting the CMS-HCC model. When a plan is chosen for a RADV audit, CMS selects a sample of the plan’s enrollees for the audited year, requires the plan to submit those enrollees’ medical records, and then assesses whether those records adequately support the enrollees’ diagnosis codes. Final RADV Methodology, AR5312-13. After an initial grace period, CMS began requiring MA plans to make repayments when a RADV audit revealed that a beneficiary’s diagnosis was not supported by the medical records.

Because CMS originally sought repayment with respect only to the particular beneficiaries in the sample found to have unsubstantiated codes, the financial impact on MA plans was “very small,” 2009 Proposed RADV Rule, AR2409, and went unchallenged. In 2008,

however, CMS announced that it would eventually start requiring “contract-level payment adjustments” based on its RADV audit findings: that is, it would extrapolate the results from the sample of audited beneficiaries to all of a plan’s enrollees and calculate an estimated payment adjustment rate for the plan’s entire contract with CMS for the audited payment year. *Id.*

That announcement prompted a multi-year conversation with MA plans about what would need to be taken into account in performing that calculation. By 2010, CMS remained committed to requiring contract-level repayment based on extrapolated rates of unsupported codes. *See* 2010 RADV Rule, AR2819. At the same time, however, it acknowledged a possible problem with defining “overpayment[s]” to include payments resulting from *all* unsupported diagnosis codes submitted by MA plans—namely, that the FFS data used to calibrate the risk adjustment model indisputably contained coding discrepancies of its own. *See id.*, AR2826. As commenters pointed out, CMS needed to assess the discrepancy rate in the FFS data and compare it to the discrepancy rate of a given MA plan before it could determine whether the plan had been overpaid. *See, e.g.*, AR2627 (Aetna); AR2744-45 (AHIP). CMS acknowledged that there was “potential merit” in this concern and said it was “currently studying this issue.” 2010 RADV Rule, AR2826.

The issue received intensified scrutiny after CMS proposed a RADV sampling and adjustment-calculation methodology that did not account for coding discrepancies in the FFS data. Proposed RADV Methodology, AR5020-22. Numerous commenters pointed out that this omission was a serious flaw. *See, e.g.*, AR5053-57 (Aetna); AR5105-08 (Humana); AR5205-07 (United). Among them was the American Academy of Actuaries, which stated that it was inappropriate to develop risk coefficients “with FFS data that . . . were not validated or audited for accuracy” but then “apply those factors only to MA data that are validated.” AR5235-36.

Multiple commenters also noted that this approach would violate the statutory requirement that risk adjustment ensure “actuarial equivalence.” *See, e.g.*, AR5053-54 (Aetna); AR5114 (Humana); *see also* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

CMS acknowledged that the commenters were right. When it published a revised sampling and error-calculation methodology in February 2012, CMS said that in determining any contract-level payment adjustments, it would apply a “FFS adjuster.” Final RADV Methodology, AR5314. “The FFS adjuster,” CMS explained, would “account[] for the fact that the documentation standard used in RADV audits to determine [an MA] contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).” *Id.*, AR5314-15. CMS had not yet determined the “actual amount of the adjuster,” but said it would “be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.” *Id.*, AR5315.

F. The 2014 Overpayment Rule

It is against this backdrop that the Overpayment Rule at issue here was adopted.

1. The Overpayment Statute

As part of the Patient Protection and Affordable Care Act, Congress enacted Section 1128J of the Social Security Act. Pub. L. No. 111-148, § 1128J, 124 Stat. 119, 753-56 (2010) (codified at 42 U.S.C. § 1320a-7k). Subsection 1128J(d), entitled “Reporting and returning of overpayments,” requires any person, including an MA plan, who has “received an overpayment” in the context of Medicare or Medicaid to report and return it to the relevant entity and to notify that entity of the reason for the overpayment. 42 U.S.C. § 1320a-7k(d)(1). As relevant here, the overpayment must be reported and returned within “60 days after the date on which the overpayment was identified.” *Id.* § 1320a-7k(d)(2)(A).

The statute defines “overpayment” as “any funds that a person receives or retains under

[Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled.” *Id.* § 1320a-7k(d)(4)(B). The statute does not define the term “identified,” which triggers the start of the 60-day clock. It does define what “[t]he terms ‘knowing’ and ‘knowingly’” mean “[i]n this subsection”—although those terms are not in fact used anywhere in the subsection. *See id.* § 1320a-7k(d)(4)(A). The statute gives these absent terms the same meaning they have in 31 U.S.C. § 3729(b), a provision of the False Claims Act (FCA).

The statute makes the requirement to return overpayments enforceable through the FCA. The continued retention of an overpayment beyond the 60-day deadline after the overpayment is “identified” constitutes an “obligation” under the FCA. 42 U.S.C. § 1320a-7k(d)(3). The FCA, in turn, authorizes the United States, or a private citizen acting on its behalf, to bring suit against “any person who . . . knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G). The FCA is a fraud statute that permits the recovery of treble damages and imposes a civil penalty between roughly \$11,000 and \$22,000 per obligation avoided or decreased. *See id.* § 3729(a); 82 Fed. Reg. 9,131, 9,133 (Feb. 3, 2017).

2. *The Overpayment Rule*

In January 2014, CMS proposed regulations to implement these new statutory provisions for the Medicare Advantage program. Proposed Overpayment Rule, AR79-82. One proposed regulation, 42 C.F.R. § 422.326, was intended to “clarify the statutory definition of overpayment.” *Id.*, AR80. Among other things, CMS proposed to define “funds” as any payment that an MA plan has received “based on data that these organizations submitted to CMS for payment purposes for which they have responsibility for the accuracy, completeness, and truthfulness of such data under existing [regulations],” including a plan’s risk adjustment data. *Id.* And it proposed that an MA plan has “identified” an overpayment when “it has actual

knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.” *Id.*, AR81.

In response to the proposed regulation, commenters asked CMS to clarify further what it would consider an “overpayment” based on inaccurate risk adjustment data. One commenter, for example, asked the agency to clarify that “an overpayment cannot exist for an MA organization’s particular contract unless CMS’s payments to the [plan] as a whole are inaccurate in light of an appropriate Fee-for-Service Adjuster that is applied to the entire contract.” AR907 (Humana). Similarly, United observed that, “[u]nder the Proposed Rule, [MA plans] will be undercompensated for the relative risk of their membership if they delete diagnosis codes from claims that are unsupported in a medical record and CMS does not simultaneously account for the equivalent diagnoses in FFS data.” AR1041. It noted that such a skewed payment system would violate “the statutory mandate that [MA plans] be paid appropriately for the health status of their members relative to costs incurred in [FFS Medicare] for similar beneficiaries.” *Id.*

Commenters also argued that CMS’s proposed definition of “identified” was too broad, pointing out that the term “knowing,” from which CMS had drawn its willful blindness and reckless disregard standard, was “not actually used in the overpayment standard set forth in [the statute].” AR613 (Blue Cross Blue Shield). Instead, United and others suggested that “an identified overpayment should be limited to actual knowledge of an overpayment.” AR1040.

CMS published the final Overpayment Rule on May 23, 2014. Overpayment Rule, AR1236. Despite the commenters’ requests, it did not clarify that determining whether an MA plan has received an overpayment requires accounting for the rate of coding discrepancies in the FFS data. To the contrary, in the preamble to the Final Rule, CMS expressly “disagree[d]” with this interpretation of the regulatory scheme. *Id.*, AR1313. Instead, CMS announced that *any*

inadequately documented diagnosis code would result in an overpayment to a Medicare Advantage plan: “[A] risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation *would result* in an overpayment.” *Id.* (emphasis added).

As to the commenters’ claim that the Overpayment Rule was inconsistent with CMS’s recognition of the need for the RADV FFS adjuster, CMS offered no explanation of why the two contexts (RADV and the Overpayment Rule) warranted different treatment. Instead, it simply pointed to a contractual requirement that MA plans “certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS.” *Id.*; see 42 C.F.R. § 422.504(l). It also asserted that the agency had a “long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.” Overpayment Rule, AR1314.

With respect to the meaning of “identified,” CMS not only refused to narrow its broad proposed definition of “identified,” it made it *broader*. CMS stated it was “revising [its] definition of an identified overpayment to state that an MA organization . . . has identified an overpayment when it has determined, *or should have determined through the exercise of reasonable diligence*, that the MA organization . . . has received an overpayment.” *Id.*, AR1315 (emphasis added). CMS refused to specify what reasonable diligence would require in “all factual scenarios,” but indicated that “at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.” *Id.*

ARGUMENT

This suit challenges two distinct aspects of the Overpayment Rule.

First, it challenges the interpretation of “overpayment” that CMS adopted in the Final Rule. This Court has already held that “[u]nder the CMS Rule, any inadequately documented diagnostic code not supported by underlying medical documentation will result in an overpayment.” Mem. Op. 6, ECF No. 25 (“MTD Order”) (citing Overpayment Rule, AR1313). As construed by CMS, the Rule requires an MA plan to delete any provider-submitted diagnosis code (and forgo the payments such a code would generate) that the plan knows lacks support in the patient’s medical charts—even though CMS uses unsupported codes in evaluating the actuarial risk posed by traditional Medicare patients and in calibrating the payment model for MA plans. That application of different methodologies for calculating risk—one to MA plan participants, and another to traditional Medicare beneficiaries—is unlawful, because it results in identical patients being assigned different risk scores based on which program they participate in. CMS’s contrary interpretation should be set aside as inconsistent with the statutory mandates that it use a common methodology for risk calculation across both programs, and that it ensure actuarial equivalence between traditional Medicare and the MA program. Moreover, even if CMS’s interpretation could be reconciled with the Medicare Act, it is also inconsistent with CMS’s own past acknowledgments that risk adjustment must be based on apples-to-apples comparisons between the plan’s patients and traditional Medicare patients that ensure identical patients are given identical risk scores. At the very least, therefore, the Overpayment Rule should be vacated as arbitrary and capricious agency action.

Second, and independently, this suit also challenges the Overpayment Rule’s interpretation of the statutory phrase “was identified.” CMS effectively has interpreted that provision to mean that an overpayment must be reported and returned within 60 days after the date on which the overpayment *should have been* identified with reasonable diligence—

replacing the actual identification requirement that Congress adopted with a negligence-based standard Congress never even contemplated. Under that interpretation, MA plans have to exercise reasonable diligence to identify and delete unsupported codes submitted by medical providers, even though CMS makes no comparable effort in connection with codes it receives in the traditional Medicare program. That requirement is directly contrary to the statutory text, and also exacerbates the distortions created by CMS's definition of "overpayment": If plans are required actively to seek out unsupported codes for deletion, while CMS takes no comparable measures, the divergence becomes even greater between the risk calculation methodologies CMS is applying to the MA program and the traditional Medicare program.⁷

I. THE OVERPAYMENT RULE IS UNLAWFUL BECAUSE IT ESTABLISHES INCONSISTENT VALIDATION CRITERIA FOR CMS AND MA PLAN DATA

A. The Overpayment Rule's Embrace Of A Validation Standard For MA Plan Data That Is Different From The Standard CMS Applies To Its Own Data Violates The Statutory Requirements For Risk Adjustment

1. In Order To Ensure Actuarial Equivalence Between MA And Traditional Medicare, Congress Required CMS To Measure Risk Profiles Of MA And Traditional Medicare Beneficiaries Using The Same Criteria

Congress established the framework for determining payments to Medicare Advantage plans in Section 1853 of the Social Security Act, codified at 42 U.S.C. § 1395w-23. That

⁷ United plainly has standing to challenge both aspects of the Overpayment Rule. As this Court recognized in denying the government's motion to dismiss, "there is ordinarily little question that a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated." MTD Order 9 (citation omitted). Here, "the CMS Rule's affirmative obligations establishes an injury-in-fact upon" United. *Id.* at 11. Specifically, as the accompanying affidavit shows, (1) in the years since promulgation of the Overpayment Rule, United has deleted millions of dollars' worth of diagnosis codes it had identified as unsupported by medical charts, depriving United of revenue to which it is otherwise entitled under a proper understanding of the law, and (2) the Rule imposes new, proactive obligations to search for unsupported codes that cost millions of dollars to undertake. *See* Declaration of Karen Erickson, ¶¶ 3-5. There thus is no reason to depart from this Court's determination at the pleading stage that "Plaintiffs have established Article III standing." MTD Order 13.

framework is organized around a comparison between, on the one hand, the predicted average annual expenditure that traditional Medicare would incur for a patient with a given actuarial risk profile, and, on the other, the amount that an MA plan predicts it will expend in caring for a patient with that same actuarial risk profile.

The comparison begins with the bid amount the plan submits, and the Secretary reviews and approves, each year. *See* 42 U.S.C. § 1395w-23(a)(1)(B). To facilitate the preparation of those bids, Congress requires CMS to publish not only its benchmark rates for the coming year, *see supra* at 5-6, but also (1) its average per capita cost (healthcare expenditures) under the traditional Medicare program in a given county, (2) its computation of the average risk score of the traditional Medicare program's patient population in that county, and (3) the methodology it used to calculate that risk score. *See id.* § 1395w-23(b)(4). Using that information as well as their own cost estimates, MA plans can assess whether they will need more, less, or the same amount of money as the traditional Medicare program to care for an average beneficiary—a beneficiary with a risk score of 1.0.⁸ For example, if an MA plan believes that it will cost the same amount to insure a patient on its plan as it would to insure the same patient through traditional Medicare, and Medicare calculates its cost of insuring an average beneficiary (with a risk score of 1.0) in that county as \$10,000, then the MA plan would submit a bid of \$10,000.⁹

⁸ As noted, the Chief Actuary is required to calculate and publish the per capita health costs for traditional Medicare in a given county, as well as the “average risk factor” in that county. 42 U.S.C. § 1395w-23(b)(4)(B), (D). Dividing the former figure by the latter figure produces the per capita cost for a patient with a 1.0 risk score in that county.

⁹ If the MA plan believes it can provide identical coverage for a patient with that same risk score more cheaply than traditional Medicare does, it would submit a bid for a lower figure, and would then be able to use a portion of the difference to provide supplemental services that make its plan more attractive to potential members. *See supra* at 6 n.2. And if the plan believes that it will cost it *more* than traditional Medicare to provide those same services, its payment from CMS is nevertheless capped at a percentage of the traditional Medicare program's expected costs, and

Even at this very first step, one can see that it is essential that MA plans and CMS use the same standards for evaluating actuarial risk: Because the bid amount reflects an MA plan's projection of its own cost for an average Medicare beneficiary, and its bid is capped at a percentage of traditional Medicare's costs for a beneficiary who presents an identical degree of risk, *see supra* at 5-6 & n.2, the MA plan and CMS must calculate risk in the same way. To illustrate this point, imagine that there are two identical patients, one using traditional Medicare (Tom) and one enrolled in a Medicare Advantage plan (Andy). Tom and Andy have the same demographics and the same health conditions, and each has three (identical) diagnosis codes, only two of which are supported by (identical) medical charts. CMS uses the diagnosis codes and demographic information to calculate a risk score of 1.0 for Tom, and establishes—based on historical claims data from the traditional Medicare program for people with similar risk scores—a benchmark rate of \$10,000 for his care in the coming year. Accordingly, if the MA plan has submitted a bid for 100 percent of the benchmark rate, then it should receive \$10,000 for its coverage of Andy, because it is taking on exactly the same amount of actuarial risk. *See* 42 U.S.C. § 1395w-23(a)(1)(B)(i).

If Andy's risk score is calculated using a different methodology than Tom's, however, the MA plan's actual payment could be different. For example, if the MA plan (unlike traditional Medicare) is required to delete any diagnosis codes that lack medical chart support, then Andy's risk score—and the resulting payment—would be artificially lower. With just two diagnosis codes instead of three, his risk score might be calculated as a 0.9, meaning that the MA plan would be paid just \$9,000 even though CMS had accepted its bid of \$10,000 for a patient presenting an identical degree of risk. Using different methodologies to assess the risk presented

the plan must generate its extra revenue by charging additional premiums. *See id.* The analysis that follows in the text applies equally in those scenarios, too.

by MA and traditional Medicare patients, therefore, results in different risk scores for identical patients, and discrepancies between MA plan bids and MA plan payments even for patients who *should* qualify as one of the average beneficiaries whom the bid amount tracks perfectly.

For the system that Congress devised to work properly, moreover, it is not enough just to ensure that identical patients are scored identically. It is also essential to ensure that *different* patients are scored *differently*, in a way that accurately captures the actuarial risk they pose to the entity responsible for their care (whether traditional Medicare or an MA plan). As CMS itself put it nearly two decades ago, “[t]he goal is to pay Medicare [Advantage] organizations based on better estimates of their enrollees’ health care utilization *relative to the fee-for-service (FFS) population.*” 1999 Report to Congress, AR11228 (emphasis added). “If payments are not adjusted for the health status of managed care enrollees relative to those remaining in FFS, plans can be over or underpaid.” *Id.*, AR11215.

For that reason, Congress directed CMS to employ a second step in its payment process, during which it takes the payment amount indicated in an MA plan’s bid—based on patients with a 1.0 risk score—and adjusts it to reflect the higher or lower actuarial risk presented by the plan’s actual patient population. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). And here again, as with the original bid amounts, an accurate comparison requires measuring risk in the same way on both sides of the ledger. To return to the diabetes example offered above, *see supra* at 12, imagine that an MA plan had four patients who were identical in every way to the four traditional Medicare patients used to calibrate CMS’s risk adjustment model with respect to diabetes payments—same true health condition, same medical charts, same diagnosis codes. Because the populations are identical, the true actuarial risk they present is identical as well. But if CMS and the MA plan used different standards in calculating that actuarial risk, it would again create

artificial differences. CMS, relying on diagnosis codes, would assign the incremental actuarial risk associated with diabetes to each of the four beneficiaries (all of whom have the diagnosis code). Reflecting CMS's average incremental per capita cost of \$3,000 for those beneficiaries, and assuming that insuring a beneficiary with a risk score of 1.0 is anticipated to cost \$10,000, that would mean that each of those four beneficiaries would have his or her risk score increased by 0.3. Meanwhile, if the MA plan was required to instead rely on medical charts, it would assign the increased actuarial risk associated with diabetes to only three of its beneficiaries (excluding the one who had a diagnosis code that was not supported in the charts). The risk scores for those three beneficiaries would be increased by 0.3, while the risk score for the fourth beneficiary would not increase at all. The result would be that the MA plan population would *appear* to present lower actuarial risk (an average of 0.225) than the traditional Medicare population (an average of 0.3) even though the populations were in fact identical.

The principle that accurate comparisons between beneficiaries or plan populations depend on the use of consistent criteria is so fundamental to the entire reimbursement scheme that Congress enshrined it directly in the statute itself. It did so in two ways. *First*, Congress required that when CMS (through its Chief Actuary) calculates and publishes each year the average risk score of CMS beneficiaries in a given county (used to determine the benchmark rate in that county), it must “us[e] the same methodology as is expected to be applied in making payments” to MA plans. 42 U.S.C. § 1395w-23(b)(4). *Second*, Congress mandated that when CMS risk adjusts an MA plan's payment amount, it must do so in a manner that will “ensure actuarial equivalence,” *i.e.*, ensure that adjustments in payment amount reflect an apples-to-apples comparison of the risk assumed by a plan in insuring a beneficiary and the relative risk (in the form of expected costs) that CMS would incur for an identical beneficiary. 42 U.S.C.

§ 1395w-23(a)(1)(C)(i).

These statutory provisions reflect Congress’s longstanding recognition that in order for the statutory reimbursement scheme to work, identical patients must be assigned identical risk scores regardless of whether they are participating in the MA or traditional Medicare program. During floor proceedings about the changes to Medicare Advantage implemented in the Deficit Reduction Act of 2005, for example, all three of the relevant committee chairs—Senator Grassley, Representative Barton, and Representative Thomas—emphasized that the statutory risk adjustment methodology requires “establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings.” 152 Cong. Rec. 511 (2006) (statement of Sen. Grassley); *see also id.* at 558 (statement of Rep. Barton) (same); *id.* at 567 (statement of Rep. Thomas) (same). As Representative Thomas explained, doing so is necessary to “ensure that traditional fee-for-service and Medicare Advantage plans are being compared and paid accurately.” *Id.* at 567.

CMS itself repeatedly has embraced that understanding of the statutory risk adjustment system’s “purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings.” 2010 Rate Announcement, AR4336; *see also* 2009 Rate Announcement, AR4275 (citing the three floor statements described above). It has explained that “[g]iven the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the same way Medicare Part A and B does.” 2009 Rate Announcement, AR4275. Because CMS uses “a model based on FFS costs and diagnoses patterns,” it has recognized that “differences in MA coding, relative to FFS coding patterns,

results in relative risk that is *measured incorrectly*.” 2014 Rate Announcement, AR4858 (emphasis added). Specifically, “MA coding patterns that differ from patterns in fee-for-service may result in risk scores that are not equivalent to the risk scores of the FFS beneficiaries used to calculate the county rates.” 2008 Advance Notice, AR4165.

The Government Accountability Office (GAO) and others have understood the statutory scheme the same way. The GAO has explained that “[r]isk scores for beneficiaries with the same diagnoses and characteristics should be identical, regardless of whether the beneficiaries are in an MA plan or Medicare FFS.” GAO, *Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments*, AR12043. Similarly, senior HHS officials explained in an article in an official CMS journal that “the implicit assumption in the design of the MA payment system” is that if “Jane Doe would have a risk score of 1.0 if she were in FFS,” then “she would have the same risk score of 1.0 if she were enrolled in MA.” Kronick & Welch, *supra*, at E4; *see also id.* (“Suppose, for example, that average expenditure per FFS beneficiary is \$10,000/year, and that the average risk score for all FFS beneficiaries is 1.0. The goal of the payment system is to assure that—if all of those beneficiaries were to enroll in MA—the average payment to MA plans would be approximately \$10,000 per beneficiary.”). And the American Academy of Actuaries likewise recognized in a 1999 report ordered by Congress that the objective of MA risk adjustment is to “ensure that for each county, the new reimbursement rates utilizing health status risk adjusters . . . produce the same total payments for the fee-for-service populations as the current approach if every Medicare FFS member in a county were enrolled in” an MA plan. American Academy of Actuaries, *Actuarial Review of the Health Status Risk Adjustor Methodology*, AR11345.

2. *The Overpayment Rule Violates The Statutory Requirement Of Actuarial Equivalence Because It Calculates Payments To Plans Using A Different Methodology Than CMS Uses To Calibrate Its Risk Adjustment Model*

The Overpayment Rule’s interpretation of “overpayment” is entirely inconsistent with these statutory requirements, producing a system in which otherwise identical MA and traditional Medicare beneficiaries will be assigned different risk scores.

“Under the [Overpayment] Rule, any inadequately documented diagnostic code not supported by underlying medical documentation will result in an overpayment.” MTD Order at 6; *see also* Overpayment Rule, AR1313. In effect, then, the Rule bases the methodology for determining risk scores of MA plan patients on medical records—*i.e.*, charts—rather than diagnosis codes: Unless an MA plan patient’s risk score can be validated with his or her charts, under the Rule it cannot provide the basis for risk adjustment payments. The Rule made no corresponding adjustment, however, to account for the fact that CMS calibrates its risk adjustment model using unverified data from FFS beneficiaries. As to those beneficiaries and calculations, CMS’s methodology depends entirely on diagnosis codes submitted by providers, without regard to whether they are supported by medical charts. *See, e.g.*, 2011 Advance Notice, AR4370 (“CMS calibrates the CMS-HCC model using FFS data, and the relative factors reflect the FFS pattern of coding.”); 2010 RADV Rule, AR2826.

This use of a chart-based methodology to determine the actuarial risk posed by MA plan patients, and a different, diagnosis code-based methodology to determine the actuarial risk posed by traditional Medicare beneficiaries, is incompatible with the statute’s requirement that CMS use the “same methodology” to calculate risk scores for both populations. 42 U.S.C. § 1395w-23(b)(4). And by failing to employ the same methodology, CMS has also failed to “ensure actuarial equivalence” between the MA and traditional Medicare programs. *Id.* § 1395w-23(a)(1)(C)(i). To return again to the diabetes example offered above, *see supra* at 12, if CMS

evaluates the risk scores of the four traditional Medicare beneficiaries with diabetes diagnosis codes using only the diagnosis codes, but requires that an MA plan evaluate the risk scores of its identical four patients using the chart-based methodology adopted in the Overpayment Rule (resulting in upward risk adjustment for only three of the patients), then the two populations will appear to present different actuarial risk even though in fact they are identical. Moreover, because the payment amounts the MA plan receives based on the risk scores of its patients (calculated using charts) are determined using values calibrated with data from traditional Medicare (based on diagnosis codes), the plan will be underpaid for the risk it has assumed: It will receive just \$9,000 for the diabetes conditions, even though the projected diabetes expenditure for that population in traditional Medicare is \$12,000 (and the MA plan has, in this hypothetical, submitted a bid for 100 percent of the benchmark rate).

CMS had several options available to it to achieve actuarial equivalence between the two populations—and avoid inaccurate payment calculations.

First, it could have adopted, prospectively, a chart-based standard for calculation of risk scores in the traditional Medicare population, just as it has done for MA plans. In that case, only the three traditional Medicare beneficiaries whose charts reflected a diabetes diagnosis would see their risk scores increased; the fourth traditional Medicare beneficiary, with the unsupported diagnosis code, would not. Requiring plans to delete (or not submit) an unsupported code then would result in the CMS population having an average risk score identical to the MA plan's (identical) population: Three beneficiaries with heightened risk scores, and one without. Further, in calibrating payment amounts for the risk adjustment model, CMS would have divided its \$12,000 cumulative added cost for patients with diabetes by three instead of four, resulting in an incremental risk adjustment payment of \$4,000 rather than \$3,000 for patients with the relevant

indicator for diabetes. The MA plan would then receive an incremental payment of \$4,000 for each of its three patients whose charts reflected a diabetes diagnosis—producing the identical \$12,000 risk adjustment payment that the “actuarial equivalence” standard requires.

Second, if CMS was committed to using a diagnosis-based standard for calculating risk scores in the FFS population, then it could have used that same diagnosis code-based standard for calculating MA plan payments as well. In that scenario, the risk scores of all four MA plan patients would reflect that they shared the relevant proxy for diabetes (a diagnosis code), and the average risk score for both the MA plan and the traditional Medicare program would again be identical. Moreover, because all four MA plan patients would have that higher risk score, the MA plan would receive the full \$12,000 in incremental risk adjustment payments (this time, a \$3,000 payment for each of the four beneficiaries)—again equivalent to the expected expenditure under traditional Medicare for a population with identical actuarial risk.

Third, if CMS was concerned that the rate of unsupported codes might be higher in data submitted by MA plans than in the traditional Medicare program, it could have adopted an adjuster to account for that difference, as commenters urged. *See* Overpayment Rule, AR1313. As with the fee-for-service adjuster that it has recognized is necessary in connection with its RADV methodology, *see supra* at 15-17, CMS could have provided plans with a method to offset the proportion of unsupported codes in an MA plan’s submission by the proportion of unsupported codes in a sample of the traditional Medicare data. Under that approach, “overpayments” would only exist if—and to the extent that—a given MA plan’s rate of unsupported codes was higher than that of traditional Medicare.

By failing to employ any of those available options (or any other option) to ensure actuarial equivalence, the Overpayment Rule violates the statutory requirements set out in 42

U.S.C. § 1395w-23. This Court should thus “hold unlawful and set aside” the Overpayment Rule as “in excess of statutory jurisdiction, authority, or limitations.” 5 U.S.C. § 706(2)(C).

B. CMS Acted Arbitrarily And Capriciously In Departing From Its Prior Recognition Of The Need For Consistency Between CMS And MA Plan Data

Beyond violating the statutory requirements of using the same methodology and ensuring actuarial equivalence, the Overpayment Rule’s interpretation of “overpayment” also is invalid because it is arbitrary and capricious.

At the most basic level, it is inherently arbitrary and irrational to calibrate a payment model using one type of data and then operate the model using a different type of data—like building an engine to work with gasoline, then filling it with diesel. The American Academy of Actuaries has made this precise point, recognizing that “[a]n underlying principle of risk-adjustment systems is that there needs to be consistency in the way the model was developed and how it is used.” Comments on Proposed RADV Methodology, AR5235. It would be actuarially improper to “apply the risk-adjustment model in a way that is inconsistent with the way it was developed” by calibrating it with one set of data—“FFS data that . . . were not validated or audited for accuracy”—and then applying it to a different set of data—consisting of “only . . . MA data that are validated.” *Id.*, AR5235-36.

The reason is straightforward: The proxy for expected costs on which CMS has chosen to rely is unverified diagnosis codes, and by using unverified diagnosis codes from the traditional Medicare program along with historical expenditure data from that program, the calculations that CMS’s model produces are calculations of the average incremental cost associated with *having that diagnosis code*. See, e.g., 2010 RADV Rule, AR2824 (“The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis.”). As in any insurance system, many (indeed most) of the people with the relevant proxy will incur lower

expenses in a given year than that average figure. *See, e.g.*, Evaluation of the CMS-HCC Risk Adjustment Model, AR11891.¹⁰ *Why* those costs are lower will vary from person to person—some traditional Medicare beneficiaries with unverified codes might have a given disease but be in remission, others might be managing their symptoms well, and still others will incur lower-than-average costs because they simply do not have the disease. But that reality is built into the model itself: FFS beneficiaries whose incremental expenses are zero because they have the diagnosis code but not the disease reduce the average incremental cost associated with having the diagnosis code, producing a calculation of CMS’s costs that is lower than it would have been if CMS had used a different proxy for true disease state (such as medical charts). *See supra* at 11-12.

That lower figure associated with unverified diagnosis codes cannot predict what the higher expected incremental cost associated with a *verified* code would be, at least without adjustment. As the American Academy of Actuaries put it, if “lower-cost enrollees no longer are considered diabetic [because their codes are unverified] but would have been considered diabetic in the FFS data used to develop the risk scores, then the payment for diabetic members . . . could be inadequate,” leading to “systematic underpayment.” Comments on Proposed RADV Methodology, AR5236. “[T]he risk score factor associated with diabetes would be understated relative to the factor that would have resulted from using only substantiated diagnoses, because the lower-cost patients would have lowered the average spending amounts among those identified as diabetics in the FFS data.” *Id.* By contrast, “[w]hen that factor”—*i.e.*, the risk

¹⁰ *See also id.*, AR11891-92 (“As with any insurance product, the system is intended to be accurate at the group level. At the individual level, predicted medical costs can be lower or higher than actual medical costs, but at the group level, below-average predicted costs balance out above-average predicted costs. . . . It is important to understand that the underlying risk assessment is designed to accurately explain the variation at the group level, not at the individual level, because risk adjustment is applied to large groups.”).

coefficient developed using unverified FFS data—“is applied to similarly non-validated data, the total payments for those with diabetes would be adequate.” *Id.*¹¹

In addition to being inherently irrational and inconsistent with the purpose of risk adjustment, the Overpayment Rule’s interpretation of “overpayment” is also arbitrary and capricious because it represents an unexplained and unjustified departure from CMS’s own past positions. “One of the core tenets of reasoned decision-making is that ‘an agency [when] changing its course . . . is obligated to supply a reasoned analysis for the change.’” *Republic Airline Inc. v. U.S. Dep’t of Transp.*, 669 F.3d 296, 299 (D.C. Cir. 2012) (alterations in original) (citation omitted). Here, CMS did not even acknowledge—let alone explain—the inconsistency between its prior positions on the need to use a consistent standard for measuring risk and the contrary interpretation of “overpayment” it was now adopting. Specifically, the Rule is inconsistent with three prior CMS pronouncements.

I. CMS’s Interpretation Of “Overpayment” Is Inconsistent With The Rationale For The RADV Fee-For-Service Adjuster

The first inconsistency relates to the RADV Fee-For-Service Adjuster. *See supra* at 15-17. The objective of the RADV program is “to recover the overpayments identified during the RADV audit.” 2010 RADV Rule, AR2819. In order to “account[] for the fact that the documentation standard used in RADV audits to determine [an MA] contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims),” CMS has acknowledged the need to apply a “FFS adjuster” when making those overpayment determinations. Final RADV Methodology, AR5314-15. The

¹¹ CMS cannot rationally calculate lower per-code payments using FFS beneficiaries with unsupported codes, then pay that lower amount only for the subset of MA beneficiaries whose diagnoses are documented in charts. That would be akin to calculating a per-capita food subsidy but paying it on a per-household basis: the payment would be inadequate.

FFS adjuster will be based on “a RADV-like review of records submitted to support FFS claims data.” *Id.*, AR5315.

In the RADV context, therefore, CMS recognized that if it was going to determine whether a plan has received an overpayment by considering only those diagnosis codes submitted by the MA plan that could be verified through review of medical charts, it had to calibrate its *own* model using the same standard. *Id.* If the proportion of unsupported diagnosis codes in the traditional Medicare data exceeded the proportion of unsupported codes in the MA plan’s data, then the plan would not have been overpaid. *Id.*, AR5314 (“If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero.”). Meanwhile, if the proportion of unsupported codes in the MA plan’s data is higher, then CMS is entitled to recovery—but only after offsetting the proportion of unsupported codes in the MA plan’s data by the proportion of unsupported codes in the traditional Medicare data. Thus, if an audit determined that 20 percent of a plan’s risk adjustment payment had been based on unsupported codes, and that the equivalent payment error in the data from traditional Medicare was 15 percent, then CMS would be entitled to recover only the 5 percent difference.

The Overpayment Rule cannot be reconciled with that approach. Under the Overpayment Rule, the full 20 percent of the risk adjustment payments that were based on unsupported diagnosis codes would qualify as overpayments, which the MA plan would be required to return. The result is that when CMS itself performs an audit, it treats a plan as having been overpaid only if, and to the extent that, the rate of unsupported codes in the plan’s data is higher than in the traditional Medicare data—but if the MA plan audits itself, it is required to use a different definition of overpayment that provides for no such offset. There is no plausible reason for this divergent treatment.

2. *CMS's Interpretation Of "Overpayment" Is Inconsistent With The Rationale For The Coding Intensity Adjustment*

CMS's adoption of the Coding Intensity Adjustment likewise was based on a recognition that risk scores of an MA plan's beneficiaries need to be calculated using the same methodology that is employed in calibrating the payment model with data from traditional Medicare. In that case, CMS recognized that MA plans were employing coding practices that CMS itself does not engage in, such as retroactive chart reviews in which expert coders identify additional codes that could have been, but were not, submitted based on the information in a patient's charts. *See, e.g.*, 2009 Advance Notice, AR4229 ("MA plans may be finding and diagnosing disease at a higher rate than FFS providers."); *id.*, AR4231 ("CMS understands that MA plans have made efforts to identify enrollees' conditions and may be coding more completely than FFS."). In CMS's view, the one-sided application of those coding activities, while not itself improper or unlawful, *see id.*, AR4231 (noting that these efforts do not represent "improper coding"), had the effect of increasing the risk scores of MA plan populations relative to the traditional Medicare population. That would produce improper payment amounts, CMS concluded: Because "MA payment methodology is based on fee-for-service payments," it follows that "MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid." 2010 Rate Announcement, AR4335.

In justifying the Coding Intensity Adjustment, CMS recognized that to the extent MA plans engage in activities (such as reviewing charts to code them more completely) that CMS itself does not engage in, the effect of which is to *increase* a plan's risk scores, CMS must impose an offsetting adjustment to ensure that risk adjustment comparisons remain valid. That logic applies equally in reverse: To the extent that CMS requires MA plans to engage in activities (such as identifying and deleting diagnosis codes that are not supported by medical

charts) that CMS itself does not engage in, the effect of which is to *decrease* a plan's risk scores, CMS must likewise impose an offsetting adjustment to ensure that risk adjustment comparisons remain valid. The Rule cannot be reconciled with CMS's rationale for the Coding Intensity Adjustment.

3. *CMS's Interpretation Of "Overpayment" Is Inconsistent With The Implementation Standard CMS Indicated It Would Utilize When It Adopted The CMS-HCC Risk Adjustment Model*

Finally, CMS's interpretation of "overpayment" in the Rule is inconsistent with the position CMS took when it originally adopted the CMS-HCC risk adjustment model in 2004. At the time, CMS indicated that it would "implement the CMS-HCC risk adjustment model following the approach used to estimate the model." 2004 Advance Notice, AR3903. "In determining a risk score for a beneficiary," it wrote, "we will determine the status of each variable included in the model based on the same definitions used to estimate the model," including "diagnoses." *Id.* That commitment was essential, under basic actuarial principles, to making the CMS-HCC model a valid basis for risk adjustment. Indeed, the Actuarial Standards of Practice, a set of industry guidelines published by the Actuarial Standards Board,¹² require that "[t]he type of input data that is used in the application of risk adjustment . . . be reasonably consistent with the type of data used to develop the model." Actuarial Standards Board, Actuarial Standard of Practice No. 45 § 3.2 (2012), <http://www.actuarialstandardsboard.org/asops/use-health-status-based-risk-adjustment-methodologies/>.

Without any explanation, however, the Overpayment Rule departed from that prior commitment. Under the Overpayment Rule, CMS no longer determines the status of each

¹² The Actuarial Standards of Practice are analogous to the Generally Accepted Accounting Principles (GAAP) published by the Financial Accounting Standards Board.

variable in determining a risk score using the same definition it used in estimating the model: The definition of “diagnosis” CMS uses in estimating relative costs under its model is still keyed to the presence of a diagnosis code in claims data, but the definition of “diagnosis” CMS now uses for determining overpayments is the presence of a diagnosis in a medical chart.

C. CMS’s Stated Rationales For Requiring Different Validation Standards Lack Merit

In the preamble to the Overpayment Rule, CMS identified two supposed justifications for its refusal to account for its own unsupported codes in interpreting the term “overpayment.” First, it pointed to the annual attestation of accuracy signed by MA plans. Overpayment Rule, AR1313. And second, it pointed to a “long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.” *Id.* Neither point provides support for the Rule.

1. CMS’s Legitimate Concerns About Accuracy Do Not Justify Using A Different Validation Standard For Data Submitted By MA Plans

Every MA plan is required by regulation to “certify (based on best knowledge, information, and belief) that the data it submits . . . are accurate, complete, and truthful.” 42 C.F.R. § 422.504(l)(2). Pointing to that requirement, CMS reasoned in the Overpayment Rule that an MA plan is not entitled to payment unless its diagnosis codes are supported with medical record documentation. Overpayment Rule, AR1313.

That argument ignores the interpretation of “accuracy” that CMS itself has long used in evaluating MA plan payments and that undergirds the entire relative reimbursement methodology. Because risk adjustment is based on a comparison between an MA plan’s patient population and that of the traditional Medicare program, CMS has explained that “*MA organizations are coding ‘accurately’ when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.*” 2010

Rate Announcement, AR4335 (emphasis added). “[D]ifferences’ in coding patterns, regardless of the source, would make the MA plan coding ‘inaccurate’ for purposes of implementing risk adjustment.” *Id.* And that is true “even if such coding is accurate or complete for other purposes.” *Id.*, AR4336 (quoting floor statement by Senator Grassley). As CMS put the point the year before promulgating the Rule, “[t]he goal of risk adjusted payments is to pay accurately using the appropriate relative risk for a beneficiary. . . . As long as we have a model based on FFS costs and diagnoses patterns, differences in MA coding, relative to FFS coding patterns, results in relative risk that is measured incorrectly.” 2014 Rate Announcement, AR4858

Under that longstanding understanding of “accuracy,” the fact that MA plans certify to the “accuracy” of their data is not a reason for holding them to a different (chart-based) documentation standard than CMS uses with respect to its FFS data. To the contrary, in light of CMS’s understanding that the accuracy at issue is *relative* accuracy, a plan’s data are accurate if the proportion of unsupported codes in its data is no greater than in CMS’s data. The fact that MA plans are required to certify to the accuracy of their data is thus yet another reason that CMS cannot require plans to implement a perfection standard that it does not apply to its own data, undermining rather than supporting the Overpayment Rule.

To the extent that the Overpayment Rule implicitly adopted a different interpretation of “accuracy” in the Section 422.504(l)(2) attestation, moreover, it would render the attestation itself unlawful. It is well-settled that “an agency interpretation that is ‘inconsisten[t] with the design and structure of the statute as a whole,’ does not merit deference.” *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2442 (2014) (alteration in original) (citations omitted). By law, CMS cannot calculate the actuarial risk of an MA plan’s patient population using a methodology that is different than the one it used to calculate the benchmark from the traditional Medicare

population. *See supra* at 26-28. It cannot circumvent that requirement by demanding that MA plans attest to the “accuracy” of the data they submit under a different validation methodology than it itself applies. Doing so would simply be another way of requiring MA plans to use a different methodology—calculating risk scores with verified diagnosis codes, rather than (as with traditional Medicare) unverified ones—and would therefore itself violate the “actuarial equivalence” and “same methodology” requirements discussed above.

This does not mean, of course, that CMS is powerless to address discrepancies between diagnosis codes and medical records. CMS has suggested that MA plans are incentivized to increase the number of diagnosis codes of their patients in ways that traditional Medicare providers are not. *See, e.g.*, U.S. Mem. in Supp. of Mot. to Dismiss 6, ECF No. 12-1. Assuming that those incentives do, in fact, lead to the submission of a higher rate of unsupported codes—something that CMS’s own data suggest is not true¹³—CMS is free to address that concern. In doing so, however, CMS is *not* free to ignore other “important aspect[s] of the problem” before it. *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“Normally, an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem . . .”). Instead, any solutions it adopts to address its concerns about unsupported codes must also take account of the requirement—embodied both in the statute itself and also in the agency’s own past pronouncements on the subject—that risk be measured consistently across the MA and traditional Medicare programs. For example, it could begin paying plans based on a model calibrated with validated codes from the FFS program, in which case requiring MA plans to validate their data using charts, too,

¹³ *See, e.g.*, 2010 Rate Announcement, AR4336-37 (describing “[t]he results of the medical record audits” that “fail[ed] to show a systematic correlation between coding pattern differences and errors in the reporting of documented coding”).

would accomplish rather than frustrate actuarial equivalence. Alternatively, CMS could decide prospectively that an MA plan is being overpaid to the extent that the proportion of unsupported diagnosis codes in its data submission is higher than in the data from the traditional Medicare population used to calibrate the payment model (which presumably is unaffected by any alleged incentives to upcode). If the MA plan's rate of unsupported diagnosis codes is 20 percent, and the rate in the traditional Medicare program is 15 percent, then there is a 5 percent "inaccuracy" in the MA plan's data. That is the route CMS took with respect to the RADV Fee-For Service Adjuster. *See supra* at 15-17. But if the MA plan's rate of unsupported codes is 15 percent, identical to the rate in traditional Medicare, then the plan's data are "accurate" for purposes of risk adjustment. And in either case, identifying which specific individual beneficiaries within the group are the ones who have an unsupported code is completely irrelevant in determining whether the plan is paid appropriately.

2. *Industry Guidelines Relating to Medical Record Documentation Do Not Support Application Of Different Documentation Standards*

CMS can draw no support, either, from guidelines stating that diagnosis codes should reflect diagnoses documented in medical charts. That principle is not a regulatory requirement applicable uniquely to MA plans—it is an industry-wide standard, codified in the ICD-9 Coding Guidelines. *See* ICD-9-CM Official Guidelines for Coding and Reporting, AR11429. It applies equally to providers in *both* the MA and traditional Medicare programs. *See, e.g.*, 42 C.F.R. § 424.32(a)(2) ("A [FFS] claim for physician services . . . must include appropriate diagnostic coding for those services using ICD-9-CM."). And in *both* programs, providers are far from perfect at meeting it. Invoking this principle thus merely raises—it does not answer—the relevant question: Given the reality that many providers submitting claims in both the MA and traditional Medicare programs do not consistently document their diagnosis codes in the medical

charts, is it consistent with the statutory requirements and CMS's prior pronouncements to impose obligations on MA plans with respect to those undocumented diagnosis codes that CMS does not impose on itself? The *answer*, as already explained, is that doing so is not consistent with either the statute or the agency's past positions.

II. THE OVERPAYMENT RULE UNLAWFULLY TREATS AN MA PLAN AS HAVING "IDENTIFIED" AN OVERPAYMENT IF THE MA PLAN NEGLIGENTLY *FAILED* TO IDENTIFY THE OVERPAYMENT

In addition to adopting an interpretation of "overpayment" that is inconsistent with both statutory requirements and CMS's own past practice, the Overpayment Rule also is unlawful in a second, independent respect: It embraces an impermissibly expansive understanding of when an overpayment has been "identified" by an MA plan. Specifically, it interprets the statutory requirement that an "overpayment . . . be reported and returned . . . [within] 60 days after the date on which the overpayment *was identified*," 42 U.S.C. § 1320a-7k(d)(2) (emphasis added), to require reporting and return even when the overpayment *has not* in fact been identified, so long as it "*should have*" been, 42 C.F.R. § 422.326(c) (emphasis added). As this Court has already recognized, CMS's new definition essentially imposes a negligence standard. *See* MTD Order 13. That definition is flatly inconsistent with—or at minimum is an unreasonable reading of—the statutory text and must be set aside. *See generally Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

First, the statutory phrase "was identified" unambiguously indicates actual knowledge, not negligence. *See id.* at 842-43 (courts "must give effect to the unambiguously expressed intent of Congress"). To "identify" is to "establish," "indicate," or "determine" the identity of something. *See, e.g.,* Identify, *New Oxford American Dictionary* (3d ed. 2010) ("to establish or indicate who or what (someone or something) is"); Identify, *Webster's II New Collegiate Dictionary* (3d ed. 2005) ("to establish the identity of" or "to determine" the classification of).

No one would think, nor does any dictionary suggest, that something has been “identified” if it merely *should have* been established, proved, or determined. If, for example, a judge told her clerk to print a copy of every case a party’s brief had “identified” as relevant, no one would expect the clerk to provide not only the cases the party had cited, but also those it *should have* cited. So too here, an overpayment has not been “identified” until an MA plan has actually determined that it exists. CMS’s contrary definition flouts the plain, unambiguous meaning of the statutory text.

Second, even if the statutory text had any ambiguity, CMS’s interpretation is unreasonable. *See Chevron*, 467 U.S. at 844-45. The legislative history shows that Congress intended “identify” to be even *stricter* than recklessness or willful blindness, not *looser*. The initial version of the statute introduced in the House of Representatives in 2009 included a provision that an overpayment had to be reported within sixty days after it was *known*. H.R. 3200, 111th Cong. § 1641 (as introduced by the House, July 14, 2009). It specified that the meaning of “known” would be the same as the FCA’s knowledge standard, which includes recklessness and deliberate ignorance. *See* 31 U.S.C. § 3729(b)(1). But Congress instead adopted the Senate version of the bill, which substituted “identified” for “known.” Pub. L. No. 111-148, § 6402(a), 124 Stat. at 755 (enacting H.R. 3590, 111th Cong. (2010)). A court must give effect to this sort of legislative choice. *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) (“Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.” (citation omitted)). When it rejected the use of “known” and chose “identified,” Congress specifically did not even include *recklessness*, let alone negligence.

This makes sense, because the failure to return an overpayment can lead to punitive False

Claims Act liability. Under CMS’s new definition, MA plans potentially are subject to this punitive liability based on merely negligent *inaction* (i.e., failing to proactively search for and find overpayments)—a stark departure from the normal rule that the False Claims Act does *not* allow liability based only on negligence. *See, e.g., United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1274-77 (D.C. Cir. 2010) (emphasizing that the False Claims Act does not allow a court to “impose liability for what is essentially negligence or mistake by another name”); *Hindo v. Univ. of Health Scis./The Chicago Med. Sch.*, 65 F.3d 608, 613-14 (7th Cir. 1995) (“negligence is not actionable” under the False Claims Act).

In addition to being substantively untenable, CMS’s definition of “identified” must also be set aside because of an independent procedural defect: it was not a “logical outgrowth” of the proposed rule. “[A]gencies may not ‘pull a surprise switcheroo on regulated entities.’” *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (citation omitted). Therefore, an agency’s rule only satisfies the APA’s notice and comment obligation if “a reasonable commenter ‘should have anticipated that such a [rule]’ would be promulgated” or the proposed rule “was ‘sufficient to advise interested parties that comments directed to the’ controverted aspect of the final rule should have been made.” *First Am. Discount Corp. v. Commodity Futures Trading Comm’n*, 222 F.3d 1008, 1015 (D.C. Cir. 2000) (citations omitted); *see also Ass’n of Battery Recyclers, Inc. v. U.S. EPA*, 208 F.3d 1047, 1058-59 (D.C. Cir. 2000).

Here, CMS initially proposed that an MA plan has “identified” an overpayment when “it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.” Proposed Overpayment Rule, AR81. CMS explained that this definition was drawn from the definition of “knowing” and “knowingly” in the False Claims Act, 31 U.S.C. § 3729(b), despite the fact that those terms are

not used in the relevant section of the Affordable Care Act. In response, commenters argued that CMS's definition of "identified" was too broad for a statute that could potentially trigger punitive damages under the False Claims Act. As United explained, "it is unreasonable to require Plans to report and return an overpayment based on the broad definition proposed." AR1040. Instead, United and others suggested that "an identified overpayment should be limited to actual knowledge of an overpayment." *Id.*; *see also, e.g.*, AR613-14 (Blue Cross Blue Shield Association). But instead of addressing these comments and narrowing the scope of "identified," CMS instead made the definition even *broad*er, to include negligent *failure* to identify. CMS provided no notice to commenters that it was considering a negligence standard, and, unsurprisingly, no commenters addressed such a standard. The Final Rule's surprise adoption of negligence was precisely the sort of "switcheroo" that the APA forbids.

CONCLUSION

For all of these reasons, the Court should declare unlawful and set aside the Overpayment Rule.

October 17, 2017

Respectfully submitted,

/s/ Daniel Meron

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE
COMPANY, *et al.*,

Plaintiffs,

v.

ERIC D. HARGAN, in his official capacity as
Acting Secretary of the Department of Health and
Human Services, *et al.*,

Defendants.

No. 1:16-cv-00157-RMC

**DECLARATION OF KAREN ERICKSON IN SUPPORT OF UNITED'S MOTION FOR
SUMMARY JUDGMENT**

I, Karen Erickson, declare and state as follows:

1. I am an Executive Vice President at Optum, Inc. (“Optum”). I have served in this role since 2011. I submit this declaration to provide additional information relevant to United’s¹ Motion for Summary Judgment. I have personal knowledge of the facts stated here and/or have verified facts using the best information available to Optum.

2. Optum is a direct corporate subsidiary of UnitedHealth, Group, Inc. and is a health services company that, directly or through various direct and indirect corporate subsidiaries of its own, provides data analytics and other support services to United related to risk adjustment.

¹ This Declaration utilizes the name “United” to refer to UnitedHealthcare Insurance Company, the lead Plaintiff in this case, as well as the following Plaintiffs: AmeriChoice of New Jersey, Inc., Arizona Physicians IPA, Inc., Care Improvement Plus South, Central Insurance Company, Care Improvement Plus of Texas Insurance Company, Care Improvement Plus Wisconsin Insurance Company, Health Plan of Nevada, Inc., Medica Healthcare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., PacifiCare Life and Health Insurance Company, PacifiCare of Arizona, Inc., PacifiCare of Colorado, Inc., PacifiCare of Nevada, Inc., Physicians Health Choice of Texas LLC, Preferred Care Partners, Inc., Sierra Health and Life Insurance Company, Inc., UnitedHealthcare Benefits of Texas, Inc. (Formerly PacifiCare of Texas, Inc.), UnitedHealthcare Community Plan of Ohio, Inc. (Formerly Unison Health Plan of Ohio, Inc.), UnitedHealthcare Community Plan Of Texas, LLC (Formerly Evercare of Texas, LLC), UnitedHealthcare Insurance Company of New York, UnitedHealthcare of Alabama, Inc., UnitedHealthcare of Arizona, Inc., UnitedHealthcare of Arkansas, Inc., UHC of California (Formerly PacifiCare of California, Inc.), UnitedHealthcare of Florida, Inc., UnitedHealthcare of Georgia, Inc., UnitedHealthcare of New England, Inc., UnitedHealthcare of New York, Inc., UnitedHealthcare of North Carolina, Inc., UnitedHealthcare of Ohio, Inc., UnitedHealthcare of Oklahoma, Inc. (Formerly PacifiCare of Oklahoma, Inc.), UnitedHealthcare of Oregon, Inc. (Formerly PacifiCare of Oregon, Inc.), UnitedHealthcare of Pennsylvania, Inc. (Formerly Unison Health Plan of Pennsylvania, Inc.), UnitedHealthcare of the Midlands, Inc., UnitedHealthcare of the Midwest, Inc., UnitedHealthcare of Utah, Inc., UnitedHealthcare of Washington, Inc. (Formerly PacifiCare of Washington, Inc.), UnitedHealthcare of Wisconsin, Inc., and UnitedHealthcare Plan of the River Valley, Inc.

3. Following the finalization of the Overpayment Rule,² United deleted diagnosis codes worth millions of dollars that it had identified as unsupported by underlying medical documentation.

4. These deletions imposed concrete economic injury on United.

5. The Overpayment Rule does not define the phrase “reasonable diligence,” or what constitutes “reasonable diligence,” which makes estimation of precise costs for such a program impossible, but if the Overpayment Rule is upheld and requires United to undertake reasonable diligence to identify diagnosis codes that are not supported by underlying medical documentation, it would impose significant concrete economic costs on United to administer such a program.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 16, 2017, in Minnetonka, Minnesota

By 
Karen Erickson
Executive Vice President - Optum

² CMS, *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule*. 79 Fed. Reg. 29,843, 29,920-24 (May 23, 2014).

EXHIBIT 38

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE)
COMPANY, *et al.*,)

Plaintiffs,)

v.)

ERIC D. HARGAN,)
Acting Secretary of Health and Human)
Services, *et al.*,)

Defendants.)
_____)

Case No. 16-cv-157 (RMC)

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR
CROSS-MOTION FOR SUMMARY JUDGMENT AND IN
OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Insurers that offer Medicare Advantage (MA) plans get larger payments for covering people with certain diagnosed diseases. Covering someone with uncomplicated diabetes, for example, will earn the insurer something on the order of \$1000 a year more than it would receive for an otherwise identical person without diabetes. Sometimes insurers report diseases that are not documented in a beneficiary's medical records, and the government pays them on the basis of that reporting. The central question in this case is whether such a payment—in our example, a payment of roughly \$1000 a year for the added cost of covering someone with diabetes, when the beneficiary in question has no documented history of the disease—is an “overpayment” that must be reported and returned if it is identified. *See* 42 U.S.C. § 1320a-7k(d). In promulgating the rule challenged here, the Secretary of Health and Human Services said that the submission of such an “invalid” diagnosis would indeed “result in an overpayment.” Policy and Technical Changes to the Medicare Advantage Program (“Overpayment Rule”), 79 Fed. Reg. 29,844, 29,921 (May 23, 2014) (AR 1313).

United's argument to the contrary rests on the proposition that the per-disease payments calculated by the Secretary systematically underestimate the costs associated with any given disease. In our scenario, on United's account, the average marginal cost of covering a patient with diabetes is really \$1200 or \$1300 a year, but the company is only paid \$1000 for each diabetic it insures. The system nonetheless functions properly, United says, because insurers regularly claim payments for diseases that their beneficiaries appear not to have, and these extra payments compensate for the fact that each individual payment is lower than the expected cost of covering someone with the disease in question. (How insurers determine the proper number of unsupported claims to submit, United does not say.) United argues that it is therefore unlawful for the Secretary

to limit insurers to claiming payment for the diseases that are actually recorded in the medical records of their beneficiaries. If insurers are not allowed to submit a substantial proportion of diagnoses not reflected in any medical record, the argument goes, they will necessarily be undercompensated. The submission of invalid diagnoses (and the receipt of payments for them) is not only permitted, United argues—it is, as a practical matter, required.

The Secretary does not recognize the payment system that United describes. Since 1998, Medicare Advantage insurers have been required to certify the “accuracy” and “truthfulness” of the diagnosis data they submit for payment. 42 C.F.R. § 422.504(*l*). The Secretary has always understood a diagnosis to be “accurate” and “truthful” if (and only if) it is substantiated by a medical record. *See United States ex rel. Swoben v. United Health Ins. Co.* (“*Swoben*”), 848 F.3d 1161, 1176 (9th Cir. 2016). The model that calculates per-disease payments has been in place since 2004. Neither the standards for data submission nor the method of calculating per-disease payments has changed in any relevant way since then.

The requirement of medical record documentation—that is, the requirement that diagnoses submitted for payment be substantiated by medical records—appears to be the principal target of United’s challenge to the Overpayment Rule, 42 C.F.R. § 422.326. But the insurer has badly missed the mark: the Overpayment Rule did not impose the requirement, and vacating that rule would not lift it. *Compare* Pls.’ Br. at 21 (claiming that the Overpayment “Rule requires an MA plan to delete any . . . diagnosis code . . . that the plan knows lacks support in the patient’s medical charts”) *and id.* at 29 (“Unless an MA plan patient’s [diagnosis] can be validated with his or her [medical] charts, under the [Overpayment] Rule it cannot provide the basis for . . . payments.”) *with, e.g.,* 2001 Medicare Managed Care Manual (“Manual”), §§ 110.2, 110.4 (AR 5349–50) (interpreting 42 C.F.R. § 422.504(*l*) to obligate insurers “to comply fully with” the Medicare

Advantage “data requirements,” which require diagnosis data to “be substantiated by the hospital’s medical record”); 2004 Manual, § 111.1, Ex. 30 (AR 5671) (providing that “a medical record must substantiate all diagnostic information provided to CMS”); 2013 Manual, § 40 (AR 5678) (“All diagnosis codes submitted must be documented in the medical record”). Nothing in the Overpayment Rule affected “the long-standing . . . requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.” Overpayment Rule, 79 Fed. Reg. at 29,921–22 (AR 1313–14). That requirement is imposed by 42 C.F.R. § 422.504(*l*), which is not being (and could not be) challenged here. *See also* 42 C.F.R. § 422.310(d), (e). It was unaffected by the Overpayment Rule, and therefore cannot support a challenge to that rule.

The requirement that Medicare Advantage insurers “exercise . . . reasonable diligence” in identifying overpayments, 42 C.F.R. § 422.326(c), similarly comports with the statutory scheme and predates the challenged rule. “CMS has long made clear that, under [42 C.F.R.] § 422.504(*l*), Medicare Advantage [insurers] have ‘an obligation to undertake “due diligence” to ensure the accuracy . . . and truthfulness’ of the [diagnosis] data they submit to CMS and ‘will be held responsible for making good faith efforts to certify the accuracy. . . and truthfulness’ of these data.” *Swoben*, 848 F.3d at 1167 (quoting Medicare+Choice Program (“2000 Rule”), 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (AR 2006)). The Overpayment Rule’s requirement that insurers “exercise . . . reasonable diligence” in identifying overpayments, 42 C.F.R. § 422.326(c), is simply a restatement of their pre-existing obligation to undertake “due diligence” to ensure the “accuracy” and “truthfulness” of the diagnosis data they submit. The Overpayment Rule merely continues the Secretary’s established practice, and should be upheld.

BACKGROUND

A. Overview of Medicare

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, which is administered on behalf of the Secretary by the Centers for Medicare & Medicaid Services (CMS).¹ Part A of the Medicare statute “covers medical services furnished by hospitals and other institutional care providers.” *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5). “Health care services covered by Part A include: inpatient hospital care, skilled nursing facility care, home health agency care, and hospice care.” Establishment of the Medicare+Choice Program (“1998 Rule”), 63 Fed. Reg. 34,968, 34,968 (June 26, 1998) (AR 1417). Medicare Part B “is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including outpatient physician services,” *Ne. Hosp.*, 657 F.3d at 2, “in both hospital and nonhospital settings,” 1998 Rule, 63 Fed. Reg. at 34,968 (AR 1417), as well as “clinical laboratory tests, and durable medical equipment,” among other things, *Ne. Hosp.*, 657 F.3d at 2 (citing 42 U.S.C. §§ 1395j to 1395w-4). First established in 1965, Parts A and B are collectively referred to as “original,” “traditional,” or—though, as explained below, it is now something of a misnomer—“fee-for-service” (FFS) Medicare. *See, e.g.*, 42 U.S.C. § 1395w-21(a)(1)(A) (discussing “the original medicare fee-for-service program under parts A and B”). The Secretary will use these terms interchangeably.

Part C of the Medicare statute, 42 U.S.C. §§ 1395w-21 to 1395w-29, enacted as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, establishes the program now known as Medicare Advantage (“MA”)—though often called “Part C”—allowing people to receive their

¹ Before July 2001, CMS was known as the Health Care Financing Administration (HCFA). We refer to both agencies as “CMS.”

Medicare benefits through a private health insurance plan.² The introduction of Medicare Advantage was “arguably the most significant change in the Medicare program since its inception in 1965,” the “primary goal” of which was “to provide Medicare beneficiaries with a wider range of health plan choices to complement the Original Medicare option.” 1998 Rule, 63 Fed. Reg. at 34,968 (AR 1417). Medicare Advantage insurers “must provide enrollees the benefits and services (other than hospice care) that are available to people . . . under Medicare Parts A and B, *see* 42 U.S.C. § 1395w-22(a)(1), and may also offer supplemental benefits approved by the Secretary of Health and Human Services, *see* 42 U.S.C. § 1395w-22(a)(3).” *Matthews v. Leavitt*, 452 F.3d 145, 146 n.1 (2d Cir. 2006).

Medicare Part D was enacted in 2003, through the Medicare Prescription Drug Improvement and Modernization Act, Pub. L. No. 108-173, to provide a voluntary prescription drug benefit program to Medicare enrollees. Under Part D, the Secretary contracts with insurers to administer prescription drug plans. Individuals entitled to Medicare benefits under Part A or enrolled under Part B (which includes those who choose to receive their benefits through Part C) may enroll in Part D plans. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

B. Medicare Payment Models

The Secretary pays differently for each of the four Medicare programs. Initially, Medicare Part A reimbursements “were based on the ‘reasonable costs’ of [the] services furnished.” *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994) (quoting 42 U.S.C. § 1395f(b) (1988)). Under this “fee-for-service” regime, “providers were reimbursed for the actual

² Medicare Advantage was originally called Medicare+Choice, which was abbreviated “M+C.” Although we consistently refer to the program as Medicare Advantage, “MA,” or “Part C,” some record documents retain the older name and abbreviation.

costs that they incurred, provided they fell within certain cost limits.” *Id.* But in 1983, “Congress . . . completely revised the scheme for reimbursing Medicare hospitals.” *Id.* (citing Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 149). Under the current Part A payment scheme, Medicare reimburses hospitals for inpatient services based on prospectively determined rates, which are applied to each patient upon discharge, depending on the “diagnosis-related group” (DRG) to which the patient is assigned. 42 U.S.C. § 1395ww(d)(1)–(4); 42 C.F.R. § 412.60; *see Appalachian Reg’l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1051 (D.C. Cir. 1997) (“Reimbursement depends on the DRG to which a patient is assigned and the average cost of treating such a diagnosis, ‘regardless of the [actual] number of conditions treated or services furnished during the patient’s stay.’” (quoting 42 C.F.R. § 412.60(c)(2))). “The classification of a particular discharge” into the appropriate DRG “is based . . . on the patient’s age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient’s admission to the hospital), secondary diagnoses, procedures performed, and discharge status.” 42 C.F.R. § 412.60(c)(1). As one might expect, correctly identifying the principal diagnosis is essential to the operation of a system based on diagnosis-related groups. *See* Form HCFA-1450/UB-92, FL 67 (AR 5462) (instructing Part A providers that “[e]ntering any other diagnosis [in place of the correct principal diagnosis] may result in incorrect assignment of a DRG and cause you to be incorrectly paid”).

Medicare Part B originally operated on a reasonable cost basis, as well. “Under the Part B reimbursement system in place before 1983,” “the Secretary paid an independent provider of outpatient services” or “an outpatient hospital-based provider” 80% of the provider’s “reasonable charge” or “reasonable cost” for providing a given service. *Kidney Ctr. of Hollywood v. Shalala*, 133 F.3d 78, 81 (D.C. Cir. 1998) (citing 42 C.F.R. pt. 405, subpts. D, E (1982); 47 Fed. Reg. at

6557). Since that time, however, “[d]octors who provide medical services to Part B beneficiaries” have received “compensation in accordance with fee schedules that limit the amount they may charge and be paid.” *United Seniors Ass’n, Inc. v. Shalala*, 182 F.3d 965, 968 (D.C. Cir. 1999) (citing 42 U.S.C. § 1395w-4(g)(2)(C), (D)). Payments for most other services provided under Medicare Part B are now also determined by a fee schedule. *See, e.g., Decatur Cnty. Gen. Hosp. v. Johnson*, 602 F. Supp. 2d 176, 179 (D.D.C. 2009) (discussing 42 U.S.C. § 1395m(l), which authorizes the fee schedule for ambulance services).

Although the Secretary requires the submission of patient diagnoses with any claim for payment under Part B, *see* Form HCFA-1500, Item 21 (AR 5554), the payments depend only on the services (or durable goods) provided and not in any way on the diagnoses submitted. For that reason, the quality of the Part B diagnosis data is generally understood to be inferior to the Part A diagnosis data. *See* Gregory C. Pope, *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model* at 129 (Summer 2004) (AR 11867) (“Concern about the quality of diagnostic reporting is the greatest in physician offices, where diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals.”).

Under Part C, Medicare Advantage insurers are not paid by the medical services provided, but instead are paid a pre-determined monthly sum for each person they cover, 42 U.S.C. § 1395w-23(a)(1)(A), based in part upon the characteristics of the particular beneficiary being covered. By statute, the payment to the insurer depends on “such risk factors” as the age, gender, and “health status” of that individual, “as the Secretary determines to be appropriate.” *Id.* § 1395w-23(a)(1)(C)(i). It does not depend on the medical services actually provided to the beneficiary. Instead, under this system of “risk adjustment,” insurers are paid the expected cost of providing Medicare benefits to a given beneficiary. Medicare Advantage insurers therefore get more for

providing benefits to older and sicker people, less for younger and healthier ones. Adjusting the payments in this way allows the Secretary “to ensure actuarial equivalence” (as the Medicare statute requires) between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional, fee-for-service Medicare, and the payments made to Medicare Advantage insurers for covering an individual with those same characteristics.³ *Id.*

C. Part C Data Submission

As noted above, risk adjustment of payments to Medicare Advantage insurers is a statutorily-mandated element of the Part C payment system. In 1997, Congress directed the Secretary to implement “a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors” by January 1, 2000. *Id.* § 1395w-23(a)(3)(C)(1). The Secretary understood that “[t]he implementation of health-status based risk adjusters” would have “major implications for [Medicare Advantage insurers’] data requirements.” 1998 Rule, 63 Fed. Reg. at 35,006 (AR 1420).

The agency accordingly announced that it would require insurers to submit “encounter data”—that is, data from each Medicare Advantage participant’s encounters with the medical system, such as hospitalizations, doctor’s visits, and so on. *Id.* at 35,092 (AR 1425) (promulgating 42 C.F.R. § 422.257(a)). CMS explained that “[t]o calculate payment rates, encounter data are necessary to tie payment to expected patient resource use using diagnosis codes.” *Id.* at 35,006 (AR 1420). The encounter data collected would “be identical to the data we require of original Medicare providers of similar services,” *id.*, and would be submitted using the same standard forms (or their electronic equivalents), *id.* at 35,007 (AR 1421). Those forms required the identification

³ Under Medicare Part D, the Secretary makes payments so as to achieve “an overall subsidy level of 74.5 percent for basic prescription drug coverage.” 42 U.S.C. § 1395w-115.

of the principal diagnosis (*i.e.*, the diagnosis that led to the encounter in question) as well as any secondary diagnoses. *See* Form HCFA-1450/UB-92, FL 67 (AR 5462) (inpatient hospital services); Form HCFA-1500, Item 21 (AR 5554) (outpatient physician services). CMS said that “[a]udit of the data” submitted by the insurers would “be necessary to ensure accuracy”; and “any audit efforts” would need to “include medical record review for a portion of the submitted data,” so that the diagnoses submitted could be confirmed. 1998 Rule, 63 Fed. Reg. at 35,007 (AR 1421); *see id.* at 35,092 (AR 1425) (promulgating 42 C.F.R. § 422.257(e) (requiring Medicare Advantage insurers “to submit medical records for validation of encounter data”)).

The Secretary therefore issued interim final regulations in 1998, requiring each Medicare Advantage insurer to “request payment on document[s] that certify the accuracy and completeness of relevant data as a condition of receiving its . . . payment.” *Id.* at 35,017 (AR 1424); *see id.* at 35,103 (AR 1429) (promulgating 42 C.F.R. § 422.502(l) (requiring a certification of “accuracy, completeness, and truthfulness”)). The Secretary explained that, when a Medicare Advantage insurer “submits the data in question to [CMS], it is making a ‘claim’ for . . . payment in the amount dictated by the data submitted,” and that “it is important that when [a Medicare Advantage insurer] is claiming payment . . . in a particular amount based upon information it is submitting to [CMS], it should be willing to certify the accuracy of this information.” *Id.* at 35,017 (AR 1424). CMS believed “that these certifications” would “help ensure accurate data submissions.” *Id.*

Although this requirement of attestation and certification “of the completeness of the data” submitted and “the accuracy of the coding” proved to be “a contentious issue,” the Secretary maintained that it was “essential for guaranteeing the accuracy and completeness of data submitted for payment purposes.” 2000 Rule, 65 Fed. Reg. at 40,250–51 (AR 1999–2000). Nonetheless, CMS acknowledged that Medicare Advantage insurers “cannot reasonably be expected to know

that every piece of data is correct,” and emphasized that this was not “the standard that [CMS] . . . believe[s] is reasonable to enforce.” *Id.* at 40,268 (AR 2006). Because the Secretary did not intend for “simple mistakes” to “result in sanctions,” he modified the Medicare Advantage regulations in the year 2000 to include a “‘best knowledge, information, and belief’ certification standard.” *Id.*; *see id.* at 40,327–28 (AR 2008–09) (revising 42 C.F.R. § 422.502(*l*) to require certification of the “accuracy, completeness, and truthfulness” of the data submitted “based on best knowledge, information, and belief”).⁴ The Secretary emphasized that because “encounter data will be used as a factor in calculating payments to” Medicare Advantage insurers, “encounter data . . . represent a ‘claim’ for payment,” and insurers therefore “have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data.” *Id.* at 40,268 (AR 2006). He described the “steps” the Medicare Advantage insurers were required to take as performing “due diligence,” and made clear that the “‘best knowledge, information, and belief’ standard” incorporated this responsibility “for making good faith efforts to certify the accuracy, completeness, and truthfulness of [the] encounter data submitted.” *Id.*

At the same time, the Secretary promulgated 42 C.F.R. § 422.257(d), which required Medicare Advantage insurers to “submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards.” *Id.* at 40,326 (AR 2007) (promulgating 42 C.F.R. § 422.257(d)(1)). The Ninth Edition of the Clinical Modification of the International Classification of Diseases (ICD-9-CM) was the chief national standard, “published by the United States Government” and “required for reporting diagnoses and

⁴ Due to a typographical error, 42 C.F.R. § 422.502(*l*) appears in the Federal Register as 42 C.F.R. § 422.502(1). This regulatory provision is now codified at 42 C.F.R. § 422.504(*l*). We refer to it consistently by its current codification, even when record documents use the earlier codification.

diseases to all U.S. Public Health Service and [CMS] programs.” ICD-9-CM Preface at 1 (AR 11375). The ICD-9-CM emphasized “[t]he importance of consistent, complete documentation in the medical record,” without which accurate diagnosis coding “is a difficult, if not impossible, task.” ICD-9-CM Coding Guidelines at 5 (AR 11385). To enable “accurate reporting of . . . diagnosis codes,” it advised that the medical record “documentation should describe the patient’s condition, using terminology which includes specific diagnoses as well as symptoms, problems, or reasons” that the patient sought medical care. *Id.* at 22 (AR 11402).

This requirement of medical record support for diagnoses submitted by Medicare Advantage insurers was emphasized in guidance and training materials dating from this period. The first edition of the Medicare Managed Care Manual—which insurers agree to comply with as a condition of their participation in the Medicare Advantage program, *see* Standard Contract with Eligible Medicare Advantage Organization, Article II, Section A (AR 11801)—reiterated each insurer’s obligation to “make a certification . . . based on best knowledge, information, and belief, that the encounter data the [insurer] submits to CMS are accurate, complete, and truthful.” 2001 Manual, § 110.2 (AR 5349). While acknowledging that “the volume and variety of data make some inaccuracies inevitable,” the Manual told insurers that “the certification standard” included their “obligation to comply fully with the [Medicare Advantage] program’s encounter data requirements.” *Id.* (AR 5349–50). One such requirement was that “[e]ncounter data . . . be substantiated by the hospital’s medical record.” *Id.*, § 110.4 (AR 5350).

In 2003, CMS began to publish a risk adjustment training manual for Medicare Advantage insurers. The manual reminded insurers that they “must submit risk adjustment data that are substantiated by the patient’s medical record.” 2003 Regional Risk Adjustment Training For Medicare+Choice Organizations, Participant Guide (“Participant Guide”) at 4-1 (AR 5821); *see*

also Quick Facts, ICD-9-CM, June 2003 (AR 5952) (noting that “[t]he medical record must justify the diagnosis” and “[t]he diagnosis reported must match the coding submitted by the hospital/physician as documented in the medical record”). A Medicare Advantage resource guide from this period repeated the requirement that “a medical record must substantiate all diagnostic information provided to CMS.” 2003 Regional Risk Adjustment Training For Medicare+Choice Organizations, Resource Guide (“Resource Guide”) at 18 (AR 6488).

In 2004, the Secretary proposed regulations to “reflect[] changes . . . made in the methodology for risk adjusting MA payments, under which [CMS] moved from the collection of extensive encounter data to collecting targeted risk-adjustment data.” Establishment of the Medicare Advantage Program (“2004 Proposed Rule”), 69 Fed. Reg. 46,866, 46,903 (Aug. 3, 2004) (AR 2027). The language in proposed 42 C.F.R. § 422.310 was “similar to that used in . . . the current MA regulations at § 422.257.” *Id.* The Secretary explained that CMS had “implemented a streamlined process for MA organizations to submit risk-adjustment data,” under which an insurer could either “submit risk-adjustment data that conform to the requirements for equivalent fee-for-service data,” as formerly required, or “submit data according to an abbreviated format as specified by” CMS. *Id.* “The purpose of the abbreviated format [was] to reduce the data submission burden on MA organizations.” *Id.* The Secretary added that the “current practice” of CMS was “to collect . . . a sample of medical records, for conducting validation studies of the risk adjustment data CMS receives,” and that Medicare Advantage insurers would “still be required to submit a sample of medical records in a manner specified by CMS to support the validation studies.” *Id.*; *id.* at 46,969 (AR 2028) (proposing 42 C.F.R. § 422.310(e)). *See generally* Establishment of the Medicare Advantage Program (“2005 Rule”), 70 Fed. Reg. 4558, 4661 (Jan. 28, 2005) (AR 2232) (language similar to the above in preamble). The proposed regulations were

finalized in 2005, with the added provision that “[t]here may be penalties for submission of false [risk adjustment] data.” *Id.* at 4731 (AR 2233). *See* 42 C.F.R. § 422.310(d), (e).

The agency’s move from mandating full encounter data to accepting more limited risk adjustment data did not affect the requirement that all diagnoses submitted for payment be supported by medical record documentation, which the agency’s guidance and training materials continued to emphasize. The 2004 edition of the Medicare Managed Care Manual said that “a medical record must substantiate all diagnostic information provided to CMS.” 2004 Manual, § 111.1, Ex. 30 (AR 5671); *see also id.*, § 111.4 (Feb. 20, 2004) (AR 5604) (explaining that an insurers’ decision to use non-standard data sources does not affect its obligation to “ensure that the diagnosis reported to CMS is recorded in the beneficiary’s medical record for the data collection period or that the medical record documents the clinical evidence of that specific diagnosis for the data collection period”). The 2004 and 2006 editions of the Participant Guide both reminded insurers that “[t]he source medical record documentation that supports each coded diagnosis must be obtainable and demonstrate adherence to official coding guidelines.” 2004 Participant Guide at 5-2 (AR 7235); 2006 Participant Guide at 5-2 (AR 8702). Guidance from 2012 continued to emphasize that “[d]iagnoses must be supported by appropriate medical record documentation.” 2012 Regional Technical Assistance, Risk Adjustment Participant Guide at 2-5 (Aug. 7, 2012) (AR 10899). And the 2013 edition of the Medicare Managed Care Manual, which included the most substantial revision of the risk adjustment chapter since 2004, retained the instruction that “[a]ll diagnosis codes submitted must be documented in the medical record.” 2013 Manual, § 40 (AR 5678). It has been clear since the beginning of the Medicare Advantage program, and remains clear today, that all diagnoses submitted by insurers as claims for payment must be supported by medical record documentation. *See Swoben*, 848 F.3d at 1176.

D. Part C Risk Adjustment

Although the submission of accurate diagnosis data substantiated by medical records is necessary for CMS to perform risk adjustment based in part on “health status” under 42 U.S.C. § 1395w-23(a)(1)(C)(i), it is not sufficient. A risk adjustment model is required to translate the diagnosis data into expected costs of coverage.

Since January 2004, the Secretary has used the CMS Hierarchical Condition Category (CMS-HCC) risk adjustment model to perform that conversion. CMS-HCC is a complex regression model built to estimate the costs associated with certain characteristics of Medicare beneficiaries. The inputs to the model are data from individuals who receive their benefits through the traditional, fee-for-service Medicare system. *See* Advance Notice of Methodological Changes for 2014 (“2014 Advance Notice”) at 17 (AR 4768). Its outputs are a set of multipliers—that is, “coefficients”—that “represent the marginal (additional) cost” of each medical “condition or demographic factor (e.g., age/sex group, Medicaid status, disability status).” 2013 Manual, § 70.1 (AR 5684). The coefficients are added together to form a “risk score,” and then computed against a base payment rate (which varies depending on geography and the bid submitted by the insurer, among other things). The model is adjusted on a regular basis, and so the coefficients can change from year to year,⁵ but the basic design of the model has been constant since 2004.⁶

To understand the operation of the risk adjustment model, imagine a 72-year-old woman living independently, without a disability. In 2014, these “demographic” characteristics—*i.e.*, her

⁵ When coefficients are updated, they are put out for public comment, and are not finalized until the conclusion of that statutorily-mandated notice and comment period. *See, e.g.*, Announcement of 2004 Medicare+Choice Payment Rates (“2004 Announcement”) at 27–33 (AR 3948–54); 2014 Announcement at 67–73 (AR 4895–901).

⁶ For a more complete description of the model, *see* Pope, Risk Adjustment of Medicare Capitation Payments at 119 (AR 11857).

age, sex, and institutional and disability statuses—were assigned a coefficient of 0.348. 2014 Announcement at 67 (AR 4895). If this woman had no diagnosed diseases, a Medicare Advantage insurer would therefore be paid 34.8% of its base rate (which is keyed to the average beneficiary) for covering her. If our imagined beneficiary had diabetes without complications, another 0.118 would be added to her score, which would become 0.466 ($0.348 + 0.118$). *Id.* The risk adjustment model would now calculate her to be 46.6% as costly as the average beneficiary, and an MA insurer would therefore be paid 46.6% of its base rate for covering her. A diagnosis of multiple sclerosis would add another 0.556 to her risk score, for a total of 1.022: that is, 0.348 for demographics, plus 0.118 for diabetes without complications, plus 0.556 for multiple sclerosis. *Id.* at 68 (AR 4896). She would now be estimated to be 102.2% as costly as the average beneficiary, and an MA insurer would therefore receive 102.2% of its base rate for covering her. When a Medicare Advantage insurer reports to CMS a relevant diagnosis for a covered beneficiary, that reported diagnosis directly increases the amount that CMS pays the insurer for providing coverage. *See* 2000 Rule, 65 Fed. Reg. at 40,268 (AR 2006) (explaining that the submission of diagnosis data represents a claim for payment).

The risk adjustment model depends on a complex multivariate regression to produce these coefficients. CMS calculates them “by regressing the total expenditure for Medicare Parts A and B benefits for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses.” 2013 Manual, § 70.1 (AR 5684). In plain English, this regression takes the expenditures for a traditional, fee-for-service Medicare beneficiary from one year and maps them onto her demographic factors, as well as her medical diagnoses from the previous year, in order to see how those diagnoses and demographics predict medical costs. *See, e.g.*, 2014

Advance Notice at 17 (AR 4768) (explaining that “2010 diagnoses were used to predict 2011 expenditures”).

To see how this works, take the same hypothetical beneficiary from our last example: a 72-year-old woman living independently, without a disability, who has multiple sclerosis and diabetes without complications. Now suppose that she elects traditional, fee-for-service Medicare, and therefore becomes part of the data set used to build the Part C risk adjustment model, rather than having that model applied to her. Suppose further that “the total expenditure for Medicare Parts A and B benefits,” 2013 Manual, § 70.1 (AR 5684), for this beneficiary in the index year is \$10,000. The regression model attempts to answer the following questions: What portion of that \$10,000 expenditure was attributable to this beneficiary’s age and sex? What portion to her diabetes? And what portion to her multiple sclerosis?

Crucially, at the level of the individual beneficiary, these questions are unknowable. All we can say for certain is that this woman was of a certain age, had certain diseases, and incurred certain medical costs. Another 72-year-old woman living independently without a disability might have diabetes without complications and cirrhosis of the liver and incur \$8,000 of traditional Medicare expenses; a third might have diabetes without complications and chronic hepatitis, and incur expenses of \$15,000. A fourth might have the exact same diagnoses and characteristics as our hypothetical beneficiary, but different costs—say, \$30,000 of Medicare expenses. And of course, beneficiaries with different demographic characteristics will share certain diagnoses. An 81-year-old man could have inflammatory bowel disease and diabetes without complications, and \$20,000 of expenses; an 89-year-old man could have diabetes without complications and schizophrenia, and \$11,000 of expenses—and so on, and so on. These are the data on which the Medicare Advantage risk adjustment model is based: millions of traditional, fee-for-service

beneficiaries with demographic characteristics, reported diagnoses, and Medicare expenses. From that data, the model estimates the marginal cost of each disease and cluster of demographic characteristics. The model is told what Medicare spent on a beneficiary and, eventually, the model tells the agency what fraction of that cost should be assigned to each of the beneficiary's characteristics. By mapping known expenditures in this way, the model calculates the expected cost of each medical condition and demographic factor.

From this description it should be clear that, before the model is run, the marginal cost of each disease is unknown. Although United makes repeated use of a hypothetical example in which the marginal cost of providing coverage to an individual with diabetes is somehow known in advance to be \$4000 per year, *see* Pls.' Br. at 11–12, 25–26, 29–31, the entire point of using a regression model is that, without such a model, it would be impossible to determine the average cost associated with a given disease. All we would know is that beneficiaries with the disease in question were responsible for widely disparate expenditures, and had a confounding variation of other diseases and demographic conditions, as in the examples above.

Moreover, it is very hard to tell how an inaccurate diagnosis would affect the model's estimate of marginal costs. Suppose that our hypothetical beneficiary—the 72-year-old woman with diabetes and multiple sclerosis, who had \$10,000 of expenditures—was misdiagnosed. Suppose that, although she was recorded as having diabetes and multiple sclerosis, she in fact had only multiple sclerosis. How would this erroneous diagnosis affect the model's calculation of marginal costs? We know that the model would be dividing \$10,000 across three factors—demographic group, diabetes, and multiple sclerosis—when it should only have been splitting those costs between demographics and multiple sclerosis (because our hypothetical beneficiary does not actually have diabetes). The inclusion of the erroneous diagnosis would cause the model

to assign to diabetes some portion of the cost actually due to demographics, and some portion of the cost actually due to multiple sclerosis. But what would follow from this error is very hard to say. Would diabetes appear more expensive than it really is, because costs had been improperly assigned to it? (And, by the same token, would multiple sclerosis and demographics appear less expensive than they should have?) Or would diabetes instead appear less expensive than it really is, perhaps because the costs mis-assigned to it here were smaller than the costs properly assigned elsewhere, bringing down the average marginal cost? What would be the cumulative effect of such errors on the model as a whole? Despite United's insistence to the contrary, these questions do not have simple answers.

E. Data Validation Audits for Part C Risk Adjustment

As early as 1999, CMS was undertaking "payment validation activity" that was "intended to improve the accuracy of the risk adjustment data . . . submitted to CMS for payment." Policy and Technical Changes to the Medicare Advantage Program ("2009 Proposed Rule"), 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009) (AR 2409). These "risk adjustment data validation (RADV) audits" sought "to confirm the presence of risk adjustment conditions (that is, diagnoses [relevant to risk adjustment]) as reported by MA organizations for their enrollees and confirmed via medical record documentation." *Id.*; see Policy and Technical Changes to the Medicare Advantage Program ("2010 Rule"), 75 Fed. Reg. 19,678, 19,746 (AR 2823) (Apr. 15, 2010) (noting that "the process of independently reviewing medical records to validate risk adjustment data submitted by MA organizations for payment purposes has been established and operational for more than 10 years"). "Under RADV, the payment error testing . . . is aimed at validating that a particular Medicare beneficiary indeed has the medical condition for which the MA organization has been paid." 2010 Rule, 75 Fed. Reg. at 19,748 (AR 2825). This validation of reported diagnoses "that

result in additional payment” is achieved by confirming “the existence of clear, unambiguous diagnostic information in a beneficiary’s medical record” that “provides the written support for the diagnosis that was made.” *Id.* at 19749 (AR 2826).

Because the data submitted by Medicare Advantage insurers “according to an abbreviated format . . . specified by” the Secretary, 42 C.F.R. § 422.310(d)(1), “is self-reported by the [insurer] and does not go through a validation review before being incorporated into a given beneficiary’s risk-profile,” the Secretary has concentrated its audit activity on that self-reported data, 2009 Proposed Rule, 74 Fed. Reg. at 54,674 (AR 2409). “Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, [the Secretary] audits plan-submitted diagnosis data to ensure they are supported by medical record documentation.” *Id.* When he does so, “[v]erifiable medical record documentation is the key to accurate payment and successful data validation.” *Id.*

In 2008, the Secretary announced that he would begin to use statistical sampling and extrapolation to “generate[] statistically valid plan-level payment error estimates for those plans selected for review” in a RADV audit. 2009 Announcement at 22 (AR 4277). (Prior to that time, CMS had identified erroneous diagnosis codes for particular beneficiaries, but had not attempted to generate a payment error rate for entire Medicare Advantage contracts.) A methodology for this statistical sampling was proposed in December 2010, *see* Notice of Payment Error Calculation Methodology (AR 5020), and finalized in February 2012, *see* Notice of Final Payment Error Methodology (“RADV Methodology”) (AR 5311). Under this methodology, the Secretary chooses a contract to audit, selects a sample of beneficiaries associated with that contract, and examines their medical records. He determines whether any diagnoses claimed by the insurer are unsubstantiated in the sample beneficiaries’ medical records and, if some diagnoses are

unsubstantiated, calculates an error rate that compares the risk scores claimed for the sample beneficiaries to the risk scores supported by their medical records. After accounting for statistical uncertainty—and giving the insurer the benefit of the doubt within the range of that uncertainty—this error rate is then extrapolated to the contract as a whole. An extrapolated error rate of 5%, for example, suggests that the Secretary paid 5% too much to cover the Medicare Advantage beneficiaries on that contract.

When the RADV audit sampling methodology was proposed, some commenters argued that it would be unfair for the Secretary to recover the full amount suggested by this error rate without accounting for the “FFS [*i.e.*, fee-for-service] medical record documentation error rates.” AHIP Comment at 27 (AR 2744). Their theory was that, because the traditional Medicare data on which the risk adjustment model relied was unaudited, that data contained errors, and those errors made the model’s coefficients inaccurate. The Secretary decided that there “may be potential merit in further refining the error rate calculation” and said that he was “currently studying this issue.” 2010 Rule, 75 Fed. Reg. at 19,749 (AR 2826). Ultimately, the Secretary agreed to study the issue further and, when that study concluded, to publish an adjustment factor that would “account[] for the fact that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).” RADV Methodology at 4–5 (AR 5314–15). That forthcoming adjustment factor became known as the “FFS Adjuster.” *Id.* at 4 (AR 5314). The Secretary did not explain how he expected to calculate this FFS Adjuster, saying only that it would “be calculated . . . based on a RADV-like review of records submitted to support FFS claims data.” *Id.* at 5 (AR 5315). Since the Secretary made these statements in February 2012, he has said nothing more about the FFS Adjuster.

F. The Affordable Care Act and the Overpayment Rule

The Patient Protection and Affordable Care Act, which was enacted in March 2010, contained a provision regarding the “[r]eporting and returning of overpayments.” 42 U.S.C. § 1320a-7k(d). Any Medicare Advantage insurer that “has received an overpayment,” *id.* § 1320a-7k(d)(1), must “report and return the overpayment,” *id.* § 1320a-7k(d)(1)(A), no later than “60 days after the date on which the overpayment was identified,” *id.* § 1320a-7k(d)(2)(A). (If the insurer fails to do so, the overpayment becomes an “obligation” for the purposes of the False Claims Act, 31 U.S.C. § 3729(b)(3). 42 U.S.C. § 1320a-7k(d)(3).) “Overpayment” means “any funds that a person receives or retains under” the Medicare statute “to which the person, after applicable reconciliation, is not entitled.” *Id.* § 1320a-7k(d)(4)(B). For the purposes of the overpayment provision, the terms “knowing” and “knowingly” were given their definitions in the False Claims Act, *id.* § 1320a-7k(d)(4)(A), where they include actual knowledge of something as well as deliberate ignorance or reckless disregard of its truth or falsity, 31 U.S.C. § 3729(b)(1)(A). But those terms were not used in the overpayment provision.

In May 2014, the Secretary promulgated the Overpayment Rule, 42 C.F.R. § 422.326, which echoed the statutory definition of overpayment. *Compare* 42 U.S.C. § 1320a-7k(d)(4)(B) *with* 42 C.F.R. § 422.326(a) (“*Overpayment* means any funds that an MA organization has received or retained under Title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.”). The preamble to the Rule noted the “long-standing . . . requirement that a diagnosis submitted . . . by an MA organization for payment purposes must be supported by medical record documentation.” Overpayment Rule, 79 Fed. Reg. at 29,921–22 (AR 1313–14); *see id.* at 29,923 (AR 1315) (“CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation.”).

Because of this requirement, which was not altered by the Overpayment Rule, the submission of an “invalid” diagnosis (i.e., one unsupported by the beneficiary’s medical records) would “result in an overpayment.” *Id.* at 29,921 (AR 1313). The requirement of medical record documentation was reiterated over the objection of insurers who believed that “an overpayment cannot exist for a particular MA contract unless CMS’ payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract.” *Id.*

The Overpayment Rule also said that an “MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.” *Id.* at 29,958 (AR 1350) (promulgating 42 C.F.R. § 422.326(c)). The preamble explained that “MA organizations . . . are responsible for ensuring that payment data they submit to CMS are accurate, truthful, and complete (based on best knowledge, information, and belief), and are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments.” *Id.* at 29,923 (AR 1315). “Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.” *Id.*

STANDARD OF REVIEW

“[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal.” *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). “The entire case on review is a question of law,” and the “complaint, properly read . . . presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action.” *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); accord *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009); *Univ. Med. Ctr. of S.*

Nev. v. Shalala, 173 F.3d 438, 440 n. 3 (D.C. Cir. 1999); *James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). The district court’s review “is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously,” *Rempfer*, 583 F.3d at 865, or in violation of another standard set out in 5 U.S.C. § 706(2).

ARGUMENT

To resolve United’s challenge to the Overpayment Rule, it is essential to understand what the Rule did, and what it did not do. The Overpayment Rule did not alter the long-standing requirement that diagnoses submitted for payment by Medicare Advantage insurers be supported by medical record documentation. It did not affect the Part C risk adjustment model in any way. It did not change the RADV audit process. The Overpayment Rule simply mapped elements of the existing Part C payment scheme onto a statutory category—overpayments—which includes a deadline by which such payments must be returned. It did not change the terms under which Medicare Advantage insurers were entitled to claim payment in the first place.

Nonetheless, United has taken the Overpayment Rule as an opportunity to attack a fundamental feature of the Part C payment scheme: that Medicare Advantage insurers can only claim payment for diseases with which their beneficiaries have actually been diagnosed, as demonstrated by their medical records. This requirement of medical record documentation dates to the beginning of the Medicare Advantage program, as the administrative record demonstrates. *See, e.g.*, 2001 Manual, § 110.4 (AR 5350) (explaining that diagnosis data must “be substantiated by the hospital’s medical record”); 2004 Manual, § 111.1, Ex. 30 (AR 5671) (providing that “a medical record must substantiate all diagnostic information provided to CMS”); 2013 Manual, § 40 (AR 5678) (“All diagnosis codes submitted must be documented in the medical record . . .”). As United accurately told the Ninth Circuit, “CMS regulations deem a diagnosis code proper if it

is supported by a . . . medical record.” *Swoben*, 848 F.3d at 1176 (quoting Joint Answering Br. at 36). Conversely, if the diagnosis is not supported by a medical record, it is not proper. That has been the rule for nearly twenty years.

But United has concocted an alternative history, in which payment on the basis of unsubstantiated diagnoses is an essential premise of everything the Secretary has done to implement the Medicare Advantage program, which the Overpayment Rule would now abruptly and arbitrarily abandon. United frames its case as a request that this Court return the system of Part C risk adjustment to a status quo that has never existed. Indeed, it appears that United is not really concerned with the Overpayment Rule at all. What United wants is not the vacatur of 42 C.F.R. § 422.326, which it barely mentions in its brief, but something far more wide-reaching: a judicial declaration that Medicare Advantage insurers can lawfully claim payments for the costs associated with diseases that their beneficiaries do not have. United is not entitled to that declaration, any more than insurers are entitled to those payments.

I. The Secretary’s interpretation of “overpayment” as including claims for payment based on diagnoses unsupported by a beneficiary’s medical records is reasonable, and not contrary to any other statute.

When a Medicare Advantage insurer is paid for the added cost of covering someone with a particular disease, but the beneficiary in question does not have any documented history of that disease, is the payment an “overpayment” that must be reported and returned if it is identified? *See* 42 U.S.C. § 1320a-7k(d). The Secretary has determined that it is: the preamble to the Overpayment Rule challenged here says that the submission of “a risk adjustment diagnosis that . . . does not have supporting medical record documentation would result in an overpayment.” 79 Fed. Reg. at 29,921 (AR 1313). This interpretation is perfectly reasonable. The Medicare statute defines “overpayment” to mean “any funds that a person receives or retains under subchapter

XVIII . . . of this chapter”—that is, the Medicare statute—“to which the person . . . is not entitled.” 42 U.S.C. § 1320a-7k(d)(4)(B). A “person” includes a Medicare Advantage insurer. *Id.* § 1320a-7k(d)(4)(C)(i). The Secretary has interpreted “funds” to mean “any payment” that a Medicare Advantage insurer “has received that is based on data submitted by the [insurer] to CMS for payment purposes.” 42 C.F.R. § 422.326(a). United does not contest that definition. The only question, then, is whether insurers are statutorily “entitled,” 42 U.S.C. § 1320a-7k(d)(4)(B), to payment for the marginal cost (or any portion thereof) associated with diseases of which their beneficiaries have no documented history in the relevant year.

They are not, and never have been. Although the Overpayment Rule did not interpret “entitled,” the preamble designated such payments as “overpayments” because, as the Ninth Circuit has noted, “CMS requires medical diagnosis codes to be supported by a medical record” when they are submitted for payment by Medicare Advantage insurers. *Swoben*, 848 F.3d at 1176.

The Secretary’s regulations provide that, “[a]s a condition for receiving a monthly payment” through Medicare Advantage, participating insurers “must . . . certif[y] (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data.” 42 C.F.R. § 422.504(l). There is no dispute that risk adjustment data, including the diagnoses reported for particular beneficiaries, are “relevant data” within the meaning of this regulation. *Id.* § 422.504(l)(2) (requiring certification of data submitted under 42 C.F.R. § 422.310, which governs risk adjustment data). From the beginning of the Medicare Advantage program, the Secretary has made it clear that the “accuracy” and “truthfulness” of diagnosis data submitted for payment depends on the reported diagnoses being documented in a beneficiary’s medical record.⁷

⁷ United may not use this lawsuit as a vehicle to challenge 42 C.F.R. § 422.504(l), or the long-standing requirement of medical record documentation that it incorporates, because any such

In 2001, the Medicare Managed Care Manual interpreted 42 C.F.R. § 422.504(*l*) to obligate insurers “to comply fully with” the Medicare Advantage “data requirements,” including the requirement that risk adjustment data “be substantiated by the hospital’s medical record.” 2001 Manual, §§ 110.2, 110.4 (AR 5349–50). This requirement has appeared in every subsequent edition of the Manual, which insurers agree to comply with as a condition of their participation in the Medicare Advantage program. Standard Contract with Eligible Medicare Advantage Organization, Article II, Section A (AR 11801); *see also* 42 C.F.R. § 422.504(*i*)(4)(v). *See* 2004 Manual, § 111.1, Ex. 30 (AR 5671) (providing that “a medical record must substantiate all diagnostic information provided to CMS”); 2013 Manual, § 40 (AR 5678) (“All diagnosis codes submitted must be documented in the medical record . . .”).

CMS training materials have also consistently noted the requirement of medical record documentation for all reported diagnoses. *See* 2003 Participant Guide at 4-1 (AR 5821) (MA insurers “must submit risk adjustment data that are substantiated by the patient’s medical record.”); 2003 Resource Guide at 18 (AR 6488) (explaining that “a medical record must substantiate all diagnostic information provided to CMS”); 2004 Participant Guide at 5-2 (AR 7235) (“The source medical record documentation that supports each coded diagnosis must be obtainable and demonstrate adherence to official coding guidelines.”); 2006 Participant Guide at 5-2 (AR 8702) (same); 2012 Participant Guide at 2-5 (AR 10899) (“Diagnoses must be supported by appropriate medical record documentation.”).

challenge is barred by the six-year limitations period imposed by the Administrative Procedure Act. *See, e.g., Mendoza v. Perez*, 754 F.3d 1102, 1018 (D.C. Cir. 2014). The Secretary’s reiteration of that requirement in issuing the Overpayment Rule did not reopen that limitations period. *Id.*

And the ICD-9-CM system of diagnosis coding, compliance with which is “required for reporting diagnoses and diseases to all . . . [CMS] programs,” ICD-9-CM Preface at 1 (AR 11375), includes medical record documentation for all reported diagnoses, ICD-9-CM Coding Guidelines at 5, 22 (AR 11385, 11402); *see also* Pope, *Risk Adjustment of Medicare Capitation Payments* at 129 (AR 11867) (“The auditing standard that CMS has promulgated for reporting of physician office diagnoses is that a physician has established the diagnosis in the medical record, and that medical coders have recorded it in accordance with ICD-9-CM rules. . . . CMS will require [insurers] to demonstrate that a diagnosis is present in the medical record . . . and has been coded according to ICD-9-CM.”). These “statements by CMS are authoritative . . . because they provided clear guidance to Medicare Advantage organizations . . . regarding their obligations under § 422.504(l).” *Swoben*, 848 F.3d at 1177.

The Secretary’s conclusion that insurers are “not entitled,” 42 U.S.C. § 1320a-7k(d)(4)(B), to receive payment for reporting diagnoses that are not documented in their beneficiaries’ medical records—and that any such payments are therefore “overpayments,” *id.*— is consistent with the “long-standing” regulatory “requirement that a diagnosis submitted to CMS by” a Medicare Advantage insurer “for payment purposes must be supported by medical record documentation.” Overpayment Rule, 79 Fed. Reg. at 29921–22 (AR 1313–14); *see Swoben*, 848 F.3d at 1176. This interpretation is, at a minimum, “a permissible construction of” 42 U.S.C. § 1320a-7k(d)(4)(B), and it is therefore controlling. *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984).

A. The statutory requirement of “actuarial equivalence” between the payments to Medicare Advantage insurers and the expected costs of providing traditional Medicare benefits does not preclude the Secretary’s interpretation of “overpayment.”

United argues that the Secretary’s interpretation of “overpayment” is contrary to the statutory requirement that the Secretary “adjust the . . . amount” of the monthly payments to Medicare Advantage insurers to account “for such risk factors . . . as the Secretary determines to be appropriate,” such as the “age, disability status, gender, institutional status, and . . . health status” of each beneficiary being covered, “so as to ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). The Secretary may develop an adjustment methodology “as he determines to be appropriate,” *id.*, a statutory phrase that Congress uses to “trumpet[,]” in “sweeping terms,” the breadth of its grant of discretionary power. *Arctic Slope Reg’l Corp. v. FERC*, 832 F.2d 158, 164 (D.C. Cir. 1987). United thus bears a heavy burden to show that, in developing a risk adjustment model, the Secretary exceeded the broad range of authority that Congress has afforded him.

United fails in this attempt. The Secretary has, in his broad discretion, designed the Part C risk adjustment model “to ensure actuarial equivalence” by paying Medicare Advantage insurers a sum equal to the cost that CMS would expect to bear in providing traditional Medicare benefits to a given beneficiary. Indeed, that is what “actuarial equivalence” means in this context: an equivalence between an expected cost, on the one hand, and a known payment, on the other, achieved through the application of actuarial principles.

Congress has used the phrase in other contexts, with evidently similar meanings. The Employee Retirement Income Security Act (ERISA) provides that, if a private pension plan “allows retirees to select a lump-sum payment in lieu of an annuity,” then “the lump sum payment

‘shall be the actuarial equivalent’ of the annual benefit.” *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011) (quoting 29 U.S.C. § 1054(c)(3)). “Although ERISA does not further define actuarial equivalence,” the D.C. Circuit has “assume[d]” that “Congress intended that term of art to have its established meaning”—namely, that “[t]wo modes of payment are actuarially equivalent when their present values are equal under a given set of actuarial assumptions.” *Id.*; see also *Berger v. Xerox Ret. Income Guar. Plan*, 338 F.3d 755, 759 (7th Cir. 2003) (“The basic tradeoff involved in determining actuarial equivalence between a lump sum and an accrued pension benefit is between a present and a future value”); *Edsen v. Bank of Boston*, 229 F.3d 154, 163 (2d Cir. 2000) (noting that ERISA requires a lump sum payment to “be worth at least as much as th[e] annuity”).

Actuarial equivalence also appears in Part D of the Medicare statute, which defines “creditable prescription drug coverage” to include a wide range of coverage options, “but only if the coverage meets the requirement of paragraph (5),” entitled “Actuarial equivalence requirement.” 42 U.S.C. § 1395w-113(b)(4), (5). That paragraph provides that “[c]overage meets the requirement . . . only if [it] is determined . . . to provide coverage of the cost of prescription drugs the actuarial value of which . . . to the individual equals or exceeds the actuarial value of standard prescription drug coverage.” *Id.* § 1395w-113(b)(5). The Secretary has said that, in this context and “[i]n very general terms, actuarial equivalence refers to a determination that, in the aggregate, the dollar value of drug coverage for a set of beneficiaries under one plan can be shown to be equal to the dollar value for those same beneficiaries under another plan.” Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4199 (Jan. 28, 2005). In Part D, then, Congress used actuarial equivalence to compare the expected value to the beneficiary (or, seen differently, the expected cost to the insurer) of different benefit plans.

From these statutory provisions, we can see that when Congress instructs an agency “to ensure actuarial equivalence,” 42 U.S.C. § 1395w-23(a)(1)(C)(i), it means to equate either an expected value with a known value (as in the case of an annuity and a lump sum payment) or two expected values (as in the case of benefit plans). Two quantities are “actuarially equivalent when their present values are equal under a given set of actuarial assumptions.” *Stephens*, 644 F.3d at 440. Or, as the Secretary’s Part D regulations put it, “actuarial equivalence” is “a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with . . . CMS actuarial guidelines.” 42 C.F.R. § 423.4. In the context of Part C, and in the exercise of the Secretary’s broad discretion, the risk adjustment model seeks to “ensure actuarial equivalence” between the fixed payments made to Medicare Advantage insurers and the expected cost of providing traditional Medicare benefits to a given beneficiary by “adjust[ing] the payment amount . . . for such risk factors . . . as the Secretary determines to be appropriate, including adjustment for health status.” 42 U.S.C. § 1395w-23(a)(1)(C)(i).

The Secretary’s interpretation of the statutory mandate “to ensure actuarial equivalence” gives “that term of art . . . its established meaning.” *Stephens*, 644 F.3d at 440. And nothing in that definition or the larger statutory scheme precludes the Secretary’s interpretation of “overpayment”: equating payments to insurers with costs avoided by the agency does not imply that the agency must pay for the expected costs associated with a disease that is unlikely to require treatment (because the beneficiary in question has no documented history of that disease in the relevant year). There is no credible argument that the statutory text of the “actuarial equivalence” requirement prohibits the Secretary’s interpretation of “overpayment.”

Although framed in statutory terms, United’s argument from “actuarial equivalence” is instead best understood as a claim that the agency has acted arbitrarily and capriciously, because

the Secretary's implementation of "actuarial equivalence" (and not the statutory text itself) purportedly precludes his interpretation of "overpayment." This Court must "defer to the [agency's] . . . implementation" of its statutory mandates if that implementation is "reasonable"—*i.e.*, not arbitrary or capricious. *Nat'l Ass'n of Broadcasters v. FCC*, 789 F.3d 165, 179–80 (D.C. Cir. 2015); *see also Boehringer Ingelheim Pharma GMBH & Co. KG v. U.S. Food & Drug Admin.*, 195 F. Supp. 3d 366, 380 (D.D.C. 2016) (finding the agency's "interpretation of the statutory requirements" to be "reasonable," and concluding that "the agency's implementation of the statutory scheme . . . is reasonable as well"). We will return to United's arbitrary and capricious arguments after demonstrating that the second statutory provision on which the insurer relies also permits the Secretary's interpretation of "overpayment."

B. The statutory requirement that the Secretary publish "[t]he average risk factor" for traditional Medicare beneficiaries, "using the same methodology as is expected to be applied in making payments" to Medicare Advantage insurers does not preclude the Secretary's interpretation of "overpayment."

Congress has commanded the "Secretary, through the Chief Actuary of the Centers for Medicare & Medicaid Services" to annually "provide for the computation and publication" of "[t]he average risk factor for the . . . population" covered by "the original medicare fee-for-service program under parts A and B . . . using the same methodology as is expected to be applied in making payments under [Medicare Advantage]." 42 U.S.C. § 1395w-23(b)(4). In plain terms, the Secretary must publish county-by-county data for traditional Medicare beneficiaries every year, calculating the average risk score for those beneficiaries based on diagnoses reported by hospitals and "other sites of service, using the same methodology" employed to calculate the risk scores of Medicare Advantage beneficiaries. *Id.* § 1395w-23(b)(4)(D). The purpose of this calculation is to allow the Secretary to adjust the county-by-county per capita expenditures for traditional

Medicare beneficiaries, *see id.* § 1395w-23(b)(4)(A), (B), to account for variations in the risk profile of a given county's beneficiaries, so as to determine the average cost in each county of providing traditional Medicare benefits to someone with average risk factors. The Secretary publishes this data every year, as the statute requires, using the same risk adjustment methodology discussed above.⁸ The statutory requirement to make this publication does not in any way preclude—or even have much to do with—the Secretary's interpretation of “overpayment.” Again, United's reliance on this statutory provision is best understood as an argument that the definition of overpayment is arbitrary and capricious in light of the way that the statutory requirement to compute and publish this data has been implemented. We therefore turn to United's arbitrary and capricious arguments.

II. The Secretary's interpretation of “overpayment” is neither arbitrary nor capricious in light of the pre-existing regulatory scheme.

A. The “accuracy” and “truthfulness” of reported diagnoses depends on their documentation in a beneficiary's medical records.

The Secretary has clearly and consistently interpreted 42 C.F.R. § 422.504(*l*) to require medical record documentation if a reported diagnosis is to be “accurate” and “truthful.” *See also* 42 C.F.R. § 422.310(d), (e). This interpretation “must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation.” *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). As the Ninth Circuit has recognized, it is not. *Swoben*, 848 F.3d at 1176.

United nonetheless contends that the terms “accuracy” and “truthfulness” have never been given their plain meaning. Instead, United explains, CMS has always understood “accuracy” to

⁸ Data from 2008 through 2015 are available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Data.html>. To see the most recent data, open the zip folder called “FFS Data 2015,” then open the Excel spreadsheet titled “Medicare FFS County 2018 Web.”

mean “*relative* accuracy” (presumably “truthfulness” has also meant “*relative* truthfulness”) such that an insurer’s risk adjustment “data are accurate if the proportion of unsupported codes in its data is no greater than” the proportion in the data collected for traditional, fee-for-service Medicare beneficiaries. Pls.’ Br. at 39; *see also* AHIP Br. at 3 (arguing that “the term ‘accuracy’ cannot mean error-free as judged against medical charts”). But United cannot identify a single instance in which the Secretary told insurers that it would be “accurate” or “truthful” to report diagnoses that were not reflected in their beneficiaries’ medical records.

United points instead to statements the Secretary made in applying a statutory adjustment to the Part C payment model. Beginning in 2008, Congress required the Secretary to “ensure” that Part C risk adjustment “reflects differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences.” 120 Stat. at 51. The Secretary did not identify any such differences in preparing for the 2008 or 2009 payment years. But the Secretary identified differences in advance of 2010, and concluded that “coding pattern differences between MA and FFS are having a notable impact on payment,” 2010 Announcement at 29 (AR 4334), even though he did not “assume that the coding pattern differences” were “the result of improper coding,” *id.* at 30 (AR 4335). Instead, the Secretary allowed that Medicare Advantage insurers could simply be coding more vigorously, because each relevant diagnosis they reported was worth money to them. Asymptomatic diseases would be unlikely to impose any additional costs, for example—but if such diseases could be diagnosed, they would be a source of additional payments to insurers.

Having identified a difference in coding patterns, the Secretary deflated the risk scores of all Part C beneficiaries by a flat 3.41% for 2010.⁹ 2010 Announcement at 29 (AR 4334). Insurers protested that their diagnosis coding was accurate (in the absolute and not the relative sense of the term). In response, the Secretary said that, even if the insurers' coding was accurate, "MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid," *id.* at 30 (AR 4335)—meaning that MA plans would collect too much money if they aggressively searched for and claimed payment on the basis of diagnoses that would never have come to the attention of someone treating traditional Medicare beneficiaries.

United now points to this statement and says it implies that, if Medicare Part A and B providers sometimes report diagnoses that are unsubstantiated in their beneficiaries' medical records (which would not earn them any additional payments), then Medicare Advantage insurers must also be allowed to report diagnoses unsupported by any medical record documentation (and collect additional payments for those unsubstantiated diagnoses). *See* Pls.' Br. at 3. United goes on to argue that not only must insurers be allowed to claim payment for reporting unsubstantiated diagnoses, in fact "unverified diagnosis codes," and not diagnoses substantiated by a beneficiary's medical records, are the very basis for the Part C risk adjustment system. *Id.* at 32. To address

⁹ Congress directed the Secretary to continue to do so in "each subsequent year," with an adjustment that was "updated as appropriate," and provided that "the adjustment factor . . . for 2014" would be "not less than the adjustment factor applied for 2010, plus 1.5 percentage points" and, "for each of years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage points; and for 2019 and each subsequent year, not less than 5.9 percent." Pub. L. No. 111-152, § 1102(e), 124 Stat. 1029, 1046 (codified at 42 U.S.C. § 1395w-23(a)(1)(C)(ii)). Despite these adjustments, the Government Accountability Office believes that "CMS's adjustment to risk scores for 2010 through 2012 to account for diagnostic coding differences was too low," and that Medicare Advantage insurers therefore "received excess payments of between \$3.2 billion and \$5.1 billion over the 3-year period." U.S. Gov't Accountability Office, Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments at 9 (Jan. 2013) (AR 12051).

that argument completely will require a discussion of United's claim that the coefficients calculated by the CMS-HCC risk adjustment model are inaccurate, which is taken up below.

For the time being, it is sufficient to note that the Secretary's varied comments about the purpose of the coding difference adjuster, made in an effort to explain why insurers' search for every supportable diagnosis would lead to overpayment, did not implicitly revise 42 C.F.R. § 422.504(*l*), as United appears to suggest. As discussed at length above, the Secretary has always understood a certification of the "accuracy" and "truthfulness" of risk adjustment data to require that any reported diagnosis be substantiated by a beneficiary's medical record. *See also* 42 C.F.R. § 422.310(d), (e). United has not come close to showing that the Secretary's comments about the coding difference adjuster render this interpretation—under which "accuracy" means "accuracy" and not "*relative* accuracy"—"plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ.*, 512 U.S. at 512. The Secretary's understanding of 42 C.F.R. § 422.504(*l*) must therefore be given "controlling weight." *Id.*

The Overpayment Rule did not (as United suggests) impose a new, disruptive requirement that, for the first time, diagnoses would have to be substantiated by medical records. It simply maintained the pre-existing documentation requirement that had been in place for over a decade, which was the necessary consequence of an insurer's obligation under 42 C.F.R. § 422.504(*l*) to certify the "accuracy" and "truthfulness" of the diagnosis data on which it claimed payment. For the Secretary to leave undisturbed the "long-standing . . . requirement that a diagnosis submitted . . . by an MA organization for payment purposes must be supported by medical record documentation," 79 Fed. Reg. at 29,921–22 (AR 1313–14), was neither arbitrary nor capricious.¹⁰

¹⁰ For similar reasons, the Secretary's statements when announcing the CMS-HCC model do not render the Overpayment Rule arbitrary or capricious. United argues that, "[u]nder the

B. The administrative record does not support United’s claim that the risk adjustment model systematically underpays insurers, and the Overpayment Rule is not the cause of any asserted underpayment.

Although United disputes the Secretary’s long-standing interpretation of 42 C.F.R. § 422.504(l)—a challenge that must fail, for the reasons explained above—the heart of its case rests on actuarial principles rather than textual interpretation. United argues that, having built a risk adjustment model upon unaudited data from traditional Medicare beneficiaries, the Secretary cannot then require that the diagnoses reported by Medicare Advantage insurers be documented in their beneficiaries’ medical records—at least, not without violating fundamental principles of actuarial science.

There are two things to say about this argument before explaining why it is wrong. First, the argument has essentially nothing to do with the Overpayment Rule, which did not alter either the Part C risk adjustment model or the requirement of medical record documentation for diagnoses on which insurers claim payment. If United believes that the risk adjustment coefficients calculated by the CMS-HCC model do not compensate it for the costs of providing Medicare benefits, it can challenge the calculation of those coefficients. But the accuracy or inaccuracy of the risk adjustment coefficients is not a function of the Overpayment Rule.

Second, this argument is a claim that the Secretary has improperly implemented a risk adjustment model that is his to design “as [he] determines to be appropriate,” and which he “may

Overpayment Rule, CMS no longer determines the status of each variable in . . . a risk score using the same definition it used in estimating the model.” Pls.’ Br. at 37–38. But, as the Secretary has explained, the Overpayment Rule did not alter the way in which risk coefficients are assigned to Medicare Advantage beneficiaries. And in any case, these coefficients are calculated exactly as intended at the time the risk adjustment model was built. *See Pope, Risk Adjustment of Medicare Capitation Payments* at 129 (AR 11867) (“CMS will require [insurers] to demonstrate that a diagnosis is present in the medical record . . . and has been coded according to ICD-9-CM.”).

add to” or “modify” if he concludes that “such changes will improve the determination of actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). As noted above, this statutory phrasing “trumpet[s]” the breadth of the discretion that Congress has granted to the Secretary to develop and implement a risk adjustment model. *Arctic Slope Reg'l Corp.*, 832 F.2d at 164. Risk adjustment is, moreover, a matter of economic modelling, a technical expertise in which CMS has invested deeply. Judicial review of such matters is especially deferential. *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1087–88 (D.C. Cir. 2014) (collecting cases). The Secretary’s risk adjustment model easily satisfies the “minimal standards of rationality” by which this Court must judge it. *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (“We must look at the decision not as the . . . statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.”).

United’s argument about the adequacy of the risk adjustment coefficients begins from the premise that the risk adjustment model is built on unaudited data about traditional, fee-for-service Medicare beneficiaries, which must contain errors (because it is unaudited). This is true, as far as it goes. United then asks the Court to imagine the effect that these data errors will have on the overall risk adjustment model. United suggests that, if the marginal cost associated with a diagnosis of diabetes is really \$4000 a year, and some traditional Medicare beneficiaries who do not have diabetes are nonetheless recorded as having the disease, then that marginal cost will appear lower than it should be: a pool of four beneficiaries, only three of whom actually had diabetes, would seem to have diabetes-associated costs of only \$3000 a year, United says, rather than \$4000. United refers to the misdiagnosed individual as a “zero-cost” beneficiary, and suggests that the solution to this problem of underpayment—what keeps the whole system in

balance—is for Medicare Advantage insurers to claim payment for unsubstantiated diagnoses. If an insurer also had a pool of four beneficiaries diagnosed with diabetes, only three of whom actually had a documented history of the disease, United says, then it would be paid the \$12,000 that it was properly owed (4 x \$3000, instead of 3 x \$4000).

United’s simplistic scenario badly mis-describes the risk adjustment system that it purports to analyze. As explained above, CMS calculates the coefficients used to determine Medicare Advantage payments “by regressing the total expenditure for Medicare Parts A and B benefits for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses.” 2013 Manual, § 70.1 (AR 5684). United’s “zero-cost” beneficiary—the one who does not actually have diabetes—would almost certainly have received some medical care in a particular year, and CMS would therefore have some “total expenditure” for providing her with “Medicare Parts A and B benefits.” The regression model is designed to allocate that cost across her demographic factors (age, sex, and so on) and relevant diagnosed diseases. Including an erroneous diagnosis would mean that the expenditures for that beneficiary would be mis-assigned—costs would be attributed to the erroneous diagnosis that should instead have been attributed to other diseases, or to demographic categories. (By the same token, failing to include a relevant diagnosis would cause the mis-assignment of costs properly attributable to that disease.) How will this mis-attribution affect the model’s calculation of marginal costs? It is very hard to say, and United neither explains why it believes that the effect of mis-assigning known costs would be to deflate coefficients across the board, nor offers any proof that erroneous diagnosis data for traditional Medicare beneficiaries would in fact cause Part C risk adjustment coefficients to be deflated in this way—rather than raising one coefficient while lowering another, or shifting the weight of the model from diagnoses to demographic factors, or vice versa.

Moreover, the solution that United suggests—allowing Medicare Advantage insurers to claim payment for diagnoses that are not recorded in the medical records of their beneficiaries—is both utterly impracticable and unrelated to the problem at hand. How is an insurer supposed to know how many erroneous diagnosis codes to report? Diagnosis-based risk adjustment has been operating on the current model since 2004, and has been calibrated on fee-for-service data that entire time. If the system functions in the way that United describes, the insurer presumably has years of experience implementing internal processes to ensure that just the right number of invalid diagnosis codes is submitted to CMS for payment—not too many, but not too few. *Cf.* 42 C.F.R. § 422.503(b)(4)(vi) (requiring the Secretary “[t]o adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’ program requirements”). How exactly does that work? Are coders instructed to submit an invalid diagnosis for every third, or sixth, or ninth beneficiary? How is a system premised on the reporting of erroneous data supposed to ensure that the correct number of errors is generated? It is no answer to say that Medicare Advantage insurers blindly relay whatever faulty diagnosis data they receive, because those insurers “have an obligation to undertake ‘due diligence’ to ensure the accuracy . . . and truthfulness” of the risk adjustment data “submitted to [CMS].” *Swoben*, 848 F.3d at 1169 (quoting 2000 Rule, 65 Fed. Reg. at 40,268 (AR 2006) (second alteration in *Swoben*)). If the system is, as United argues, premised on the submission of erroneous data, then insurers must certify that the correct number of errors have been submitted.

Not that the proportion of erroneous codes in the fee-for-service data is the proper measure of anything. The only question relevant to United’s payments is whether the risk coefficients published by the Secretary accurately predict the average marginal cost of providing Medicare benefits to an individual with a given disease profile and set of demographic characteristics. If the

model accurately predicts relative costs, on average and on the whole, then there is nothing to correct for. It simply does not matter how many erroneous diagnoses went into the production of accurate coefficients. If, on the other hand, the risk coefficients did not accurately predict the average marginal cost of providing Medicare benefits—perhaps they *all* really are too low, as United suggests and its amicus explicitly argues (though it is hard to see how that could be possible in a model designed to allocate a set of known costs)—then the problem would be that the coefficients were inaccurate. If that is the case, they should be corrected. But there is no reason to think that a certain proportion of unsupported diagnosis codes in the fee-for-service data produce coefficients so precisely deflated that, by reporting an equal proportion of unsupported Medicare Advantage diagnoses, insurers can guarantee that they are compensated properly.

And in any event, this analysis of the risk adjustment model is ultimately immaterial to the case at hand. United has challenged the Overpayment Rule, 42 C.F.R. § 422.326. Whether the Part C risk adjustment coefficients are accurate or inaccurate, they were not affected by the Overpayment Rule. Nor did the Overpayment Rule alter the standards with which Medicare Advantage insurers must comply when submitting diagnosis codes. *See Swoben*, 848 F.3d at 1176 (noting that “CMS requires medical diagnosis codes to be supported by a medical record”); 2013 Manual, § 40 (AR 5678) (“All diagnosis codes submitted must be documented in the medical record . . .”). If United believes that the risk adjustment coefficients undercompensate it given the requirements of “accuracy” and “truthfulness” in the reporting of diagnosis data, 42 C.F.R. § 422.504(*l*), then it can bring a challenge to the calculation of those coefficients. Or, if United instead believes that the requirements of “accuracy” and “truthfulness” are incompatible with the way that the risk adjustment coefficients are calculated, it can petition the Secretary to alter 42

C.F.R. § 422.504(*l*), which imposes those requirements, and file suit if he refuses to do so.¹¹ But it cannot do what it is attempting here, and object to the Overpayment Rule’s categorization of payments to which insurers have never been entitled as “overpayments” within the meaning of 42 U.S.C. § 1320a-7k(d), on the grounds that insurers should always have been entitled to claim payment on the basis of diagnoses that are not reflected in their beneficiaries’ medical records.

C. The Secretary’s audits of risk adjustment data do not render the Overpayment Rule arbitrary or capricious.

Finally, United argues that the Overpayment Rule is inconsistent with the Secretary’s audits of risk adjustment data. Those RADV audits, which began in 1999, are “intended to improve the accuracy of the risk adjustment data . . . being submitted to CMS for payment,” by “confirm[ing] the presence of risk adjustment conditions (that is, diagnoses . . .) . . . via medical record documentation.” 2009 Proposed Rule, 74 Fed. Reg. at 54,674 (AR 2409). This validation of reported diagnoses “that result in additional payment” is achieved by confirming “the existence of clear, unambiguous diagnostic information in a beneficiary’s medical record” that “provides the written support for the diagnosis that was made.” 2010 Rule, 75 Fed. Reg. at 19,749 (AR 2826); *see also* Pope, *Risk Adjustment of Medicare Capitation Payments* at 129 (AR 11867). Medicare Advantage insurers are “required to submit a sample of medical records for the validation of risk adjustment data.” 42 C.F.R. § 422.310(d).

When the Secretary announced his intention to begin extrapolating contract-level payment error rates from statistically valid samples of RADV audit data, some commenters argued that it would be unfair for the Secretary to recover the full amount indicated by his audits without

¹¹ As noted above, however, United cannot *in this lawsuit* challenge 42 C.F.R. § 422.504(*l*), or the long-standing requirement of medical record documentation that that regulation incorporates, because such a challenge is long since time-barred. *See supra* n.7.

accounting for the “FFS medical record documentation error rates.” AHIP Comment at 27 (AR 2744). Their theory about the presence of unsubstantiated diagnoses in the fee-for-service data closely resembled United’s argument discussed above. Some insurers suggested that the process of extrapolation would exacerbate the payment distortions supposedly caused by those erroneous diagnosis codes. *See, e.g.*, Comment of Lovelace Health System at 4–5 (AR 2604–05). The Secretary concluded that there “may be potential merit in further refining the [RADV] error rate calculation” and said that he was “currently studying this issue.” 2010 Rule, 75 Fed. Reg. at 19,749 (AR 2826). He agreed to study the issue further, and publish an adjustment factor that would “account[] for the fact that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).” RADV Methodology at 4–5 (AR 5314–15). The Secretary said that this FFS Adjuster would “be calculated . . . based on a RADV-like review of records submitted to support FFS claims data.” *Id.* at 5 (AR 5315).

United argues that the Overpayment Rule is inconsistent with the Secretary’s announcement that an FFS Adjuster would be applied to RADV audit recoveries. But, as explained at length above, the Overpayment Rule did not alter the terms on which Medicare Advantage insurers are entitled to claim payment. United’s quarrel is, again, not with the Overpayment Rule at all, but rather with the idea that there could be any rational basis on which to apply the FFS Adjuster only to contracts subject to RADV audits. But the commenters who suggested that the Secretary adopt a fee-for-service adjuster did not frame their proposal as an adjustment to the entire payment system, but rather as an adjustment to the amounts to be recovered by RADV audits. Some suggested that the mechanics of extrapolating a contract-level error rate made such a RADV-specific adjustment advisable. *See, e.g.*, Comment of Lovelace Health System at 4–5 (AR 2604–

05). But the obligation of Medicare Advantage insurers to report accurate data is not limited to any sample, and so this rationale for a RADV adjustment simply has nothing to do with that obligation. The Overpayment Rule thus simply noted that the “RADV methodology does not change [the] existing contractual requirement that MA [insurers] must certify (based on best knowledge, information, and belief) the accuracy . . . and truthfulness of the risk adjustment data they submit to CMS.” Overpayment Rule, 79 Fed. Reg. at 29,921 (AR 1313). In making that announcement, the Secretary did not abandon *sub silentio* the “long-standing . . . requirement that a diagnosis submitted . . . by an MA organization for payment purposes must be supported by medical record documentation.” *Id.* at 29,921–22 (AR 1313–14). United’s argument from the FFS Adjuster is simply another fruitless attack on that well-established requirement.

III. The Secretary’s interpretation of “identified” lawfully reiterated a pre-existing obligation to exercise due diligence.

Under the Medicare statute, “overpayments” that have been “identified” must be “reported and returned.” 42 U.S.C. § 1320a-7k(d). The Overpayment Rule defines an “identified overpayment” as existing whenever a Medicare Advantage insurer “should have determined through the exercise of reasonable diligence, that [it] has received an overpayment.” 42 C.F.R. § 422.326(c). United objects to this provision on two grounds—first, that it is an untenable interpretation of the statutory language, and second, that it was not a logical outgrowth of the proposed rule.

In fact, this provision merely reiterates an obligation to which Medicare Advantage insurers have been subject since at least the year 2000. As the Ninth Circuit put it, “CMS has long made clear that, under [42 C.F.R.] § 422.504(*l*), Medicare Advantage organizations have ‘an obligation to undertake “due diligence” to ensure the accuracy, completeness, and truthfulness’ of the

[diagnosis] data they submit to CMS and ‘will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness’ of these data.” *Swoben*, 848 F.3d at 1167 (quoting 2000 Rule, 65 Fed. Reg. at 40268 (AR 2006)); *see id.* at 1174. Although these “statements by CMS in 2000 regarding due diligence and good faith . . . are authoritative . . . because they provided clear guidance to Medicare Advantage organizations . . . regarding their obligations under 42 C.F.R. § 422.504(l),” *id.* at 1177, the terms “due diligence” and “reasonable diligence” had never been incorporated into regulatory text.

The Overpayment Rule incorporated the pre-existing duty of Medicare Advantage insurers to undertake due diligence to ensure the accuracy and truthfulness of their claims for payment, *see* 2000 Rule, 65 Fed. Reg. at 40268 (AR 2006), by requiring the “exercise of reasonable diligence” in identifying overpayments. 42 C.F.R. § 422.326(c). This requirement is indistinguishable from the earlier obligation: there is no meaningful difference between “reasonable diligence” and “due diligence.” And the reiteration of a lawful, existing obligation cannot be “a surprise switcheroo” that causes a logical outgrowth problem. *Env’tl Integrity Proj. v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). Moreover, as one court has recognized, when Congress enacted 42 U.S.C. § 1320a-7k(d), it intended “to subject willful ignorance of Medi[care] overpayments to the [False Claims Act’s] stringent penalty scheme.” *United States ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 391 (S.D.N.Y. 2015). The obligation to “exercise . . . reasonable diligence” in identifying overpayments prevents such willful ignorance (or reckless disregard), but no more. (It does not, as United claims, create a negligence standard.) The final rule’s requirement of reasonable diligence is therefore a logical outgrowth of—indeed, a near-synonym for—the “reckless disregard or deliberate ignorance” standard that appeared in the proposed rule. 79 Fed. Reg. at 2055 (proposing 42 C.F.R. § 422.326(c)).

As the Secretary explained in the preamble to the Overpayment Rule, “MA organizations . . . are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments.” 79 Fed. Reg. at 29923 (AR 1315); *see* 42 C.F.R. § 422.503(b)(4)(vi) (Medicare Advantage insurers must “[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’ program requirements.”). “Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.” Overpayment Rule, 79 Fed. Reg. at 29923 (AR 1315). Failure to comply with this regulatory requirement might well demonstrate deliberate ignorance or reckless disregard of the existence of overpayments. And, “[i]n certain circumstances, . . . reasonable diligence might [also] require an investigation conducted in good faith and in a timely manner by qualified individuals in response to credible information of a potential overpayment.” *Id.* Failure to undertake a good faith investigation in those circumstances would surely constitute “willful ignorance of Medi[care] overpayments,” which Congress intended to subject “to the [False Claims Act’s] stringent penalty scheme.” *Kane*, 120 F. Supp. 3d at 391. In sum, 42 C.F.R. § 422.326(c) merely reiterated existing obligations, and is consistent with congressional intent.¹²

CONCLUSION

The Overpayment Rule should be upheld in its entirety.

¹² If the Court finds 42 C.F.R. § 422.326(c) to be invalid—which it should not, for the reasons discussed above—it should sever that provision and uphold the remainder of the Overpayment Rule. This would not be a case in which “the invalid portion cannot be severed from the rest of the rule,” *Harmon v. Thornburgh*, 878 F.2d 484, 495 (D.C. Cir. 1989), nor one in which there was “substantial doubt that a partial affirmance would comport with the [agency’s] intent,” *Telephone & Data Sys., Inc. v. FCC*, 19 F.3d 42, 50 (D.C. Cir. 1994).

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EXHIBIT 39

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE
COMPANY, *et al.*,

Plaintiffs,

v.

ERIC D. HARGAN, in his official capacity as
Acting Secretary of the Department of Health and
Human Services, *et al.*,

Defendants.

No. 1:16-cv-00157-RMC

**UNITED'S OPPOSITION TO THE GOVERNMENT'S MOTION
FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT
OF UNITED'S MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

United showed in its opening brief that the risk adjustment payment system CMS embraced in the Overpayment Rule violates the Medicare Act, basic tenets of rationality, and fundamental actuarial principles to which CMS had previously committed itself. As the American Academy of Actuaries has explained, requiring MA plans to delete unsupported diagnosis codes in their data, without accounting for the prevalence of such codes in CMS's own data, necessarily results in "systematic underpayment." Comments on RADV Methodology, AR5236.

Remarkably, the government offers almost no response on the merits. It ignores the American Academy of Actuaries. It never even *tries* to offer a direct argument that it is rational to calibrate the model with traditional Medicare data containing unsupported codes, and then apply it only to supported MA codes. And it concedes that the Medicare Act requires that payments to an MA plan be equivalent to the amount CMS would expect to spend insuring the plan's beneficiaries through traditional Medicare—but then fails to explain how the Overpayment Rule satisfies that statutory mandate. The government's wholesale failure to set forth a principled defense of the Overpayment Rule warrants setting it aside.

Ultimately, the most the government offers is that "[i]t is very hard to say" what the results of the Overpayment Rule will be. Gov. Br. 38. That is hardly a defense of the Rule. And in fact even that is wrong: The government's own examples, as well as its broader account of the risk adjustment methodology CMS uses, show that under the Rule, the risk scores of MA plan beneficiaries are artificially deflated relative to identical beneficiaries in traditional Medicare, necessarily resulting in MA plans being underpaid.

The government goes on at great length to argue that any illegality here is the result of some *other* agency action beyond this Court's reach. That is meritless. This suit chiefly

concerns CMS's interpretation of a provision on the "Reporting and returning of overpayments" Congress enacted in 2010. *See* Pub. L. No. 111-148, § 1128J, 124 Stat. 119, 753-56 (2010) (codified at 42 U.S.C. § 1320a-7k(d)). Congress defined "overpayment" there to include "any funds that a person receives or retains under [Medicare or Medicaid] to which the person . . . is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B). But Congress did not lay out in 2010 the circumstances in which a person is "not entitled" to payment and did not "state explicitly whether 'overpayments' are intended to incorporate an FFS adjustor threshold as do RADV audits," Mem. Op. 6, ECF No. 25 ("MTD Order"). CMS's first attempt to "clarify th[at] statutory definition of overpayment" came in 2014 in the Overpayment Rule, AR80, where CMS construed "overpayment" to include any payment resulting from a "risk adjustment diagnosis that has been submitted for payment but . . . found to be invalid because it does not have supporting medical record documentation." Overpayment Rule, 79 Fed. Reg. 29,844, 29,921 (May 23, 2014), AR1313. United's first opportunity to *challenge* that "clarif[ication]," therefore, came in this suit.

The government's contrary argument depends on the proposition that, in interpreting the new statutory "overpayment" provision, CMS was just building on its longstanding interpretation of a regulation, 42 C.F.R. § 422.504(*l*), that requires MA plans to attest to the "accura[cy]" of their risk adjustment data. That defense is both historically inaccurate and legally insufficient. Before the Overpayment Rule, CMS never had interpreted Section 422.504(*l*) to demand the absolute, perfection-based standard of accuracy the government invokes here. CMS instead had employed a *relative* standard for its RADV overpayment audits, under which a plan that had submitted unsupported codes would still be entitled to payment (*i.e.*, not "overpa[id]") if its data were accurate when compared to the rate of medical chart support in CMS's own traditional

Medicare data—even though the data of plans undergoing RADV audits were subject to the same attestation the government invokes here. In other contexts, too, CMS had stated that plans are coding accurately when they code in a manner similar to coding patterns in the traditional Medicare population to which they are being compared.

Moreover, even if CMS *had* previously required plans to certify that they believed their data were perfectly accurate, that does not mean the Overpayment Rule is lawful. It means instead that Section 422.504(*l*) *also* is unlawful because, so construed, it applies a different standard to MA plans' data than to CMS's own data without accounting for the difference. Under settled administrative law, this Court has authority to decide that insofar as CMS has interpreted Section 422.504(*l*) to require absolute accuracy, that interpretation was itself unlawful and thus an inadequate basis for the Rule's interpretation of the new statutory "overpayment" provision. And as *amicus* America's Health Insurance Plans explains, clarifying that issue is tremendously important to the Medicare Advantage industry as a whole, which needs to know whether this standard of absolute accuracy—a standard that CMS itself has recognized plans will "inevitabl[y]" fail to meet, 2001 Medicare Managed Care Manual, § 110.2, AR5349—may lawfully be applied without further modifications to the MA program.

This Court also can and should declare invalid the Overpayment Rule's interpretation of the new statutory term "identified." The government makes no effort to demonstrate that "was identified" may be read, as a textual matter, to mean "should have been identified." That by itself is enough to resolve the question, even if the government's other arguments were correct—and, as United explains below, they are not.

For these reasons, and as explained further below, the Court should grant United's motion for summary judgment and deny the government's cross-motion for summary judgment.

I. THE OVERPAYMENT RULE IS INCONSISTENT WITH THE STATUTORY REQUIREMENTS FOR RISK ADJUSTMENT

As United explained in its opening brief, the Overpayment Rule impermissibly treats MA plans as “not entitled” to funds they are lawfully entitled to receive under controlling statutory requirements. The Rule violates CMS’s statutory obligations to ensure “actuarial equivalence” between the MA and traditional Medicare programs, and use the “same methodology” to calculate the risk scores of traditional Medicare beneficiaries that it uses to calculate those of MA beneficiaries. *See* 42 U.S.C. §§ 1395w-23(a)(1)(C)(i), 1395w-23(b)(4)(D). Those statutory provisions entitle MA plans to receive payments for a given member that are equivalent—as the government itself puts it—to “the average payments that CMS would expect to make . . . under traditional, fee-for-service Medicare . . . for covering *an individual with those same characteristics*.” Gov. Br. 8 (emphasis added). The Overpayment Rule, however, results in CMS calculating the expected costs for “individual[s] with th[e] same characteristics” differently depending on whether they are in the traditional Medicare program or the MA program. That decision to measure risk in the two programs in different ways necessarily means that MA plans are *not* paid the same amount for insuring their members as CMS would expect to expend on identical beneficiaries in the traditional Medicare program, and thus violates the government’s own interpretation of the Medicare Act.

The government scarcely even *attempts* to reconcile the Overpayment Rule with those pre-existing requirements of the Medicare Act. Instead, the government simply declares that United’s suit is “best understood” as involving only the Administrative Procedure Act, and not the Medicare Act. Gov. Br. 30, 32. That is incorrect. This suit directly implicates the Medicare Act’s specific requirements, and the government cannot make those requirements go away just by pronouncing them co-extensive with the arbitrary and capricious standard of the APA.

Even if the government could collapse the whole suit into an arbitrary and capricious challenge, the Overpayment Rule still would not survive. It is irrational to measure two populations using fundamentally different criteria when trying to compare them. In addition, as the American Academy of Actuaries has explained, it violates core actuarial principles to calibrate a payment model using one type of data (costs associated with all diagnosis codes in CMS's claims data, supported or not), then apply that model to make payment decisions on a materially different type of data (only supported diagnosis codes) without accounting for the difference. The government never argues otherwise—it neither claims that it is rational to calibrate a risk adjustment model using unsupported codes and then apply it only to supported codes, nor denies that that is precisely what CMS has done here. And while the government insists (at 38) that “[i]t is very hard to say” what the result of this practice is for any *particular* code, the Rule's overarching effect is clear: It will, to a mathematical certainty, artificially deflate the *average* risk scores of MA plan beneficiaries relative to identical beneficiaries in traditional Medicare. Under the Overpayment Rule, therefore, MA plans are paid less because CMS is measuring the comparative risk their beneficiaries pose in a fundamentally inconsistent and irrational way.

A. The Overpayment Rule Violates The “Actuarial Equivalence” Requirement

1. The Government Agrees That Congress's “Actuarial Equivalence” Standard Requires That Payments To MA Plans Be Equivalent To The Costs CMS Would Have Incurred For Those Same Patients

Congress's actuarial equivalence requirement means that the risk-adjustment system must, as United previously explained, “reflect an apples-to-apples comparison of the risk assumed by a plan in insuring a beneficiary and the relative risk (in the form of expected costs) that CMS would incur for an identical beneficiary.” United Br. 26. That apples-to-apples comparison requires “risk scores [that] are consistent across both fee-for-service and Medicare

Advantage settings.” 2010 Rate Announcement, AR4336; *see also* GAO, *Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments*, AR12043 (“Risk scores for beneficiaries with the same diagnoses and characteristics should be identical . . .”).

The government does not dispute that interpretation of the actuarial equivalence requirement. Indeed, it *concedes* (at 8) that CMS is required to ensure equivalence “between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional, fee-for-service Medicare, and the payments made to Medicare Advantage insurers for covering an individual with those same characteristics.” *See also* Gov. Br. 28 (acknowledging that actuarial equivalence requires ensuring “equivalence between an expected cost, on the one hand, and a known payment, on the other”).

2. *The Overpayment Rule Impermissibly Treats An MA Plan As Overpaid Even Where CMS Would Have Expected To Expend The Same Amount—Or More—Insuring The Same Population Through Traditional Medicare*

Under the parties’ mutually agreed understanding of that statutory requirement, the Overpayment Rule cannot be upheld.

The hypothetical the government itself offers at pages 16-18 of its brief proves the point. It examines a traditional Medicare beneficiary with \$10,000 in costs and three risk adjustment factors: (1) her demographic group; (2) an unsupported diabetes diagnosis code; and (3) a chart-supported multiple sclerosis diagnosis code. The government claims (at 17) that it is “very hard to tell” how the inclusion of the unsupported diabetes diagnosis code would affect the precise “estimate of marginal costs” for each of the three risk adjustment factors. United addresses that point in more detail below. *See infra* at 20-22. For now, though, what matters is a point the government deliberately sidesteps: It is not at all hard to tell that the *overarching* effect of including the unsupported code when allocating costs on the traditional Medicare side, then

excluding that same code when determining payment amounts on the MA side, will be to underpay MA plans.

The government acknowledges (at 17-18) that in its hypothetical, the model would “assign to diabetes some portion of the cost actually due to demographics, and some portion of the cost actually due to multiple sclerosis.” Adding the three factors up would produce exactly \$10,000—the true expected cost for this beneficiary in traditional Medicare. Under the Overpayment Rule, however, a plan is required to delete the diabetes code and submit only the demographic and multiple sclerosis codes when CMS is determining its MA payment amount for the exact same person. Absent the sort of offsetting adjustment that CMS rejected in the Overpayment Rule, that approach unavoidably violates actuarial equivalence: CMS would have allocated the \$10,000 in expected costs across three codes, but would then pay the MA plan for only two of those codes, resulting in an MA payment amount that is less than \$10,000. The government’s own hypothetical thus violates its description of the statutory standard—that the “expected cost” be equivalent to the “known payment”—because the MA plan would not receive the “portion of the [\$10,000] cost actually due to demographics” or the “portion of the cost actually due to multiple sclerosis” that CMS had assigned to the diabetes diagnosis code. Gov. Br. 28, 17-18.

This problem is, if anything, even more obvious on a population-wide basis. Suppose a county contains two perfectly identical groups of 1,000 patients—one in traditional Medicare, one in MA. Both groups have the same 1,000 different demographic statuses, the same true health conditions, and the same collection and distribution of diagnosis codes—say, 5,000 codes, including precisely the same 500 unsupported codes. CMS might estimate, based on its traditional Medicare expenditure data, that it would spend \$10 million to insure those patients in

a given year in the traditional Medicare program. It would then regress that \$10 million in expected costs across the 1,000 different demographic statuses and 5,000 different diagnosis codes from traditional Medicare. For present purposes, it is irrelevant what precise value it assigns to each of the 5,000 diagnosis codes and 1,000 demographic statuses in particular; what matters is that taken together, the incremental costs for all 6,000 would add up to exactly \$10 million. If CMS then requires the MA plan to delete the 500 unsupported codes without making any offsetting adjustment, the result is that the plan will be underpaid, because it will not receive whatever portion of the \$10 million in expected traditional Medicare costs CMS had allocated to those 500 codes. It might be, as the government contends (at 18), “hard to say” exactly *how much* the MA plan has been underpaid—but the fact of underpayment is unavoidable.¹

3. *The Government Offers No Meaningful Argument That The Overpayment Rule Ensures Actuarial Equivalence Between The Traditional Medicare And MA Programs*

The government makes little effort to reconcile the Overpayment Rule with the Medicare Act’s demand that CMS “ensure actuarial equivalence” between the traditional Medicare and MA programs. 42 U.S.C. § 1395w-23(a)(1)(C)(i). It spends roughly three pages on that statutory requirement, most of which just agrees with United’s interpretation of “actuarial equivalence.” As for applying that interpretation to the Overpayment Rule, the government offers only a single paragraph on page 30 of its brief, where it asserts that “equating payments to insurers with costs avoided by the agency does not imply that the agency must pay for the expected costs associated with a disease that is unlikely to require treatment (because the

¹ It makes no difference whether the costs allocated to the 500 unsupported diagnosis codes were truly caused by other medical conditions documented in the beneficiaries’ medical charts, by more general demographic factors, or by some combination of the two. What matters is just that CMS assigned real costs it actually incurs in FFS Medicare to a type of code (unsupported diagnosis codes) for which MA plans, under the Overpayment Rule, are unable to recover.

beneficiary in question has no documented history of that disease in the relevant year).”

That defense of the Overpayment Rule is premised entirely on an inaccurate description of the payment system CMS adopted. If CMS had built a model that truly estimated the “expected costs associated with a disease” by using only verified codes, then it would be reasonable for CMS to make payments under that model only for verified diagnosis codes for the disease. Doing so would ensure actuarial equivalence because it would measure risk in the same way in both programs. But that is not what CMS did. CMS instead relied on unverified data from the traditional Medicare program to build its model, and thus chose a system that estimates the “expected costs associated with” the presence of an *unverified diagnosis code in claims data*—not (as the government’s single-paragraph defense supposes) the cost associated with actually having the disease. *See, e.g.,* Gov. Br. 37 (conceding it is “true” that “the risk adjustment model is built on unaudited data about traditional, fee-for-service Medicare beneficiaries, which must contain errors”). Having built a model that estimates the expected costs associated with unverified codes in the traditional Medicare population, it thus is required to apply that model to the equivalent risk indicator in the MA population or adopt a means of accounting for the difference. The Overpayment Rule rejects either solution (using an equivalent data source, or adopting an adjuster), and thus violates the actuarial equivalence standard.

The government also offers a more atmospheric defense of the Rule. It invokes the discretion Congress gave the Secretary in devising the risk adjustment scheme, and urges the Court that these are “hard” questions on which the Court should defer to the agency’s expertise. *See, e.g.,* Gov. Br. 17-18, 28, 37. But whatever discretion the Secretary may have with respect to other aspects of the MA program, Congress provided *no* discretion about whether the risk adjustment system must ensure actuarial equivalence. While Congress gave the Secretary

discretion about which factors to consider, it pointedly directed that the Secretary “*shall . . . ensure actuarial equivalence*” and may only “add to, modify, or substitute” adjustment factors if doing so “will *improve* the determination of actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i) (emphasis added). CMS had no discretion to depart from the actuarial equivalence standard in promulgating the Overpayment Rule.

B. The Overpayment Rule Also Violates The “Same Methodology” Requirement

In its opening brief, United explained that Congress has imposed a second relevant requirement on CMS, directing that it must calculate risk scores for both FFS and MA beneficiaries using the “same methodology.” 42 U.S.C. § 1395w-23(b)(4)(D). The government does not dispute the content of that requirement, either: It concedes that the average FFS risk score CMS is required to publish for each county “must” be calculated “‘using the same methodology’ employed to calculate the risk scores of Medicare Advantage beneficiaries.” Gov. Br. 31 (quoting 42 U.S.C. § 1395w-23(b)(4)(D)).

The government makes no effort to show that the Overpayment Rule complies with that requirement. Instead, it offers the sleight-of-hand that the “Secretary publishes this data every year, as the statute requires, using the same risk adjustment methodology *discussed above*.” Gov. Br. 32 (emphasis added). The reference to the methodology “discussed above” is circular, meaning only that CMS publishes risk scores for the FFS population using the same FFS methodology that the government discusses earlier in its brief. What the statute requires, however, is that the Secretary publish risk scores for the FFS program “using the same methodology *as is expected to be applied in making payments*” to MA plans. 42 U.S.C. § 1395w-23(b)(4) (emphasis added). The government never explains how the Overpayment Rule meets that requirement.

CMS treats all diagnosis codes submitted in the FFS program as valid for purposes of calculating FFS risk scores, even though that data is “unaudited” and “contain[s] errors.” Gov. Br. 37. Calculating a traditional Medicare beneficiary’s risk score thus involves simply adding up the coefficients associated with her demographic status and all of the diagnosis codes in her claims forms, whether they are supported by charts or not. Under the Overpayment Rule, by contrast, a diagnosis code for an MA plan beneficiary is “invalid” if it lacks “supporting medical record documentation.” Overpayment Rule, AR1313. Calculating an MA plan beneficiary’s risk score, therefore, requires first identifying and deleting any unsupported codes in her claims forms, then adding up only the coefficients associated with the chart-supported diagnosis codes that remain (along with her demographic-based coefficient). Those are indisputably different methodologies.²

Those different methodologies also produce materially different results. Consider again the government’s hypothetical 72-year-old woman with an unsupported diagnosis code for diabetes and a chart-supported diagnosis code for multiple sclerosis. As the government explains, under the methodology that it uses to calculate risk scores in the traditional Medicare program, her risk score is 1.022, reflecting coefficients for demographics (0.348), multiple sclerosis (0.556), and diabetes (0.118). Gov. Br. 14-15. Under the Overpayment Rule, however, her risk score in the MA program would be just 0.904, because the MA plan would be required to delete the diabetes diagnosis code before her risk score is calculated.³

² This may be why the government’s brief uses “as the statute requires” to describe only the fact that the “Secretary publishes this data every year,” and not the methodology he uses to calculate it. Gov. Br. 32 (“The Secretary publishes this data every year, as the statute requires, using the same risk adjustment methodology discussed above.”)

³ Assuming the plan bid a benchmark rate set at 100% of CMS’s costs, the plan would be paid only \$8,845 for an identical beneficiary who cost CMS \$10,000 to insure (.904/1.022 times \$10,000). If the plan voluntarily bid below the benchmark, it would be paid even less.

Lacking any argument that the Overpayment Rule complies with the “same methodology” requirement, the government suggests instead (at 32) that its noncompliance does not matter: “The statutory requirement to make this publication does not in any way preclude—or even have much to do with—the Secretary’s interpretation of ‘overpayment.’” It offers no support for that naked assertion. Nor could it. Congress requires CMS to use the same methodology for both its published FFS risk scores and the risk scores that it uses to calculate MA payment amounts, and CMS is not free to ignore that requirement by decreeing some diagnosis codes “invalid” for purposes of MA plans’ risk calculations that it treats as valid for purposes of FFS risk calculations. Overpayment Rule, AR1313.

The fact that the Overpayment Rule violates the “same methodology” requirement warrants setting aside the rule, without regard to the consequences of that violation. But the violation also has significant practical effects. The Medicare Act directs that the average county-by-county FFS risk scores CMS publishes are a component of the “Annual announcement of payment rates.” 42 U.S.C. § 1395w-23(b). While the government tries to dismiss the “same methodology” requirement for those scores as dealing only with the “publication” of data, Gov. Br. 32, CMS uses the published scores to determine the benchmark rate in each county. CMS divides the per capita health costs for traditional Medicare in each county (which it is required to publish under Section 1395w-23(b)(4)(B)) by the average FFS risk score in each county (required, as discussed, by Section 1395w-23(b)(4)(D)). This produces a “standardized” per capita expenditure for a beneficiary with a risk score of 1.0 in that county, which is then the basis for the benchmark rate.⁴

⁴ The CMS publication of the average risk scores from 2015, which the government cites (at 32 n.8) and which can be found at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Data.html>, reflect this calculation. To see that, open

Because CMS uses its published FFS risk scores in calculating the benchmark rate, artificially deflating MA risk scores compared to the FFS risk scores will lead to MA plans being underpaid. Consider again the hypothetical above, with two identical populations of 1,000 patients each and an expected CMS expenditure for the 1,000 FFS beneficiaries of \$10 million. The average per capita FFS expenditure in that county is therefore \$10,000. Now suppose that when CMS applies its risk adjustment model to the 5,000 risk adjustment codes and 1,000 demographic codes it has collected for the FFS beneficiaries there, it determines that the average risk score in the county is 1.1 (slightly higher than the national average). It would divide the \$10,000 average per capita expenditure in the county by 1.1 to produce a standardized per capita expenditure of \$9,090.91 for a FFS beneficiary with a risk score of 1.0. That standardized amount would then serve as the basis for the benchmark rate, dictating the maximum amount CMS will pay an MA plan for insuring a 1.0 beneficiary within the county. Suppose further that the MA plan, with its identical patient population, submits a bid at exactly the benchmark rate. The MA plan *should* receive a total of \$10 million for its population, since its population is identical. *See supra* at 5-6. Because the Overpayment Rule requires MA plans to use a different methodology than CMS uses to calculate the average risk score in traditional Medicare, however, the plan's payment will be lower than that: The MA plan will have to delete the 500 unsupported codes, reducing the average risk score of the MA plan's beneficiaries from the 1.1 it would be with those codes included to something lower than that. If the average risk score using only supported codes is 0.9, for example, then the plan would receive a total payment of \$8.18

the zip folder called "FFS Data 2015," then open the document titled "Medicare_FFS_Glossary." Its first page notes that the "Calendar year 2011-2015 risk scores" published as required by Section 1395w-23(b) are "[u]sed to standardize the FFS per capita cost," and that the "per capita cost calculation is a component used in determining the Medicare Advantage benchmarks."

million, representing a \$1.82 million underpayment.⁵

If CMS had complied with the “same methodology” requirement in the Overpayment Rule, it would have avoided this systematic underpayment. It could have done so in at least two ways. First, it could have allowed the MA plan to use all 5,000 risk adjustment codes (including the 500 unsupported codes) when calculating its risk scores for payment purposes. The MA plan’s average risk score in that scenario would have been 1.1, the same as the FFS program’s, and it would have received a payment of \$10 million.⁶ Second, CMS could have excluded unsupported codes when calculating the average FFS risk score in the county. In that scenario, the average FFS risk score would have been 0.9, which would have produced a benchmark rate of \$11,111.11. The MA plan, with its own average risk score of 0.9 (likewise calculated on the basis of only verified codes), would then have received a total payment of \$10 million.⁷

In the Overpayment Rule, CMS refused to take either of those approaches—or any other approach that would have produced a materially similar effect, such as use of an adjuster. Instead, it opted to continue using one methodology (unverified codes) to calculate the average traditional Medicare risk score in each county, and a different, stricter methodology (only supported codes) to calculate MA beneficiary risk scores for payment purposes. That violation of Section 1395w-23(b)(4)(D) results in identical beneficiaries receiving lower risk scores in the

⁵ To get this figure, multiply the standardized bid amount of \$9,090.91 by the average risk score of 0.9, then multiply that by 1,000 to reflect the MA plan’s 1,000 beneficiaries.

⁶ To get this figure, multiply the standardized bid amount of \$9,090.91 by the average risk score of 1.1, then multiply that by 1,000 to reflect the MA plan’s 1,000 beneficiaries.

⁷ To get this figure, multiply the recalculated standardized bid amount of \$11,111.11 by the average risk score of .9, then multiply that by 1,000 to reflect the MA plan’s 1,000 beneficiaries.

MA program, and thus leads inevitably to MA plans being underpaid.⁸

C. The Medicare Act’s “Actuarial Equivalence” And “Same Methodology” Requirements Are Distinct From The Administrative Procedure Act’s Prohibition On Arbitrary And Capricious Agency Action

Without a persuasive argument that the Overpayment Rule complies with the Medicare Act’s “actuarial equivalence” and “same methodology” requirements, the government instead suggests that United is “best understood” as not raising a challenge under those provisions at all. Gov. Br. 30, 32. The government argues that United’s challenges can only sound under the arbitrary and capricious standard, not the Medicare Act, because they are based on inconsistencies in the way CMS has constructed its risk adjustment scheme.

That argument is meritless. As the next section explains, the inconsistencies in CMS’s position indeed provide a basis for setting aside the Overpayment Rule under the arbitrary and capricious standard. But the Administrative Procedure Act is not the only law that requires consistency of a particular type or imposes a comparative standard. *See, e.g.*, U.S. Const., Amend. XIV. The Medicare Act *also* imposes requirements that depend on comparisons, demanding “equivalence” and “same[ness],” respectively, with the traditional Medicare program. 42 U.S.C. §§ 1395w-23(a)(1)(C)(i), 1395w-23(b)(4)(D). Those statutory demands are distinct from the requirements of basic rationality and consistency in the Administrative Procedure Act, and CMS cannot disregard them even if it thinks that doing so would be better policy.

In trying to channel this Court’s resolution of the case toward the arbitrary and capricious standard, CMS may be hoping to maximize its flexibility if the Overpayment Rule is set aside. As the brief of *amicus* America’s Health Insurance Plans makes clear (at 15-17),

⁸ CMS will not accept bids higher than the benchmark rate (based on its own expected costs), so plans cannot solve this problem by increasing their bid amount to offset the systematically lower risk scores CMS assigns to their MA beneficiaries under the Overpayment Rule.

however, the *last* thing the MA program needs is a years-long delay awaiting guidance from the agency. The government notes that, in the nearly six years since CMS acknowledged the need for a FFS Adjuster in the RADV context, the Secretary has “said nothing more about the FFS Adjuster.” Gov. Br. 20. But MA plans need to know *now* whether CMS may require them to delete all unsupported codes they have identified while paying them under a model calibrated with unverified data. And if the interpretation of the Medicare Act United has laid out here is correct, then no further words of explanation from the agency could possibly justify using a stricter standard to measure risk in the MA program than in the FFS Medicare program without accounting for that difference. Thus, there is no reason for this Court to accept the government’s implicit invitation to delay resolution of this important matter.

II. THE OVERPAYMENT RULE ALSO IS ARBITRARY AND CAPRICIOUS

The fact that the Overpayment Rule violates the Medicare Act is sufficient, by itself, to warrant setting aside the Rule. But the Overpayment Rule also independently violates the arbitrary and capricious standard of the Administrative Procedure Act, because it implements risk adjustment in an irrational way that contradicts basic principles of actuarial science, and departs from CMS’s own past statements about risk adjustment. The Rule should be invalidated on those additional grounds as well.

A. The Overpayment Rule Requires That Risk Adjustments Be Made In An Irrational Way

It is a requirement of rationality that when comparing two things, one must use the same form of measurement. If a trucking company says it will charge its customers for fuel at the same volume-based price at which it purchases for itself, it cannot then take the \$2.39 per-gallon price it pays and charge it to its customers as a \$2.39 per-*liter* price. In the context of insurance, that requirement is expressed as the actuarial principle that risk adjustment models must be

applied in a manner consistent with the way in which they were developed. *See* Actuarial Standards Board, Actuarial Standard of Practice No. 45 § 3.2 (2012), http://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop045_164.pdf. Just as per-gallon prices must be applied to gallons (or adjusted accordingly) in order to determine an appropriate fuel payment, so too must prices of risk be applied to the same measures of risk that were used to set them (or adjusted accordingly) in order to determine an appropriate risk adjustment payment.

Prior to the Overpayment Rule, CMS appreciated this. It recognized repeatedly that because “the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans,” “MA plans must code the way Medicare Part A and B does” in order “for this comparison to be valid.” 2009 Rate Announcement, AR4275. If *different* standards were used to measure risk scores in the two populations, that would frustrate the objective of “establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings,” 2010 Rate Announcement, AR4336, and “result[] in relative risk that is measured incorrectly,” 2014 Rate Announcement, AR4858. CMS committed that “[i]n determining a risk score for a beneficiary” in the MA program, it would “determine the status of each variable included in the model based on the same definitions used to estimate the model,” including “diagnoses.” 2004 Advance Notice, AR3903. After all, the alternative of using “FFS data that . . . were not validated or audited for accuracy” to calibrate the model, then “apply[ing] those factors only to MA data that are validated,” would be irrational and result in—as the American Academy of Actuaries put it—“systematic underpayment.” American Academy of Actuaries Comments on Proposed RADV Methodology, AR5235-36.

In the Overpayment Rule, though, CMS changed course. The Rule treats unsupported diagnosis codes submitted by MA plans as “invalid” for purposes of *applying* the payment model, without accounting for the fact that CMS treats unsupported codes from traditional Medicare as valid when *calibrating* the model. Overpayment Rule, AR1313; *see also* Gov. Br. 37. This violates the “underlying principle of risk adjustment systems . . . that there needs to be consistency in the way the model was developed and how it is used.” American Academy of Actuaries Comments on Proposed RADV Methodology, AR5235.

The government promises in its brief (at 36) that it will “explain why [this argument] is wrong,” but never delivers. It never disputes the basic actuarial principle that the data used to calibrate a risk adjustment model should be consistent with the data to which that model is then applied. It never suggests that the data CMS uses to calibrate the MA risk adjustment model (unverified FFS diagnosis codes) are consistent with the data to which the Overpayment Rule requires that the model be applied (only supported diagnosis codes). It never defends the rationality of measuring two populations utilizing different criteria when comparing the two. And it never even acknowledges, let alone responds to, the American Academy of Actuaries’ expert analysis condemning the use of FFS and MA data in that mismatched way.⁹

The government instead asserts that is “very hard to say” what the *consequences* of its

⁹ The government notes that the outside experts who developed CMS’s risk adjustment model anticipated that CMS would require plans to “demonstrate that a diagnosis is present in the medical record.” Gov. Br. 36 n.10 (quoting AR11867). That statement described the auditing process CMS would use with respect to MA plan data, and did not suggest that such verification would be done on *only* the MA side without making any corresponding adjustment on the traditional Medicare side. When CMS later developed the methodology for those audit-based recoveries, it acknowledged that in order to maintain consistency between the data used to calibrate its model and the data to which the model is applied, it would need to perform a “RADV-like review of records submitted to support FFS claims data.” RADV Methodology at 5 (AR5315). The government is wrong, therefore, inasmuch as it suggests that the designers of its model intended to apply different documentation standards to data from MA plans and traditional Medicare when calibrating and applying the model.

irrational, mismatched approach are. Gov. Br. 38. It acknowledges the possibility that, under its approach, United is correct that the risk coefficients “all really are too low,” *id.* at 40, but suggests that there are other possibilities, too. It might instead be the case, the government says, that inclusion of “erroneous diagnosis data for traditional Medicare beneficiaries” results in “raising one coefficient while lowering another,” or “shifting the weight of the model from diagnoses to demographic factors, or vice versa.” *Id.* at 38.

This is no defense of the Overpayment Rule. Actuarial principles require the use of consistent criteria in making comparisons precisely to avoid the uncertainties inherent in comparing apples and oranges; the fact that these questions arise at all is evidence of the Overpayment Rule’s irrationality. And the government’s professed uncertainty about the *answer* to them provides all the more reason to set aside the Rule. Through the Overpayment Rule, CMS took the categorical position that “*any* inadequately documented diagnostic code . . . will result in an overpayment.” MTD Order 6 (emphasis added). But in its brief (at 38), the government accepts the possibility that at least some of the coefficients are too low when applied only to chart-supported diagnosis codes. If that is true (and it surely is, *see infra* at 20-22), then the mere fact that a plan has been paid based on an unsupported code is not a sufficient basis to determine that the plan has been *overpaid*. Instead, it is necessary to determine and adjust for the rate of unsupported codes in the data used to calibrate the model before one could know whether an overpayment existed. That is what MA plans have been saying all along—not that unsupported codes can *never* produce overpayments, but that they do not *always* produce overpayments, because the (payment reducing) effects of the unsupported codes in the FFS data may have more than offset the (payment increasing) effect of unsupported codes in a given MA plan’s data.

The government tries to flip the burden on this issue, suggesting that once CMS picked an approach, it was up to regulated entities to prove that CMS's approach will always lead to underpayment. *See* Gov. Br. 38. But when an agency promulgates a rule, it is the *agency* that must make the findings necessary to its decision. *See, e.g., Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48-49 (1983). If the burden were otherwise, it would reinforce rather than prevent arbitrary decision making. CMS could have directed that risk adjustment scores be assigned using a random number generator, for example, then defended that arbitrary rule on the ground that it was "very hard to say" whether the randomly chosen numbers would be lower than, higher than, or the same as the numbers that the government would have produced using a properly calibrated model.

In any event, at the level of CMS's entire FFS population, these questions are not nearly as difficult as the government suggests. If CMS systematically deleted unsupported diagnosis codes in the FFS data, the overall *average* value of the remaining undeleted conditions (the combined set of both the chart-supported diagnosis codes and the demographic groupings) would *necessarily* increase, even if some individual coefficients decreased.¹⁰ Suppose that including unsupported diagnosis codes, the average beneficiary in traditional Medicare has five risk coefficients (one based on demographics, and four based on diagnosis codes). Because the model is calibrated so that the risk score of an average beneficiary is 1.0, the average numerical value of a risk coefficient across the entire traditional Medicare program (including all demographic and diagnosis codes) would have to be 0.20. If CMS were to delete all of the unsupported diagnosis codes in its traditional Medicare data, however, the average number of risk coefficients for each beneficiary would drop, meaning that the average value of a risk

¹⁰ The government notably speaks of uncertainty only about the effect on specific, individual coefficients, not uncertainty about the overall effect.

coefficient would now be higher. For example, if the average beneficiary now had just four risk coefficients (one based on demographics, and three based on diagnosis codes), the average numerical value of all the coefficients would be 0.25.

The same point is clear if one considers dollar values rather than coefficients. Consider the group of 1,000 traditional Medicare beneficiaries with \$10 million in costs, 1,000 different demographic codes, and 5,000 diagnosis codes (including 500 unsupported codes). *See supra* at XX. Distributing the \$10 million in costs across the 6,000 risk factors in that population (1,000 based on demographics and 5,000 based on diagnosis codes) would produce an average value for each risk factor of \$1,666.67. If CMS deleted the 500 unsupported codes before calibrating its risk adjustment model, by contrast, the average value for each remaining risk factor would be \$1,818.18.¹¹ This is just basic math, reflecting the distribution of the same expected costs (the numerator) over a smaller number of coefficients (the denominator).

In its opening brief, United illustrated this point using a hypothetical in which \$12,000 in diabetes-related costs were incurred for four patients with diagnosis codes for diabetes, only three of whom actually had the disease. *See* United Br. 11-12, 25-26, 29-31. If CMS distributed the \$12,000 in costs across all patients with an unverified code, it would calculate an expected cost of \$3,000 for each code. By contrast, if CMS distributed the \$12,000 across only those patients with a confirmed case of diabetes, it would calculate an expected cost of \$4,000.

The government now asserts that this hypothetical is “simplistic” and “badly mis-describes the risk adjustment system that it purports to analyze.” Gov. Br. 38. But the point the

¹¹ Because risk adjustment payments to MA plans are based on the combined demographic and health status coefficients assigned to plan members, it makes no difference whether the primary impact of deleting unsupported codes would be to increase the demographic coefficients or increase the diagnostic coefficients. What matters is that the *average* value of all the coefficients would have been higher had CMS calibrated its model based only on supported diagnostic codes.

hypothetical illustrates, while simple, is neither simplistic nor inaccurate: Increasing the number of diagnosis codes across which a fixed set of costs is distributed (by not deleting unsupported codes) will reduce the average expected incremental cost associated with having one of those codes. If that lower average cost associated with unverified codes then is used to calculate payments based only on supported codes, MA plans will be underpaid. On that basic, simple point, the government has no response.

Indeed, CMS's own internal experts, including the head of its Division of Payment Validation, used this same simple hypothetical to explain to CMS's most senior leaders how "[i]nclusion of undocumented diagnoses tends to *reduce risk adjustment values*"—as the materials addressed in United's pending motion to supplement the administrative record show. *See* Ex. B. to ECF No. 44 at 6 (emphasis added). And the American Academy of Actuaries made the same simple point in a letter already included in the record, stating that calibrating the risk adjustment model using "FFS data that . . . were not validated or audited for accuracy" will lead to risk factors that are "understated relative to the factor[s] that would have resulted from using only substantiated diagnoses." AR5236. The government ignores these analyses by its own experts and the leading association of professional actuaries, but they offer further confirmation that the approach CMS took in the Overpayment Rule "is so irrational as to be arbitrary or capricious." *Citizens for Jazz on WRVR, Inc. v. FCC*, 775 F.2d 392, 396 (D.C. Cir. 1985) (Scalia, J.).

B. The Overpayment Rule Is Inconsistent With The RADV Fee-For-Service Adjuster

The Overpayment Rule also is arbitrary and capricious because it departed from CMS's prior positions without any reasoned explanation.

As United described in its opening brief (at 34-35), the Overpayment Rule is not the first

time CMS considered how its use of risk coefficients developed using unverified diagnosis data would affect its calculation of overpayments MA plans might have received based on unsupported codes. That issue also arose in the context of the RADV methodology that CMS developed “to recover the overpayments identified during the RADV audit.” 2010 RADV Rule, AR2819.

There, as here, CMS needed to decide what constituted an “overpayment,” *id.*, so that it could then recover an appropriate amount. The functional definition of overpayments CMS adopted in the RADV context, however, is irreconcilable with the definition that CMS later announced in promulgating the Overpayment Rule. In the Final RADV Methodology, CMS agreed that before it could determine the overpayment that it would require an MA plan to return, it first needed to apply a “FFS adjuster” that would “account[] for the fact that the documentation standard used in RADV audits to determine [an MA] contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).” Final RADV Methodology, AR5314-15. The FFS Adjuster would operate as a setoff to reduce the overpayment amount, and “[i]f the FFS Adjuster amount is *greater* than the preliminary recovery amount, the final recovery amount is equal to zero.” *Id.*, AR5314 (emphasis added). CMS thus recognized in RADV that if the impact of unsupported diagnosis codes on an MA plan’s average risk score is lower than the impact of the unsupported codes in CMS’s FFS data, then there *has been no overpayment* to the MA plan at all.

During the notice-and-comment period on the Overpayment Rule, commenters argued that CMS needed to apply a similar adjuster when requiring MA plans to identify overpayments on their own. *See* United Br. 16-17 (summarizing comments). But CMS “disagree[d].” Overpayment Rule, AR1313. Instead, it adopted a different interpretation of “overpayment” for

purposes of the Overpayment Rule, under which an overpayment exists whenever an MA plan's data contains a single unsupported code—*regardless* of whether an “FFS Adjuster amount [would be] greater than the preliminary recovery amount” the plan has identified, Final RADV Methodology, AR5314.

In its brief (at 42), the government attempts to distinguish CMS's adoption of a FFS adjuster in the RADV context on the ground that it was not “an adjustment to the entire payment system, but rather . . . an adjustment to the amounts to be recovered by RADV audits.” That is a distinction without a difference. The “amounts to be recovered by RADV audits,” *id.*, are “overpayments,” 2010 RADV Rule, AR2819. The government offers no reasonable explanation for why payments based on unsupported codes should *not* constitute “overpayments” in the RADV context but *should* constitute “overpayments” under the Overpayment Rule.

In the Overpayment Rule itself, CMS's only explanation is that the “RADV methodology does not change [the] existing contractual requirement that MA [insurers] must certify (based on best knowledge, information, and belief) the accuracy . . . and truthfulness of the risk adjustment data they submit to CMS.” Overpayment Rule, AR1313. But MA plans that are undergoing a RADV audit have submitted the exact same attestations about their data that all other MA plans do, and yet CMS recognized in the RADV methodology that it was *still* necessary to adopt an adjuster to account for the different documentation standards. The contractual attestations thus provide no basis for distinguishing between the RADV methodology and the Overpayment Rule.¹²

The government (at 42) also offers an additional supposed justification for the departure

¹² CMS's adoption of the FFS adjuster does demonstrate, however, that CMS's commitment to requiring plans to attest to the accuracy of their data does not prevent it from simultaneously accounting for unsupported codes in its own data. United addresses that aspect of the FFS adjuster, and the meaning of the attestations more generally, below. *See infra* at 33-34.

from the RADV FFS adjuster: It claims that the use of extrapolation in the RADV context somehow made it more necessary to use an adjuster there than in other contexts. But CMS itself offered no such rationale in either the Overpayment Rule or in the final rule on the RADV methodology, and the government thus is left to assert here that “[s]ome insurers suggested that the process of extrapolation would exacerbate the payment distortions supposedly caused by those erroneous diagnosis codes.” Gov. Br. 42 (citing the comment of a single insurer).¹³ This post hoc attorney argument is not a valid basis for upholding a rule. *See, e.g., NLRB v. Kentucky River Cmty. Care Co.*, 532 U.S. 706, 715 n.1 (2001). And here, the argument also is incorrect: The government never explains how extrapolation from a statistically valid sample would exacerbate the effects of using different documentation standards,¹⁴ nor does it explain why such exacerbation—if it did exist in the RADV context—would justify ignoring precisely the same problem in the context of the Overpayment Rule.

C. The Overpayment Rule Is Inconsistent With The Rationale For The Coding Intensity Adjustment

The Overpayment Rule also represents an unjustified departure from CMS’s past statements about the need for a Coding Intensity Adjustment. In that context, CMS has recognized that “MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid.” 2010 Rate Announcement, AR4335. In the Overpayment Rule, however, CMS determined that risk adjustments are *invalid*, and thus produce overpayments, even when MA plans are coding in a manner identical to Medicare Part A and B providers.

¹³ If this Court grants United’s motion to supplement the record, the supplemental materials would show that CMS adopted the FFS Adjuster because “[u]nder RADV, plans are being held to a different (higher) standard for diagnoses” than in traditional Medicare, not because of concerns about extrapolation. *See* Ex. B to Motion to Supplement at 6.

¹⁴ The one comment to which the government points did not do so, either. Instead, it argued that the samples CMS chose for audit in RADV were not appropriate samples in the first place. *See* Comment of Lovelace Health System at 4-5, AR2604-05.

The government defends this departure from CMS's past practice on the ground that those earlier comments were intended to "explain why insurers' search for every supportable diagnosis code would lead to overpayment" unless CMS adopted the Coding Intensity Adjustment. Gov. Br. 35. But again, that is no real answer. The rationale for adopting an adjustment in that context was that payments would be invalid if MA plans were coding differently than traditional Medicare providers. 2010 Rate Announcement, AR4335. CMS cannot adhere to that rationale only when doing so operates to its financial benefit. *See* United Br. 36-37. CMS has identified no justification for departing from the comparative approach to validity that it previously adopted in the context of the Coding Intensity Adjustment.¹⁵

III. THE GOVERNMENT CANNOT AVOID REVIEW BY RECHARACTERIZING UNITED'S CHALLENGE OR CLAIMING THAT UNITED SHOULD HAVE OBJECTED TO OTHER ASPECTS OF THE RISK ADJUSTMENT PROGRAM

A. United Is *Not* Challenging In Isolation The Principle That Diagnosis Codes Should Be Supported By Charts

In the face of United's clear showing that CMS has interpreted "overpayment"

¹⁵ The government notes (at 34 n.9) that GAO has concluded that the Coding Intensity Adjustment was at times too low and that plans had been overpaid for those years. That is remarkable, since CMS—the executive branch client agency in this case—has itself examined GAO's analysis in a predecessor report that utilized the same methodology, and formally disagreed with its conclusions: "CMS uses a different methodology than was used in GAO's analysis and, while we found their method informative, we believe that our methodology results in an accurate measure of the coding differential between FFS and MA." 2013 Rate Announcement, AR4712. CMS and GAO do agree, by contrast, that while plans have an incentive to gather more *complete* sets of codes than does CMS, there is little to no correlation between that coding intensity and the rate of unsupported codes in plan data. *See* 2010 Announcement, AR4337; U.S. Gov't Accountability Office, GAO-16-76, Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments 10 (2016), <https://www.gao.gov/assets/680/676441.pdf> ("[T]he coding intensity scores CMS calculated were not strongly correlated with the percentage of unsupported diagnoses within a contract."). That suggests that the rate of unsupported codes in plan data would be expected to be similar to that in CMS's FFS data—and CMS never has found otherwise. At any rate, no form of rough justice would warrant upholding the Overpayment Rule here.

unlawfully and irrationally, the government’s primary response is to claim that United actually is challenging the requirement that diagnosis codes be supported by medical charts. *See, e.g.*, Gov. Br. 2 (describing “[t]he requirement of medical record documentation” as “the principal target of United’s challenge”); *id.* at 23-24, 25 n.7, 35.

Not so. United has never challenged the agency’s authority to require diagnosis codes to be supported by medical charts in itself. In fact, the first of several alternatives United identified that would ensure actuarial equivalence was that CMS could measure the health status of *both* MA and FFS beneficiaries based on only chart-supported diagnosis codes. United Br. 30-31.

United instead is challenging CMS’s decision to “require MA plans to delete provider-submitted diagnosis codes that lack medical record documentation *without making a corresponding adjustment in its own data or accounting for the difference.*” United Br. 3. The government completely ignores the italicized portion of this sentence, as though the un-italicized language captures all of United’s challenge. But United could not have been clearer: CMS is free to require that codes submitted by MA plans be supported by charts, so long as it also demands chart support for all the FFS codes it uses to calibrate its model or accounts for the different standards. United Br. 30-31, 40-42; Complaint ¶¶ 86-89.

Put another way, United’s objection is not to the idea that codes must be supported by charts—it is to the implementation of that principle in only *half* of the risk adjustment process. As United said in its opening brief (at 41), and the government nowhere denies, the requirement of chart support “applies equally to providers in *both* the MA and traditional Medicare programs.” Yet CMS does not ensure that this requirement is met in the FFS data used in MA risk adjustment. In that circumstance, and in the absence of any kind of adjustment to account for unsupported FFS codes, CMS cannot say that every unsupported MA code results in an

overpayment. *That* is United's position, and the government is wrong to recharacterize it as a categorical attack on the requirement of medical record documentation.

B. United Is Challenging The Overpayment Rule Because That Is What Renders The Payment Scheme Illegal

As a direct result of the Overpayment Rule, the current risk-adjustment payment scheme combines three distinct features that, together, render it unlawful: (1) CMS calibrates its risk-adjustment model using unaudited FFS data, including unsupported diagnosis codes; (2) CMS requires plans to delete any diagnosis code not supported by charts; and (3) in calculating overpayments, CMS does *not* employ any kind of adjuster to account for the prevalence of unsupported diagnoses in the FFS data. None of these features on its own is incompatible with a lawful system of risk adjustment. It is the *combination* that is unlawful.

United is challenging the Overpayment Rule because it was only with that Rule's promulgation that CMS embraced all three elements of that combination. The Rule was the first time CMS took the position that the submission of *any* "risk adjustment diagnosis that . . . does not have supporting medical record documentation would result in an overpayment," AR1313, and simultaneously rejected the need for an adjuster to account for unsupported codes in CMS's own traditional Medicare data, *see* AR1313-1314. *See also* MTD Order 6 ("Under the CMS Rule, any inadequately documented diagnostic code not supported by underlying medical documentation will result in an overpayment."). In other words, CMS said in the Overpayment Rule (in the above-numbered terms) that despite #1, CMS would require #2 *without* implementing #3. That precise combination is the source of United's harm, and so the Overpayment Rule is the proper target of its challenge.

The adjuster issue confirms that United is properly challenging the Overpayment Rule and is not attacking the requirement of medical record support in itself. If, as part of the

Overpayment Rule, CMS had agreed to adopt an appropriate adjuster akin to the RADV FFS Adjuster, as commenters requested, United would have had no similar basis to challenge the risk-adjustment payment scheme. That is, even a requirement of perfect coding accuracy would be unobjectionable so long as CMS accounted through an adjustment mechanism for the imperfections in the coding in the FFS data. And notably, CMS did not say in the Overpayment Rule that anything in the statutory scheme *compelled* it to reject such an adjuster; it simply made a decision to do so. *See* Overpayment Rule, AR1313-14. If the Court vacates the Overpayment Rule and holds that it is invalid for failing to include an adjuster or otherwise account for the different documentation standards for FFS and MA plan data, that will solve the illegality United has identified—and will confirm the Court’s earlier conclusion (which the government is effectively seeking to relitigate) that United’s injury is redressable. *See* MTD Order 11-13.

C. The Existence Of A Regulatory Attestation Requirement Does Not Support Or Justify The Overpayment Rule’s Violation Of The Medicare Act And Basic Rationality

In its brief, the sole justification the government offers for its interpretation of “overpayment” is 42 C.F.R. § 422.504(*I*), the regulation requiring MA plans to “certif[y] (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness” of data they submit to CMS. The government asserts that Section 422.504(*I*) is the true source of United’s injury; that this regulation already established that a plan’s diagnosis code data must be entirely error-free; and that it did so more than six years ago, so that it is too late for United to bring an APA challenge. *See, e.g.*, Gov. Br. 25-27 & n.7, 40-41 & n.11. That is meritless for several reasons. First, although CMS promulgated Section 422.504(*I*) in 1998, it has not previously interpreted it as establishing an absolute accuracy standard (as its RADV methodology demonstrates). Second, even if it had previously adopted that interpretation, and even if it did so more than six years before this suit, United could still challenge that

interpretation. And third, that interpretation would itself violate the Medicare Act.

1. Prior To The Overpayment Rule, CMS Had Not Interpreted Section 422.504(l) As Establishing An Absolute Accuracy Standard

The government is incorrect that, long before the Overpayment Rule, Section 422.504(l) already established that the submission by an MA plan of *any* unsupported diagnosis code would result in an overpayment. Section 422.504(l) certainly does not say *expressly* that any such requirement exists; on its face it does not even say anything about medical records. What it does say expressly is that plans must certify that their risk-adjustment “data” are “accurate.” But that falls far short of establishing a requirement that codes be error-free.

Although the government minimizes the idea, “accurate” is in fact an ambiguous term, and especially so in this context. As dictionaries confirm, “accurate” sometimes means “correct in all details” or “[i]n exact conformity to fact”—the meaning the government relies on here. *See* Accurate, *New Oxford American Dictionary* (3d ed. 2010); Accurate, *Webster’s II New Collegiate Dictionary* (3d ed. 2005). But it also sometimes means “[c]onforming closely to a standard,” “conforming . . . with a given standard,” or “[d]eviating only slightly or within acceptable limits from a standard.” Accurate, *Oxford English Dictionary* (3d ed. 2011); Accurate, *Webster’s II New Collegiate Dictionary* (3d ed. 2005); Accurate, *American Heritage Dictionary of the English Language* (4th ed. 2000); *see also* AHIP Amicus Br. 13-14. The existence of alternative dictionary definitions precludes the government’s claim (at 30) that CMS is just giving the term “accurate” its “plain meaning.” The attestation language is ambiguous, and does not necessarily mean that plans must attest that *every single code* in their data is supported by medical charts. The regulation could instead reasonably be read to mean that the number of unsupported codes in a plan’s data does not exceed a certain *standard* of accuracy. And one highly logical standard would be the degree of supported coding exhibited by the FFS

data that CMS uses to calibrate the risk-adjustment model and to set plan payments.

Recognizing that Section 422.504(*l*) does not by its own terms demand absolute accuracy, the government suggests that CMS “interpreted” the regulation to have this meaning in sub-regulatory guidance documents, specifically the 2001 Medicare Managed Care Manual (and subsequent iterations). Gov. Br. 26. That is incorrect. Although the Manual did indeed repeat the general requirement that codes be supported by charts, *see* 2001 Manual, § 110.4, AR5350, it by no means interpreted Section 422.504(*l*) to mean that risk-adjustment data is “accurate” only if each and every provider-submitted code is supported. To the contrary, in its discussion of what Section 422.504(*l*) demands, the Manual acknowledged that “the volume and variety of data make some inaccuracies *inevitable*.” *Id.* § 110.2, AR5349 (emphasis added). If anything, then, the Manual demonstrates that CMS did *not* interpret “accuracy” in Section 422.504(*l*) to mean absolute accuracy.¹⁶

Indeed, if the attestation mandated by Section 422.504(*l*) *did* require absolute accuracy, it is hard to see how any MA plan employee could ever sign it. MA plans submit *millions* of provider-based codes per year, and even the most conscientious healthcare providers are bound to make mistakes. As CMS recognized from the outset of the program, the presence of some unsupported codes in a plan’s data is “inevitable.” *Id.* How, then, could a plan employee ever have the “belief” that the plan’s data contained *no* unsupported codes?¹⁷ The only way to make

¹⁶ In addition to the Managed Care Manual, the government’s brief also cites a number of “CMS training materials.” Gov. Br. 26. But none of these subregulatory materials even purports to be interpreting Section 422.504(*l*). Nor does Section 422.310, which the government cites (at 32, 35) without elaboration. That regulation neither mentions Section 422.504(*l*) nor offers any gloss on “accuracy.”

¹⁷ The government might respond that a plan could sign the attestation so long as it was not aware of any *specific* codes that were unsupported. But that is still a rejection of the idea that Section 422.504(*l*) demands absolute accuracy. If the presence of some unsupported codes is inevitable, then even if a plan does not know *which* codes are unsupported, it could not have a

any sense of the attestation is to recognize that it requires plans to attest to the accuracy of their provider-submitted data by reference to a standard *other than* absolute perfection.

That understanding of Section 422.504(*I*) draws further support from CMS's own past statements about what "accuracy" means in the context of the risk adjustment program. As United explained in its opening brief (at 13-15, 36-37), CMS has rejected the idea that "accurate" coding is only a matter of whether codes are supported by charts. Instead, CMS has properly acknowledged that the accuracy of MA plan coding cannot be assessed without reference to FFS coding: "MA organizations are coding 'accurately' when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared." 2010 Rate Announcement, AR4335. By contrast, "'differences' in coding patterns, regardless of the source, would make the MA plan coding 'inaccurate' for purposes of implementing risk adjustment." *Id.* That is true "even if such coding is accurate or complete for other purposes." *Id.*, AR4336 (quoting 152 Cong. Rec. 511 (2006) (statement of Sen. Grassley)); *see also* 2014 Rate Announcement, AR4865 (acknowledging that "to ensure payment accuracy," CMS must account for "differential coding patterns in MA and FFS").

The government does not reproduce the key portions of these statements in its brief or otherwise respond to them directly. Instead it seeks to gloss over them, deeming it "sufficient to note" that these statements "did not implicitly revise 42 C.F.R. § 422.504(*I*)." Gov. Br. 35. But even if these statements did not "revise" Section 422.504(*I*), they squarely address the meaning of "accurate" in the specific context of diagnosis coding. And as noted, Section 422.504(*I*) itself does not use "accurate" in a different sense. Thus, along with the absence of any similarly considered or formal agency statements interpreting Section 422.504(*I*) to require a "perfection"

good-faith "belief" that every single code (of the millions it has submitted) is adequately supported by medical record documentation.

standard of accuracy, and the absurdity of such an interpretation in light of the “inevitable” presence of many unsupported codes, these statements further refute the idea that CMS ever interpreted Section 422.504(*I*) to require an attestation that plan data was entirely error-free.

Finally, RADV provides the strongest indication of all that Section 422.504(*I*) did not already impose an absolute accuracy standard, such that a single unsupported code results in an overpayment. While developing rules governing RADV audits in 2009-2010, CMS was confronted by commenters who pointed out the problem of applying one documentation standard (unverified codes) to the FFS data used to build the model and another (medical charts) to MA plan data submitted for payment. 2010 RADV Rule, AR2826. CMS acknowledged there was “potential merit” in this concern, *id.*, and after receiving further input concluded that an adjuster was necessary to account for the difference in documentation standards, *see* Final RADV Methodology, AR5314-15.¹⁸

It is critical to note what CMS did *not* say in response to these commenters: It did *not* say that their contentions were baseless in light of Section 422.504(*I*)’s independent requirement of absolute accuracy in coding. Instead, notwithstanding Section 422.504(*I*), CMS acknowledged that it *did* need to take account of the unsupported codes in the FFS data before it could conclude that an MA plan’s submission of unsupported codes had resulted in overpayment. CMS’s adoption of the RADV FFS Adjuster thus contradicts the notion that the agency has always interpreted Section 422.504(*I*) to require absolute accuracy. At the same time, it shows

¹⁸ The 2010 RADV Rule preamble notes that “[i]f, in fact, a diagnosis code was not justified by the enrollee’s medical condition, the higher payment amount associated with that diagnosis code would have been an overpayment.” AR2819. But CMS was not interpreting Section 422.504(*I*) there. Later in that same rule, CMS acknowledged that it might need to “first account for any error rates inherent in Medicare FFS data” before it could determine whether an overpayment existed. AR2826. And CMS agreed, in its final RADV audit methodology, that it needed to account for those unsupported FFS codes.

that CMS can address *both* its concerns about accuracy *and* MA plans' statutory right to be paid in a manner that accurately measures the risk plans take on compared to that which CMS retains.

In sum, because the first time CMS ever interpreted Section 422.504(l) to adopt an absolute, perfection-based standard of accuracy was in its defense of the Overpayment Rule, United's challenge to that standard in this case is both timely and appropriate.

2. *Even If CMS Had Previously Interpreted Section 422.504(l) To Establish An Absolute Accuracy Standard, United Can Challenge That Interpretation Here*

Even if CMS had previously interpreted Section 422.504(l) to mean that the inclusion of *any* unsupported code renders the data (and the attestation) inaccurate, that interpretation could still be challenged here.

First, as noted, the government does not and cannot claim that Section 422.504(l) on its face addresses the meaning of “accurate”—*i.e.*, whether the attestation requires absolute accuracy. The government instead says CMS *interpreted* Section 422.504(l) to impose this requirement in the 2001 Managed Care Manual and in subsequent manuals and training materials. *See* Gov. Br. 26. If that were correct, then it would not be too late for United to challenge the validity of that interpretation. That is so because these subregulatory materials were not “final agency action” subject to judicial review. *See Sierra Club v. EPA*, 873 F.3d 946, 951 (D.C. Cir. 2017) (non-binding interpretive rules are not final agency action); *see also Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 90, 99 (1995) (describing Medicare manual as an “informal . . . guideline” lacking “the force and effect of law”); Gov. Br. 43 n.10, *Regents of the Univ. of California, Inc. v. Burwell*, No. 16-5098 (D.C. Cir. Nov. 10, 2016) (noting that CMS manuals “are non-binding, interpretive guidelines issued to clarify the statute and implementing regulations” and “do not carry the full force of law and thus are not binding on the courts or agency adjudicatory bodies”). Because United could not have challenged any interpretation

contained in these materials, the APA's statute of limitations did not begin running. *See Baltimore Gas & Elec. Co. v. ICC*, 672 F.2d 146, 149 (D.C. Cir. 1982) ("A time limitation on petitions for judicial review [of agency action], it should be apparent, can run only against challenges ripe for review."); 2 Richard J. Pierce, Jr., *Administrative Law Treatise*, § 11.7, at 1055 (5th ed. 2010) ("The statute of limitations does not begin to run until the agency has taken a final action that is ripe for judicial review . . .").

In addition, even if CMS *had* interpreted Section 422.504(*l*) to require a perfection standard of accuracy as part of its formal promulgation of the regulation, United could still challenge that interpretation here. The D.C. Circuit has drawn a clear distinction between challenges to a regulation's *procedural* validity (*e.g.*, whether it went through the proper notice-and-comment process) and challenges to a regulation's *substantive* validity (*e.g.*, whether it has a rational basis and is consistent with the agency's statutory authority). *See, e.g., JEM Broad. Co., Inc. v. FCC*, 22 F.3d 320, 324 (D.C. Cir. 1994). A party challenging a regulation's procedural validity must do so within the applicable statute of limitations. *See, e.g., id.* at 324-25. But a party may challenge a regulation's substantive validity even after the statute of limitations has run if the agency relies on the regulation in taking further action that is otherwise final and reviewable. *See, e.g., Weaver v. Federal Motor Carrier Safety Admin.*, 744 F.3d 142, 145-46 (D.C. Cir. 2014). "[T]he statutory time limit restricting judicial review of agency action is applicable only to cut off review directly from the order promulgating a rule. It does not foreclose subsequent examination of a rule where properly brought before this court for review of further agency action applying it." *NLRB Union v. Fed. Labor Relations Authority*, 834 F.2d 191, 195-96 (D.C. Cir. 1987) (citation and alterations omitted). And the D.C. Circuit has held that "the sort of 'application' that opens a rule to such a challenge is not limited to formal

‘enforcement actions,’” but rather can be any subsequent “rule, regulation or order” that is otherwise reviewable. *Weaver*, 744 F.3d at 145-46. This principle makes sense: An agency may not build on top of an illegal regulation in perpetuity simply because no one challenged it when first promulgated. Nor should an agency be able to use piecemeal rulemaking to insulate from review a regulatory scheme that is illegal when viewed in its entirety. *See, e.g., United States Ass’n of Reptile Keepers, Inc. v. Jewell*, 103 F. Supp. 3d 133, 142-43 (D.D.C. 2015) (agency could not use two-step rulemaking to render challenges untimely), *aff’d*, 852 F.3d 1131 (D.C. Cir. 2017).

This principle applies fully here. In promulgating the Overpayment Rule (as in its summary judgment brief), CMS relied exclusively on Section 422.504(*l*) as a justification for rejecting commenters’ calls for an adjuster. *See* Overpayment Rule, AR1313. That reliance puts the substantive validity of CMS’s interpretation of Section 422.504(*l*) squarely in play, regardless of when CMS adopted that interpretation.

At the end of the day, the Overpayment Rule was the first occasion on which CMS declared that submission of any unsupported code would result in an overpayment, *notwithstanding* CMS’s failure to employ an adjuster to account for errors in the FFS data. That interpretation of “overpayment” violates the Medicare Act and is arbitrary and capricious. CMS cannot argue that this unlawful interpretation must be upheld because of how CMS interprets Section 422.504(*l*). An agency cannot rely on its interpretation of a *regulation* to trump the requirements of a *statute*. Nor can a court give any deference to such an interpretation. *See, e.g., City of Idaho Falls, Idaho v. FERC*, 629 F.3d 222, 230 (D.C. Cir. 2011) (“[W]e may not defer to an agency interpretation that would cause a regulation to violate the very statute the agency administers.”). This is true no matter when CMS adopted the interpretation of

Section 422.504(l) it now espouses, for “[a] regulation’s age is no antidote to clear inconsistency with a statute.” *Brown v. Gardner*, 513 U.S. 115, 122 (1994).

3. *Interpreting The “Accuracy” Certification As Imposing A Perfection Standard That CMS Does Not Apply To Its Own Data Renders The Certification Requirement Unlawful*

Interpreting the “accuracy” referred to in Section 422.504(l) to mean “entirely error free” would not merely fail to save the Overpayment Rule. In fact, it would render the certification requirement (so interpreted) itself unlawful. *See* United Br. 39-40.

At a minimum, that interpretation of the requirement would not be entitled to *Auer* deference. As explained above, CMS has only recently made clear that it embraces this “perfection” interpretation. But the Overpayment Rule holds MA plans accountable for overpayments received up to six years ago. AR1316-17. CMS’s new interpretation of Section 422.504(l) would therefore threaten “to impose potentially massive liability” on MA plans “for conduct that occurred well before that interpretation was announced.” *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-56 (2012) (denying *Auer* deference on this basis).

But not even *Auer* deference could save this interpretation of the certification requirement. To start, the requirement would lack the basic rationality all agency action must possess, because no MA plan could ever honestly attest to the perfect accuracy of its data. The existence of some unsupported codes among the millions submitted is indeed “inevitable,” so a plan could never certify in good faith that it believed in the absolute perfection of its risk adjustment data. And a regulation that demands an attestation that no member of the regulated industry can ever make is manifestly irrational.

Moreover, so interpreted, Section 422.504(l) would itself violate the Medicare Act. A requirement that regulated parties “certify” that they have done X or not done Y is the functional equivalent of requiring X or forbidding Y. Thus, forcing MA plans to attest that they have only

submitted supported codes is tantamount to requiring them to delete all unsupported codes they have identified. But for all the reasons explained earlier, requiring MA plans to delete all unsupported codes they identified *when CMS does not do the same with the FFS data (or otherwise account for the FFS errors)* violates the “same methodology” and “actuarial equivalence” requirements of the statute. Requiring plans to certify to a perfection standard of coding accuracy would simply implement *indirectly* the same thing CMS cannot implement directly: the use of different methodologies for measuring risk in the FFS and MA populations, in a way that undermines rather than ensures actuarial equivalence.

CMS’s current interpretation of the attestation requirement is inconsistent with the basic statutory requirement of accurate and valid risk adjustment. As CMS has recognized, valid risk adjustment requires that “risk scores . . . [be] consistent across both fee-for-service and Medicare Advantage settings.” 2010 Rate Announcement, AR4336. And “differences in MA coding, relative to FFS coding patterns, results in relative risk that is measured incorrectly.” 2014 Rate Announcement, AR4858. An interpretation of Section 422.504(*l*) that requires MA plans to adopt a perfection standard that CMS concededly does *not* employ in the FFS setting contravenes these key principles of valid risk adjustment.

But there is no need to read Section 422.504(*l*) as imposing an irrational, impossible, and unlawful requirement. There is a straightforward reading that harmonizes the regulatory scheme and reads the attestation in light of its purpose: So long as CMS continues to calibrate its risk-adjustment model with unaudited FFS data, then a MA plan’s data are “accurate” when they conform to the standard of accuracy exhibited by the FFS data. After all, as CMS agreed only months before the Overpayment Rule, “[a]s long as we have a model based on FFS costs and diagnoses patterns, differences in MA coding, relative to FFS coding patterns, results in relative

risk that is measured incorrectly.” 2014 Announcement, AR4858.

D. United Is Not Required To Challenge The Risk Coefficients Directly

At several points, the government suggests that United is effectively complaining that CMS’s risk coefficients are too low and that therefore United should have challenged the coefficients themselves, instead of the Overpayment Rule. *See* Gov. Br. 36, 40. That is wrong.

To start, United is not contending that the values of the risk coefficients are inherently “wrong.” Risk coefficients calculated with unaudited FFS data *can* be used in a way that is perfectly consistent with actuarial equivalence. Indeed, if the rate of unsupported codes in MA plans’ provider-submitted data is similar to that in the FFS data, then applying those coefficients to MA plans’ unaudited claim data would result in accurate payments. United’s complaint is not with the coefficients *per se*; it is with using coefficients calculated in this manner *and also* requiring MA plans to delete *all* codes they identify are unsupported, without employing any kind of adjuster.

Moreover, directly challenging the coefficients as too low is not actually consistent with United’s view of how best to implement a lawful risk adjustment system. Although United has conceded that it would be legal to use “a chart-based standard for calculation of risk scores in the traditional Medicare population,” United Br. 30, which would result in higher coefficients, United does not think that is the most efficient of the legally permissible options. Instead, United believes it makes more sense to continue using a code-based standard to calculate risk scores but to adopt an adjuster to ensure that an “MA plan’s rate of unsupported codes [is no] higher than that of traditional Medicare.” *Id.* at 31; *see also* AHIP Amicus Br. 7.

More fundamentally, even if challenging the coefficients themselves might be one way of addressing the unlawful payment system CMS has built, nothing compels United to make that challenge. If an agency takes two final actions, the combination of which is unlawful, there is no

principle of administrative law that requires aggrieved parties to challenge only one or only the other. The government certainly cites no authority for any such proposition. It is careful, in fact, to say only that United “can” challenge the coefficients, not that it must. Gov. Br. 36, 40.

E. Vacatur Of The Overpayment Rule Will Provide Redress

Before the Overpayment Rule, CMS never had authoritatively construed the new provision on the identification and return of “overpayments” Congress added to 42 U.S.C. § 1320a-7k(d) in 2010. This Court therefore unquestionably has authority to vacate CMS’s unlawful interpretation that an MA plan has received an “overpayment” within the meaning of 42 U.S.C. § 1320a-7k(d) any time any of its diagnosis codes is unsupported, which the Plan must return in order to avoid liability.¹⁹ Doing so will eliminate an (unlawful) regulatory obligation with which United would otherwise be required to comply at pain of significant liability.

The government suggests that this *partial* redress is not sufficient because even if the Overpayment Rule were set aside, plans would still be required to attest to the accuracy of their data under 42 C.F.R. § 422.504(*I*). As United already has described, the attestation that regulation requires is entirely consistent with United’s arguments here. To the extent that CMS has interpreted it to impose a “perfection” standard, this Court can redress the illegality that that interpretation creates, too. And in any event, a “plaintiff satisfies the redressability requirement when [it] shows that a favorable decision will relieve a discrete injury to [it]self. [It] need not

¹⁹ CMS has never denied that this *is* its view of the law. This is not a case, then, where a plaintiff is trying to vacate an agency’s vague or tentative comments on a legal issue. *Cf. Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) (finding agency’s “conditional” and “equivocal” statements unreviewable). The government’s brief could not be clearer that this is CMS’s considered, authoritative interpretation of “overpayment,” and that this interpretation is set forth in “the preamble to the Overpayment Rule.” Gov. Br. 24. This Court may vacate that interpretation, without regard to whether CMS placed it in the codified text of 42 C.F.R. § 422.326. *See, e.g., Fertilizer Inst. v. U.S. EPA*, 935 F.2d 1303, 1307-10, 1313 (D.C. Cir. 1991) (vacating interpretation contained in final rule preamble); *Reptile Keepers*, 103 F. Supp. 3d at 139 n.1 (noting reviewability of agency’s statutory interpretation in regulatory preamble).

show that a favorable decision will relief [its] *every* injury.” *Larson v. Valente*, 456 U.S. 228, 244 n.15 (1982).

IV. THE GOVERNMENT MAKES NO EFFORT TO RECONCILE THE OVERPAYMENT RULE’S INTERPRETATION OF “IDENTIFIED” WITH THE STATUTORY TEXT

United’s opening brief showed (at 42-45) a second, independent aspect of the Overpayment Rule that is unlawful: its impermissibly expansive definition of “identified overpayment.” The relevant statutory provision requires an overpayment to be reported and returned within “60 days after the date on which the overpayment *was identified*.” 42 U.S.C. § 1320a-7k(d)(2) (emphasis added). But in the Overpayment Rule, CMS required reporting and return as soon as an overpayment “*should have*” been identified, regardless of whether it actually had been. 42 C.F.R. § 422.326(c) (emphasis added). As this Court recognized at the motion to dismiss stage, by creating liability on the basis of what a party should have known, the Rule imposes a negligence standard with respect to knowledge. MTD Order 13 (noting that Rule would allow FCA liability to be proved “by negligence alone”). And as United explained in its opening summary judgment brief, a negligence standard is clearly inconsistent with the statutory text.

The government makes no effort to defend the Rule insofar as it enacts a negligence standard, contending instead—without acknowledging what this Court said in its earlier opinion—that the Rule reaches only reckless disregard and deliberate ignorance. Gov. Br. 44. But that retreat from the broad meaning of the Rule’s actual language is not sufficient, because even narrowed to the recklessness standard that the government now espouses, the Rule is still unlawful.

First, the plain text of the statute requires *actual* knowledge. The 60-day clock starts running on the date an overpayment “was identified.” 42 U.S.C. § 1320a-7k(d)(2). Dictionaries

confirm the commonsense notion that something has been “identified” when its identity is determined or established—not when someone recklessly *fails* to determine or establish its identity. *See* United Br. 42-43. Nor would any English speaker use the word that way. A witness has not “identified” a suspect just because she *should* recognize him. The relevant portion of the government’s brief, however, is totally devoid of any analysis of the statutory text—and of any response to United’s textual arguments. *See* Gov. Br. 43-45. If the government had any textual argument to make, its opposition brief was the appropriate time to do so; it should not be permitted to make new arguments in its reply to which United cannot respond. *See, e.g., Saunders v. Mills*, 172 F. Supp. 3d 74, 93 n.10 (D.D.C. 2016) (Collyer, J.).

Second, recklessness is the one standard we know Congress considered *and rejected*. As United explained in its brief, the initial version of the statute used the word “known” and the FCA definition of that term, which includes reckless disregard and deliberate ignorance. United Br. 32. But Congress instead adopted a different version of the statute that substituted “identified” for “known.” *Id.* “Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.” *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987). “Identified” can therefore not possibly embody the same recklessness standard as the rejected, defined term “known.” The government’s brief ignores this point, too.

There also was good reason for Congress to reject recklessness and require actual knowledge. The purpose of this statutory provision is to pinpoint the moment in time at which failure to return an overpayment triggers liability under the FCA. The penalties under the FCA, a fraud statute, are severe: treble damages, statutory penalties, and even potential exclusion from the Medicare program. Given the potential severity of the consequences of failing to return an

overpayment on time—and the fact that those consequences flow from *inaction*, not from affirmative conduct—it is critical that MA plans be able to determine with certainty when the 60-day clock starts to run. A plan can have little doubt about when it *actually* identified an overpayment, but the point at which it *would* have identified an overpayment had it not exhibited reckless disregard will be anything but clear.

At the end of the day, the only defense the government offers is that the Rule’s definition of “identified overpayment” “merely reiterates an obligation” already imposed by 42 C.F.R. § 422.504(*l*) and § 422.503(b)(4)(vi). Gov. Br. 43. That is wrong. As the Court already held, this aspect of the Rule “imposes (for good reason or not) new obligations.” MTD Order 13. The Rule specifies the degree of knowledge of an overpayment sufficient to trigger the ACA’s 60-day clock—an issue neither Section 422.504(*l*) nor Section 422.503(b)(4)(vi), both of which pre-date the ACA, even purports to address.

But even if that characterization otherwise were accurate, it would still be no defense at all. “It is a basic tenet that regulations, in order to be valid, must be consistent with the *statute* under which they are promulgated.” *Decker v. Nw. Env’tl. Def. Ctr.*, 568 U.S. 597, 609 (2013) (emphasis added) (citation omitted). Consistency with other regulations is not enough. If a statute requires all widgets to be painted red, an agency cannot implement that statute with a regulation requiring all widgets to be painted blue—regardless of what the agency’s other regulations say. *See, e.g., Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 11 (D.C. Cir. 2002) (“FERC cannot rely on one of its own regulations to trump the plain meaning of a statute.”). Here, the statute sets forth an *actual* knowledge standard—and neither the negligence standard indicated by the Rule’s text nor the recklessness standard to which the government has now retreated is consistent with that requirement.

CONCLUSION

MA plans agree to assume the risk of insuring Medicare beneficiaries—costs that CMS would otherwise incur. In return, as the government now concedes, those plans are statutorily entitled to payments that equal the amounts CMS would have expected to expend in insuring those identical beneficiaries through traditional Medicare. By measuring the health status of MA beneficiaries using stricter criteria than it applies in calculating CMS’s own population’s risk scores, the Overpayment Rule violates this mandate and confers a windfall on CMS.

The Rule represents an unprincipled “mix and match” approach to risk adjustment comparisons. It requires plans to delete any *unsupported* codes they have identified in their data, using charts as the measure of validity for this purpose because that is to CMS’s financial advantage. Yet when it comes to a plan’s *supported* codes, CMS will continue to calculate those payments based on its own unverified claims data from traditional Medicare, not codes supported by charts—because the lower resulting payments (and avoidance of auditing requirements) are to CMS’s financial benefit for that purpose. This “heads I win, tails you lose” methodology violates the statute and is arbitrary and capricious.

The government seeks (at 39) to distract from that problem by attacking some of the potential *solutions* to it. As with its account of United’s position, however, its description of those solutions erects straw men rather than grappling with what United really has proposed—an adjuster akin to the one that CMS already has recognized is both necessary and feasible in RADV audits. Just as government auditors depend on CMS to tell them how to compare an MA plan’s unsupported diagnosis codes to CMS’s own unsupported diagnoses in order to determine whether an “overpayment” has been made in that context, *see* Final RADV Methodology, AR5314-15, so too would MA plans rely on CMS to provide them with the data and process necessary to determine “overpayments” in this context. In all likelihood, an offset would

demonstrate that the MA plan had not been overpaid at all, because MA plans generally are passing along diagnosis codes submitted by the same medical professionals who provide the codes for traditional Medicare beneficiaries, and CMS has never found that they make more errors when coding for MA plans than for traditional Medicare. *See* 2010 Rate Announcement, AR4337. If some MA plans do engage in practices to increase the rate of *unsupported* codes over and above the “inevitable” rate reflected in CMS’s own data, an adjuster plainly would allow CMS to recover all of the overpayments that activity generates. That is hardly an impractical or absurd solution. And at bottom, CMS cannot complain about the complexity of solving a problem it itself created by utilizing different criteria to compare the two populations; if CMS either measured both populations based on unaudited claims data, or first validated its own data with medical records before setting payment rates, no adjuster would have been necessary in the first place.

Put simply, the Overpayment Rule is unlawful. It *inevitably* results in MA plans being paid less to insure a given population than CMS would have expected to expend insuring that same population through traditional Medicare, and reads “identified” to mean “should have identified,” an interpretation so outlandish the government does not even bother to defend it. Those legal errors—and the real-world harms they impose on the MA system—should not be allowed to stand, and should instead be remedied by an order that is, contrary to the government’s assertions, well within this Court’s authority.

January 18, 2018

Respectfully submitted,

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EXHIBIT 40

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE)
COMPANY, *et al.*,)

Plaintiffs,)

v.)

ALEX M. AZAR II, in his official)
capacity as Secretary of Health and)
Human Services, *et al.*,)

Defendants.¹)

Case No. 16-cv-157 (RMC)

**DEFENDANTS' REPLY IN SUPPORT OF THEIR
CROSS-MOTION FOR SUMMARY JUDGMENT**

¹ Pursuant to Fed. R. Civ. P. 25(d), Alex M. Azar II is substituted as a defendant in his official capacity as Secretary of Health and Human Services.

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INTRODUCTION

Turn back to early 2010: before the Affordable Care Act, long before the Overpayment Rule. Medicare Advantage insurers are paid less for covering healthier people, and more for covering sicker ones. So that this system of risk adjustment can function properly, insurers are required to submit diagnosis data supported by medical record documentation. The Secretary audits some of the data submitted, to confirm that the diagnoses claimed are documented in medical records. And those diagnoses are fed into a risk adjustment model calibrated on the best data available: the costs and characteristics of traditional, fee-for-service Medicare beneficiaries, as recorded in the Secretary's claims database. By 2010, these elements of the risk adjustment system—diagnoses supported by medical record documentation, audits to ensure compliance with that requirement, and a model calibrated on fee-for-service data—had been in place for years.

Now turn to 2014. The Affordable Care Act has required Medicare Advantage insurers to promptly return any “overpayment” they identify; the Overpayment Rule has echoed the statutory definition of that term as funds to which an insurer is “not entitled.” 42 U.S.C. § 1320a-7k(d)(4)(B); 42 C.F.R. § 422.326(a). “[T]he long-standing risk adjustment data requirement that a diagnosis submitted . . . for payment purposes must be supported by medical record documentation” is still in place. Policy and Technical Changes to the Medicare Advantage Program, (“Overpayment Rule”), 79 Fed. Reg. 29,844, 29,926 (May 23, 2014) (AR 1318). The Secretary still audits some of the data submitted, to ensure compliance with that long-standing requirement. And the risk adjustment model is still calibrated on fee-for-service data. None of these features was altered by the adoption of the Overpayment Rule—and none of them would be altered if that Rule were vacated here.

United believes elements of the Medicare Advantage risk adjustment system that have been in place for nearly twenty years are, in combination, unlawful. It argues that the requirement of medical record documentation is incompatible with a risk adjustment model calibrated on the Secretary's database of fee-for-service claims, absent some adjustment to account for that supposed incompatibility. Opp. & Reply at 28. To find for United, this Court would need to write an opinion that said, in sum, "The Overpayment Rule is invalid because the Secretary has been operating an unlawful risk adjustment system since the inception of the Medicare Advantage program."

Of course, United does not put it precisely that way. Instead, United speaks of "the risk adjustment payment system CMS embraced in the Overpayment Rule," *id.* at 1, as though that system was altogether different from what came before. It was not. Before the Overpayment Rule, Medicare Advantage insurers were entitled to payment for the marginal costs associated with certain diseases documented in the medical records of their beneficiaries, as calculated by the Secretary's risk adjustment model. After the Overpayment Rule, insurers were entitled to the exact same payments—nothing more, and nothing less. United's alternative history, in which the Overpayment Rule unlawfully deprived insurers of their long-standing right to claim payment for the costs associated with unsupported diagnoses, cannot survive an encounter with the administrative record. Insurers simply never had that right.

ARGUMENT

An "overpayment" is a payment to which a Medicare Advantage insurer "is not entitled." That is what the Medicare statute says, 42 U.S.C. § 1320a-7k(d)(4)(B), and it is what the Overpayment Rule says, 42 C.F.R. § 422.326(a). United does not take issue with that definition.

The preamble to the Overpayment Rule gave an example of a payment to which an insurer is not entitled: a payment made on the basis of a diagnosis that is not documented in a patient's medical records. The preamble explained that "a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment," pursuant to "the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation." 79 Fed. Reg. at 29,921–22. This is the statutory interpretation that United chiefly challenges here.¹ Opp. & Reply at 40 (asking the Court "to vacate CMS's unlawful interpretation that an MA plan has received an 'overpayment' within the meaning of 42 U.S.C. § 1320a-7k(d)" whenever it claims payment on the basis of a diagnosis that "is unsupported" by medical record documentation).

In arguing that this interpretation is incorrect, and that a payment on the basis of diagnoses absent from a beneficiary's medical records is not necessarily an overpayment, United makes two distinct claims. First, it argues that the preamble to the Overpayment Rule altered the risk adjustment system in place when the Rule was promulgated. Under that pre-existing system, it says, insurers were actually permitted to claim and retain payment for diagnoses that were not documented in the medical records of their beneficiaries, so long as they did not claim such payments too often. On this account, all diagnoses submitted for payment were considered valid so long as *a certain percentage of them* were supported by medical record documentation. The

¹ United quibbles that it "has never challenged the agency's authority to require diagnosis codes to be supported by medical charts *in itself*," nor made a "*categorical* attack on the requirement of medical record documentation." Opp. & Reply at 27, 28 (emphases added). But there is no question that United is challenging the existing requirement of medical record documentation as actually implemented by the Secretary, even if the insurer concedes that the requirement could, theoretically, be lawfully implemented in some other way.

fraction of claims requiring medical record support was, United says, established by the proportion of supported diagnoses in the claims of fee-for-service Medicare beneficiaries. Opp. & Reply at 2 (arguing that, “[b]efore the Overpayment Rule,” “a plan that had submitted unsupported codes would still be entitled to payment . . . if its data were accurate when compared to the rate of medical chart support in CMS’s own traditional Medicare data”). United says that the statutory interpretation articulated in the preamble to the Overpayment Rule is invalid because it ignores (and thereby purports to take away) an insurer’s right to claim and retain payment for some number of diseases that their beneficiaries appear not to have.

United’s second, distinct argument is that, whatever the effects of the Overpayment Rule, the risk adjustment system described in its preamble is unlawful (contrary to statute, or internally inconsistent to the point of being arbitrary) and should therefore be vacated. United often weaves these arguments together—saying, for example, that the pre-existing payment system must have been as United says it was, because it would have been unlawful for the system to be otherwise, and the Secretary’s actions should be interpreted in a way that makes them lawful—to conclude that the Overpayment Rule is to blame for any flaws now present in the payment system. *See, e.g.*, Opp. & Reply at 37–38. But the insurer’s arguments are distinct, and must be distinguished if the Court is to make sense of this challenge to the Overpayment Rule.

United’s first claim is clearly justiciable here. If the Overpayment Rule altered the risk adjustment payment system in place at the time the Rule was promulgated, defining certain payments that insurers were then entitled to retain as “overpayments” which they must now return, this Court can certainly say so. But United cannot challenge the Overpayment Rule on the grounds that “the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation,” 79

Fed. Reg. at 29,921–22, though unchanged by the Rule, has always been unlawful. Unless the Overpayment Rule imposed or altered the requirement of medical record documentation, or rendered it newly illegal, that requirement cannot be challenged here. The first question for the Court, therefore, is what the parameters of the payment system were when the Overpayment Rule was promulgated.

I. Long before the Overpayment Rule was promulgated, medical record documentation was required for all diagnoses submitted for payment, and the risk adjustment model was calibrated on a database of fee-for-service claims.

The Medicare Advantage payment system has two parts: a standard for the submission of diagnosis data, *see* Gov’t MSJ at 8–13, and a model to translate that data into expected costs, *see id.* at 14–18. The Overpayment Rule did not change either one.

A. The requirement of medical record documentation has been clearly established for almost twenty years.

When are Medicare Advantage insurers entitled to claim payment for the costs associated with a particular disease? Long before the Overpayment Rule was promulgated, the answer was perfectly clear: Medicare Advantage insurers may claim payment for the costs associated with insuring a beneficiary who has a particular disease when that diagnosis is documented in the person’s medical records. That has always been the rule, and it remains the rule today—as United has acknowledged in other forums, as the Ninth Circuit has correctly held, and as the administrative record amply demonstrates.

In June 2013, almost a year before the Overpayment Rule was promulgated, United told a federal district court that “CMS’ regulations make clear that so long as a particular diagnosis is adequately documented by a . . . medical record, the diagnosis will be deemed valid.” Mot. to Dismiss, *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 2:09-cv-5013, ECF No.

114 at 7 (C.D. Cal. filed June 26, 2013); *see id.* at 15–16 (describing diagnosis codes unsupported by medical record documentation as “erroneous” and “not documented appropriately”). On appeal the following year, it told the Ninth Circuit that “CMS regulations deem a diagnosis code proper if it is supported by a . . . medical record.” Joint Answering Br., *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746, Doc. 39 at 36 (9th Cir. filed June 2, 2014). And the Ninth Circuit agreed with United that “CMS requires medical diagnosis codes to be supported by a medical record” when they are submitted for payment by Medicare Advantage insurers.² *United States ex rel. Swoben v. United Health Ins. Co.* (“*Swoben*”), 848 F.3d 1161, 1176 (9th Cir. 2016).

What United said and the Ninth Circuit held in *Swoben* is correct: “Each diagnosis code submitted” for payment “must be supported by a properly documented medical record.” *Id.* at 1168. As the preamble to the Overpayment Rule notes, the “risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation” is “long-standing.” 79 Fed. Reg. at 29,921–22. It was clearly established years before the Overpayment Rule was promulgated.

The administrative record contains considerable evidence of this long-standing requirement, which has appeared in every edition of the Medicare Managed Care Manual.³ United protests that the Manual does not itself carry the force of law, Opp. & Reply at 34, but the insurer does not—and could not—deny that it agreed to comply with the Manual as a condition of

² In more than 120 pages of collective briefing, neither United nor the amicus found any space to discuss United’s representations in *Swoben* or the Ninth Circuit’s holding there, which the Secretary mentioned repeatedly in his opening brief.

³ *See* 2001 Manual, § 110.4 (AR 5350) (explaining that diagnosis data must “be substantiated by the hospital’s medical record”); 2004 Manual, § 111.1, Ex. 30 (AR 5671) (providing that “a medical record must substantiate all diagnostic information provided to CMS”); 2013 Manual, § 40 (AR 5678) (“All diagnosis codes submitted must be documented in the medical record . . .”).

participation in the Medicare Advantage program. *See* Standard Contract with Eligible Medicare Advantage Organization, Article II, Section A (AR 11801) (participating insurer agrees to operate Medicare Advantage plans “in compliance with the . . . Medicare Managed Care Manual”); *see* Gov’t MSJ at 11, 26 (discussing insurers’ contractual obligation to comply with the Manual).

CMS training materials regularly reminded insurers about the requirement of medical record documentation.⁴ Although United dismisses these training documents as “subregulatory materials,” *Opp. & Reply* at 31 n.16, they were clear restatements of the documentation standard with which every Medicare Advantage insurer had already agreed to comply. *See* Standard Contract, Article II, Section A (AR 11801) (insurer will operate Medicare Advantage plans “in compliance with” CMS “policies”).

The Ninth Edition of the Clinical Modification of the International Classification of Diseases (ICD-9-CM), “published by the United States Government” and “required for reporting diagnoses and diseases to all . . . [CMS] programs,” ICD-9-CM Preface at 1 (AR 11375), also clearly stated the requirement of medical record documentation.⁵ ICD-9-CM Coding Guidelines

⁴ *See* 2003 Regional Risk Adjustment Training For Medicare+Choice Organizations (“2003 Risk Adjustment Training”), Participant Guide at 4-1 (AR 5821) (emphasizing that Medicare Advantage insurers “must submit risk adjustment data that are substantiated by the patient’s medical record”); 2003 Risk Adjustment Training, Resource Guide at 18 (AR 6488) (repeating the programmatic requirement that “a medical record must substantiate all diagnostic information provided to CMS”); 2004 Risk Adjustment Training, Participant Guide at 5-2 (AR 7235) (reminding insurers that “[t]he source medical record documentation that supports each coded diagnosis must be obtainable and demonstrate adherence to official coding guidelines”); 2006 Risk Adjustment Training, Participant Guide at 5-2 (AR 8702) (same); 2012 Regional Technical Assistance, Risk Adjustment Participant Guide at 2-5 (Aug. 7, 2012) (AR 10899) (continuing to emphasize that “[d]iagnoses must be supported by appropriate medical record documentation”).

⁵ The Secretary adopted the ICD-9-CM, “including The Official ICD–9–CM Guidelines for Coding and Reporting,” 45 C.F.R. § 162.1002(a)(1), as the official methodology for diagnosis coding from October 2002 until October 2015, when it was superseded by the Tenth Edition, known as ICD-10-CM. *See id.* § 162.1002(a)(1)(i), (b)(1), (c)(2)(i).

at 5 (AR 11385) (explaining “[t]he importance of consistent, complete documentation in the medical record,” without which accurate diagnosis coding “is a difficult, if not impossible, task”); *see also* Quick Facts, ICD-9-CM, June 2003 (AR 5952) (noting that “[t]he medical record must justify the diagnosis” and “[t]he diagnosis reported must match the coding submitted by the hospital/physician as documented in the medical record”). The Secretary noted each insurer’s obligation to comply with this national coding standard. Gov’t MSJ at 27; *see* 42 C.F.R. § 422.310(d)(1) (requiring the submission of risk adjustment data that conform “to all relevant national standards”). United chose not to address it in reply.⁶

Ultimately, the requirement of medical record documentation derives from a regulation in place since 1998, which requires diagnoses submitted for payment to be “accurate” and “truthful.” *See* 42 C.F.R. § 422.502(l) (1998); *id.* § 422.504(l) (2005). United suggests that “accurate” is an ambiguous term that can be taken to mean something like “in conformity with a given standard.” Opp. & Reply at 30. Even if that were so (but United’s interpretation does not account for “truthful”) it merely prompts the question of what the given standard is. The administrative record, as discussed at length in the Secretary’s opening brief and summarized above, makes clear that the governing standard—the standard to which United and every Medicare Advantage insurer agrees to conform as a condition of its participation in the program—is medical record documentation. United does not even attempt to explain how these many agency statements of the long-standing requirement of medical record documentation are consistent with its position in this case.⁷

⁶ In its opening brief, United acknowledged the ICD-9-CM “guidelines stating that diagnosis codes should reflect diagnoses documented in medical charts,” United MSJ at 41, but suggested that Medicare Advantage insurers were not bound by them because traditional Medicare providers do not comply with them perfectly.

⁷ United suggests that it can challenge the lawfulness of 42 C.F.R. § 422.504(l), but the Overpayment Rule did not “alter the status quo” with respect to that regulation, and so did not

United and its amicus instead make several attempts to show that a different documentation standard was in place before the Overpayment Rule was promulgated. First, United points to several CMS statements about the risk adjustment model. In two instances, CMS responded to insurers' suggestions that it could only make a particular adjustment to its payment model—a “coding intensity” adjustment—if it found that insurers had been submitting unsupported diagnosis codes. CMS explained that aggressive coding on the part of Medicare Advantage insurers was enough to support such an adjustment, even if all of the diagnosis codes submitted by those insurers were properly supported by medical record documentation. *See* 2009 Rate Announcement at 19–20 (AR 4274–75); 2010 Rate Announcement at 20–21 (AR 4335–36). In another instance, CMS explained that it had removed certain disease categories from the risk adjustment model, with a focus on diseases that were reported more frequently by Medicare Advantage insurers. 2014 Rate Announcement at 30 (AR 4858). In each of these cases, CMS made clear that it was attempting to account for some insurers' practice of seeking out and claiming additional payments for certain diagnoses. In none of them did CMS suggest that the Secretary was revising the long-standing requirement of medical record documentation for each diagnosis submitted for payment. That requirement, which had been in place for years, continued to be emphasized. *See, e.g.,* 2013 Manual, § 40 (AR 5678); 2012 Regional Technical Assistance, Risk Adjustment Participant Guide at 2-5 (AR 10899).

United also argues that the Secretary knew that Medicare Advantage insurers would be incapable of complying with a requirement of medical record documentation, and so could not have meant to impose one. *Opp. & Reply* at 31–32. United notes that insurers “submit *millions*

“restart the statute of limitations” for challenges to it. *Mendoza v. Perez*, 754 F.3d 1002, 1018 (D.C. Cir. 2014) (citing *Impro Prods., Inc. v. Block*, 722 F.2d 845, 850 & n.9 (D.C. Cir. 1983)).

of [diagnoses] per year” and are therefore “bound to make mistakes.” *Id.* at 31. The Secretary is well aware of this, and has never intended for “simple mistakes” to “result in sanctions.” 65 Fed. Reg. at 40,268 (AR 2006). Indeed, the purpose of the “best knowledge, information, and belief” certification standard is to avoid that very result. 42 C.F.R. § 422.504(*l*). As the Ninth Circuit has explained, “§ 422.504(*l*) has always required due diligence and good faith,” but not absolute perfection. *Swoben*, 848 F.3d at 1169. “Medicare Advantage organizations ‘cannot reasonably be expected to know that every piece of data [they submit] is correct,’” *id.* (quoting 65 Fed. Reg. at 40,268 (AR 2006)), but they are nonetheless responsible “for making good faith efforts to certify the accuracy, completeness, and truthfulness” of that data, 65 Fed. Reg. at 40,268 (AR 2006). Having done so, an insurer can lawfully certify that, to the best of its knowledge, the diagnoses being submitted for payment are accurate and truthful—even if the insurer knows that, probabilistically speaking, the data are likely to include some errors that have escaped detection.

United suggests that the Secretary has only two choices: unless he punishes every insurer that does not achieve absolute accuracy in the diagnoses submitted for payment, he must admit that medical record documentation is not actually required. *Opp. & Reply* at 31–32 & n.17. But the Secretary is not limited to such drastic options. As long as a Medicare Advantage insurer has a valid compliance program in place (as required by 42 C.F.R. § 422.503(b)(4)(vi) and the express terms of its contract with the Secretary) and works in good faith to ensure that the diagnoses submitted for payment are supported by medical record documentation, innocent errors will not be penalized—although they still must be corrected if they ever come to light. Nothing about this system undermines the deference due to the Secretary’s interpretation of “accuracy” and “truthfulness” in data submissions, 42 C.F.R. § 422.504(*l*), as requiring medical record documentation of each diagnosis submitted for payment. *Cf. Opp. & Reply* at 37 (suggesting that

deference to the Secretary's interpretation is inappropriate here "because no MA plan could ever honestly attest to the perfect accuracy of its data").⁸

Finally, United suggests that the Secretary's audit methodology demonstrates that, before the Overpayment Rule, insurers were permitted to claim and retain payment for some number of diagnoses unsupported by medical record documentation. The audit methodology will be discussed below, but the short answer is that it did not make any change to the terms on which insurers were entitled to claim payment. *See* 74 Fed. Reg. at 54,674 (explaining that, in the RADV audits, diagnoses "reported by MA organizations for their enrollees" are "confirmed via medical record documentation").

United often asks when an insurer can be required to delete a previously-submitted diagnosis code, and return the associated payment, rather than asking when an insurer is authorized to submit a claim for payment in the first place. *See, e.g.,* United MSJ at 21 (arguing that an insurer cannot be required "to delete any . . . diagnosis code (and forgo the payment such a code would generate)" simply because the insurer "knows [that the diagnosis] lacks support in the patient's

⁸ The Secretary's interpretation of this regulation "must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). United argues that the Secretary's interpretation violates two statutory provisions, but that is not so for the reasons discussed in the Secretary's brief at 28–32, and below at 19–24. The amicus raises three arguments that United did not see fit to pursue, asserting that the interpretation 1) is inconsistent with the regulation itself, 2) would impose impermissibly retroactive liability, and 3) does not reflect the considered judgment of the agency. AHIP Reply at 15–16. As explained above, even though "accurate" means "supported by medical record documentation," a certification that data is "accurate" to the "best knowledge" of the submitter is not an affirmation that literally every piece of data is known to be accurate, but rather that reasonable steps have been taken to ensure accuracy and no known inaccuracies have been transmitted. No retroactive liability is imposed by this interpretation, as insurers have been obliged to submit only diagnoses supported by medical record documentation since the beginning of the Medicare Advantage program. And the considered judgment of the agency is reflected in its many statements and restatements of that requirement. *See supra* at 5–8.

medical charts”). That framing elides away each insurer’s responsibility for the accuracy of the data it submits, or allows to be submitted on its behalf. If one asks not “When must diagnoses be deleted?” but rather “When may diagnoses be reported?”, it becomes clear that medical record documentation is the only manageable standard. And even if it were not, it is the standard that the Secretary has reasonably chosen since the beginning of this program.⁹

B. The risk adjustment model has always been calibrated on fee-for-service data.

United does not argue that the Overpayment Rule changed the risk adjustment model used to convert diagnoses into payments. Since it was first implemented in 2004, that model has been calibrated on the costs and characteristics of traditional, fee-for-service Medicare beneficiaries, as recorded in the Secretary’s claims database. Every year, the Secretary publishes tables setting forth the coefficients associated with each diagnosis included in the model, and each set of demographic characteristics. As the Secretary explained in his opening brief, a risk score for each Medicare Advantage beneficiary is then computed by summing the coefficients for that beneficiary: one for his demographic characteristics (age, sex, and so on) and one for each relevant diagnosis. This is common ground between the parties.

II. The RADV audit process ensures compliance with the requirement of medical record documentation; it does not alter that requirement.

Since the beginning of the Medicare Advantage program, the Secretary has performed audits to promote compliance with the requirement of medical record documentation. As early as

⁹ The Secretary strenuously objects to the suggestion by the amicus that limiting health insurers to payments for costs associated with the diseases actually recorded in the medical charts of their beneficiaries is “not a workable system.” AHIP Br. at 17. United concedes that such a documentation standard is among “the legally permissible options” available to the Secretary. Opp. & Reply at 39. That concession binds United, whether or not the amicus agrees.

1999, CMS was undertaking “payment validation activity” that was “intended to improve the accuracy of the risk adjustment data . . . submitted to CMS for payment.” Policy and Technical Changes to the Medicare Advantage Program, 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009) (AR 2409). These “risk adjustment data validation (RADV) audits” sought “to confirm the presence of risk adjustment conditions (that is, diagnoses [relevant to risk adjustment]) as reported by MA organizations for their enrollees and confirmed via medical record documentation.” *Id.*; see Policy and Technical Changes to the Medicare Advantage Program, 75 Fed. Reg. 19,678, 19,746 (AR 2823) (Apr. 15, 2010) (noting that “the process of independently reviewing medical records to validate risk adjustment data submitted by MA organizations for payment purposes has been established and operational for more than 10 years”).

These audits are “aimed at validating that a particular Medicare beneficiary indeed has the medical condition for which the MA organization has been paid.” 75 Fed. Reg. at 19,748 (AR 2825); see 42 C.F.R. § 422.310(e) (requiring insurers “to submit a sample of medical records for the validation of risk adjustment data”). This validation is achieved by confirming “the existence of clear, unambiguous diagnostic information in a beneficiary’s medical record” that “provides the written support for the diagnosis that was made.” *Id.* at 19,749 (AR 2826). “Verifiable medical record documentation is the key to accurate payment and successful data validation” through the audit process. 74 Fed. Reg. at 54,674; see also Pope, Risk Adjustment of Medicare Capitation Payments at 129 (AR 11867) (“The auditing standard that CMS has promulgated for reporting of physician office diagnoses is that a physician has established the diagnosis in the medical record . . .”).

To state the obvious: the risk adjustment data validation audits provide strong evidence, if more were needed, of the centrality of the medical record documentation standard to the Medicare

Advantage payment system. The whole point of the data validation audits is that diagnoses submitted for payment are “valid” if they are supported by medical record documentation, and “invalid” if they are not. *Cf.* Overpayment Rule, 79 Fed. Reg. at 29,921 (AR 1313) (explaining that a “diagnosis that has been submitted for payment” would be “found to be invalid” if it did “not have supporting medical record documentation”). RADV audits, “intended to improve the accuracy of the risk adjustment data . . . submitted to CMS for payment,” 2009 Proposed Rule, 74 Fed. Reg. at 54,674 (AR 2409), are powerful proof that, in the Medicare Advantage program, “accuracy” has always been synonymous with “medical record documentation.”

For years, very little money was recouped through the audit process. *See id.* A relatively small number of records was examined in each audit and, at most, the insurer was required to return any invalid payments discovered there. But in 2008, the Secretary announced that he would not simply use the audit process to correct the payments made for covering particular beneficiaries, as he had done up to that point, but would instead calculate a contract-level payment error rate and make significantly larger recoveries. 2009 Annual Announcement, AR 4277. Some insurers suggested that this payment error rate should be reduced to account for errors in the fee-for-service data on which the risk adjustment model was calibrated. The Secretary ultimately agreed to reduce the sums recouped in the RADV audits by applying a “fee-for-service adjuster” (FFS Adjuster), which has not yet been calculated.

The Secretary has made it clear that the FFS Adjuster is simply a mechanism that reduces audit recoveries, an “offset to the preliminary recovery amount.” AR 5314. It does not, and was never intended to, redefine the terms on which Medicare Advantage insurers are entitled to claim

payment in the first place.¹⁰ The announcement of the FFS Adjuster did not change the “existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS.” Overpayment Rule, 79 Fed. Reg. at 29,921. And it did not “change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.” *Id.* at 29,921–22. It simply informed insurers that, if they were audited and determined to owe the government a potentially very large sum of money, the audit recovery would be reduced by an adjustment factor before it was finalized.¹¹

¹⁰ The Overpayment Rule made an exception for insurers currently subject to RADV audits, pursuant to which “an MA organization [that] has a contract selected for a RADV audit” is “not allowed to report and return an overpayment under [42 C.F.R.] § 422.326 that is due to errors in the data used to risk-adjust payments for the audited contract for the payment year that is subject to the RADV audit” during the course of the audit. 79 Fed. Reg. at 29,922; *see* 42 C.F.R. § 422.326(d) (insurers must return overpayment in a timely fashion “unless otherwise directed by CMS for purposes of § 422.311,” which governs RADV audits). This exception “protects the integrity of the RADV audit process, including the sampling frame of beneficiaries in a selected MA plan, whose diagnoses will be audited.” 79 Fed. Reg. at 29,922. The principal effect of the exception is to prevent insurers from reducing the audit recovery rate by voluntarily returning overpayments while they are subject to audits. But freezing the audited records in this way also ensures that the FFS Adjuster will be applied to audited contracts in the same way that it was described before the Overpayment Rule was promulgated.

¹¹ The FFS Adjuster was described as an “offset to the preliminary [payment] recovery amount.” AR 5314. For example, if the payment error rate was 5%, and the FFS Adjuster was 6%, then nothing would be recovered on the audit. If the FFS Adjuster was 1%, then the final recovery would be 4%; if it was 0.1%, the final recovery would be 4.9%. But nothing in the RADV methodology or anywhere else suggested that the FFS Adjuster would calculate a permissible rate for the submission of diagnoses unsupported by medical records.

III. United’s theory cannot support a challenge to the Overpayment Rule, because the three elements of the risk adjustment system to which it collectively objects were each in place years before the Rule was promulgated.

United argues that the Overpayment Rule, for the very first time, brought together three elements of the Medicare Advantage payment system: 1) a requirement of medical record documentation for all diagnoses submitted for payment, 2) a risk adjustment model calibrated on the Secretary’s database of fee-for-service claims, and 3) the absence of an adjustment factor to render that documentation standard compatible with the risk adjustment model. Opp. & Reply at 28. If that is not true—and it is not true—then the Overpayment Rule had nothing to do with the supposed harms that United would chiefly have the Court address, and United’s suit must fail.¹² As the Secretary showed in his opening brief, and has again explained here, all three elements to which United objects were in place long before the Overpayment Rule was promulgated.

Medical record documentation of diagnoses submitted for payment has been a central element of the Medicare Advantage program from its inception, as the administrative record makes perfectly clear. Although United and the amicus have attempted to show that the requirements of “accuracy” and “truthfulness” in data submission, 42 C.F.R. § 422.504(l), impose some standard

¹² Although United suggests that the Secretary is “effectively seeking to relitigate” this Court’s conclusions about standing, Opp. & Reply at 29, the insurer does not dispute that it must actually identify a flaw in the Overpayment Rule in order to prevail here. *See id.* at 28 (suggesting that “the Overpayment Rule is the proper target of [United’s] challenge” because it “was the first time CMS” brought together the three elements to which United objects). That is a basic predicate of the Administrative Procedure Act’s cause of action, in which a plaintiff must prove that it is “suffering legal wrong because of” the “final agency action” that it has challenged. 5 U.S.C. §§ 702, 704; *cf. Ctr. for Law & Educ. v. Dep’t of Educ.*, 396 F.3d 1152, 1160 (D.C. Cir. 2005) (explaining that APA plaintiffs “must . . . demonstrate a causal relationship between the final agency action and the[ir] alleged injuries”); *accord Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014). This Court found standing on the basis of the Rule’s requirement of “proactive compliance activities . . . to monitor the receipt of overpayments,” 79 Fed. Reg. at 29,923, which remain in place regardless of the substantive definition of overpayment. *See MTD Op.*, ECF No. 25 at 13. The Secretary does not seek to re-open that finding here.

lower than medical record documentation, that effort is belied by the record before this Court. As the Ninth Circuit has said, quoting *United*, “CMS regulations deem a diagnosis code proper if it is supported by a . . . medical record.” *Swoben*, 848 F.3d at 1176 (quoting Joint Answering Br. at 36). That was true long before the Overpayment Rule, and it is true today.

United does not argue that the Overpayment Rule changed the way in which the risk adjustment model was calibrated. The model has been calibrated on the Secretary’s database of fee-for-service claims since it was first established, and remains so.

That leaves the third element of the allegedly illegal combination: the absence of any adjustment factor to render the documentation standard compatible with the risk adjustment model. Here it helps to look at the history of the Medicare Advantage program. No adjustment factor was applied in any payment year from the inception of the program through 2010, despite the fact that medical record documentation was always required and the risk adjustment model was always calibrated on fee-for-service data. The Overpayment Rule clearly was not “the first time CMS” combined a requirement of medical record documentation and a model calibrated on fee-for-service data without the application of an adjustment factor. *Cf. Opp. & Reply* at 28.

For payment year 2011, the Secretary announced that an FFS Adjuster would be applied as an “offset to the preliminary recovery amount” calculated in risk adjustment data validation audits. AR 5314. With that statement, was the Secretary also announcing a program-wide payment adjustment, which the Overpayment Rule later arbitrarily reversed? The question for the Court is purely factual: was the FFS Adjuster an offset to reduce audit recoveries, which were about to spike dramatically, or was it a program-wide license for insurers to submit diagnoses unsupported by medical record documentation and retain at least a portion of the payments

received for them? There is no evidence in the record for the latter proposition, and the Secretary has explicitly endorsed the former.

But United's case depends on the latter being correct. To prevail here, United must show that when the Secretary announced the FFS Adjuster as a mechanism to reduce audit recoveries, which were about to increase substantially as the Secretary began to calculate a payment error rate for entire contracts rather than particular beneficiaries, he was actually implementing a program-wide change to the Medicare Advantage payment methodology without saying so. If that is not true—and it is not—then United has no plausible argument that the Overpayment Rule's failure to include an FFS Adjuster redefined funds to which the insurer had previously been entitled as funds to which it now was “not entitled” within the meaning of 42 U.S.C. § 1320a-7k(d)(4)(B). If the Overpayment Rule did not do that, if it did not change the terms on which United was entitled to claim payment through the Medicare Advantage program, then the insurer's challenge cannot go forward. Even United does not suggest that it can defeat the Overpayment Rule by objecting to policies that the Rule did not affect. *See supra* at 16 n.12.

The parties agree that, for the Court to reach the merits of United's objections to the payment system in this case, the insurer must first identify some way in which the Overpayment Rule changed the terms by which it was entitled to collect and retain Medicare Advantage funds. But United cannot do so. The medical record documentation requirement was in place for many years before the Overpayment Rule, as was a model calibrated on fee-for-service data. No adjustment factor was ever generally applied to the Medicare Advantage program. The FFS Adjuster did not exist at all until the payment year 2011, and then it was merely a feature of the audit recovery system, as it remains today. After the Overpayment Rule, United was entitled to precisely the same funds for which it had been authorized to claim payment before the Rule, and

it was “not entitled” to any others. 42 U.S.C. § 1320a-7k(d)(4)(B). The Overpayment Rule merely described pre-existing features of the Medicare Advantage payment system. It did not change the terms of United’s entitlement in any way. United’s principal challenge to the Overpayment Rule must therefore fail.

IV. The pre-existing Medicare Advantage payment system was lawful, and remains so.

United argues that the Medicare Advantage payment system violates two statutory requirements. Although United’s complaints about that system have nothing to do with the Overpayment Rule, as explained above, and no merit, as explained in the Secretary’s opening brief, they are addressed in turn below.

A. The payment system does not violate the “actuarial equivalence” requirement.

The Secretary must “adjust the . . . amount” of his monthly payments to Medicare Advantage insurers to account “for such risk factors . . . as the Secretary determines to be appropriate . . . so as to ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). As explained in the Secretary’s opening brief, in this context “actuarial equivalence” is an equivalence between an expected cost, on the one hand, and a known payment, on the other, calculated by actuarial means. The Secretary has designed the Part C risk adjustment model “to ensure actuarial equivalence” by paying Medicare Advantage insurers a sum equal to the cost that CMS would expect to bear in providing traditional Medicare benefits to a given beneficiary. United does not dispute any of this.

But United suggests that the Secretary has used actuarially invalid methods to design the Medicare Advantage payment system. The insurer invites this Court to consider several hypothetical scenarios and excerpted statements and reach its own, apparently *de novo*,

conclusions about whether the payment system comports with actuarial standards. As the Secretary has explained, Gov't MSJ at 30–31, that is not the proper framework for judicial review. If the question is whether the payment system violates accepted actuarial standards—and that is clearly what United is arguing here—then the Court must evaluate the Secretary's actuarial methodology “as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality.” *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (en banc). United is right to say that “actuarial equivalence” is a statutory demand “distinct from the requirements of basic rationality and consistency in the Administrative Procedure Act,” Opp. & Reply at 15, but the Court must channel any review of the Secretary's attempt to satisfy that demand through the arbitrary and capricious standard, and “defer to the [agency's] . . . implementation” of its statutory mandate if that implementation is “reasonable.” *Nat'l Ass'n of Broadcasters v. FCC*, 789 F.3d 165, 179–80 (D.C. Cir. 2015); see, e.g., *St. John's United Church of Christ v. FAA*, 550 F.3d 1168, 1172 (D.C. Cir. 2008) (“We review the [agency's] compliance with statutory . . . requirements under the highly deferential arbitrary and capricious standard.”). And the Court must bear in mind that the Secretary is authorized to develop a risk adjustment methodology “as he determines to be appropriate,” 42 U.S.C. § 1395w-23(a)(1)(C)(i), a phrase that Congress uses to “trumpet[,]” in “sweeping terms,” the breadth of its grant of discretionary power, *Arctic Slope Reg'l Corp. v. FERC*, 832 F.2d 158, 164 (D.C. Cir. 1987).

United argues that the Secretary has designed the Medicare Advantage risk adjustment payment system in such a way that it is guaranteed to pay insurers less than it should. The administrative record contains two lengthy evaluations of the risk adjustment model, including analyses of its predictive accuracy, which reach no such conclusion, and which United does not discuss at any length. See Gregory C. Pope, *Risk Adjustment of Medicare Capitation Payments*

Using the CMS-HCC Model (Summer 2004) (AR 11878) (“The model has evolved over two decades of research, with careful attention to clinical credibility, real-world incentives and feasibility tradeoffs.”); Gregory C. Pope, *Evaluation of the CMS-HCC Risk Adjustment Model* (March 2011) (AR 11880–12006). Instead, United asks the Court to declare the model actuarially unsound on the basis of simple hypothetical examples that its counsel have crafted.

In his opening brief, the Secretary noted that the regression model used to calculate risk adjustment coefficients takes each traditional Medicare beneficiary’s characteristics, both demographic and health-related, and distributes her medical costs across them. Gov’t MSJ at 16–18. For example, in the case of a 72-year-old woman with diabetes and multiple sclerosis, and \$10,000 of medical expenses in the index year, the model would attribute some portion of that \$10,000 to the beneficiary’s age and sex, some to her diabetes, and the remainder to her multiple sclerosis. If one of her diagnoses was inaccurate—if, for example, she was erroneously recorded as having diabetes—then whatever portion of her \$10,000 expenditure was assigned to that erroneous diagnosis should instead have been assigned to her other, valid characteristics.

United makes three fruitless attempts to show that this simple description of a regression model calibrated on imperfect data (as any model must necessarily be) proves that Medicare Advantage insurers are systematically underpaid. First, United suggests that although the traditional Medicare program paid \$10,000 to cover this woman in the index year, a Medicare Advantage insurer would receive less than \$10,000 for covering her, because it would not be permitted to report her erroneous diagnosis. Opp. & Reply at 7. United badly misses the point: the risk adjustment model does not work by finding a traditional Medicare beneficiary equivalent to a Medicare Advantage enrollee, and then paying the insurer whatever costs the traditional beneficiary incurred in a given year. Whether or not our hypothetical patient’s diagnoses are

accurate, no Medicare Advantage insurer is getting paid \$10,000 because of them. Instead, the model uses that data to determine how much of the programmatic cost of providing traditional Medicare benefits is attributable to each disease and demographic category. One patient will be misdiagnosed with diabetes, another will be misdiagnosed with multiple sclerosis; sometimes multiple sclerosis costs will therefore be mis-attributed to diabetes while, other times, diabetes costs will be mis-attributed to multiple sclerosis. “Each time the risk adjustment model is recalibrated, the relative factors [or ‘risk coefficients’] can change,” 2013 Manual, § 70.1 (AR 5684), but there is no reason to think that such offsetting errors, if uncorrected, would drive down the model’s estimate of the cost of both diseases.

United’s second hypothetical, *id.* at 7–8, makes a similar error. The insurer imagines a population of 1,000 traditional Medicare patients, each of whom has five diagnosed diseases, and who collectively incur \$10 million of medical expenses in a given year. If some portion of those diagnoses are inaccurate, United says, costs will nonetheless be attributed to them, such that insurers would be paid less than \$10 million for covering an identical population of 1,000 Medicare Advantage beneficiaries. That is quite wrong. The risk adjustment model currently uses approximately 70 disease categories; in United’s example, therefore, the model is spreading \$10 million of costs across those approximately 70 categories (along with demographic categories). An erroneous diagnosis code may cause money to be placed in the wrong category (diabetes rather than multiple sclerosis, or vice versa) but there is no way for money to leech out of the system as United suggests when a known set of expenditures is allocated across a fixed set of categories.

United suggests a third mechanism for overpayment: if the risk adjustment model were recalibrated on a data set from which all erroneous diagnoses had been deleted, then there would be fewer diagnoses in the set, and the remainder would each receive greater weight. *Id.* at 20–22.

This mechanism ignores the fact that not only are erroneous diagnoses included in the fee-for-service dataset, but accurate diagnoses are also omitted from it. To “correct” the data, then, the Secretary would need to both delete any diagnoses unsupported by medical records and add any unreported diagnoses indicated therein. There is no reason to assume that the rate (or value) of unsupported diagnoses exceeds the rate (or value) of unreported diagnoses, and therefore no reason to conclude that the inclusion of unsupported diagnoses in the fee-for-service data set leads to systematic underpayment.

The Secretary’s risk adjustment model is not an arbitrary effort to calculate the expected costs of providing Medicare benefits. It is calibrated on the best data available to the Secretary: the known medical expenditures for millions of traditional Medicare beneficiaries. The data is not perfect, and the model is not perfect, but it has been developed and refined for many years, and there is no reason to believe that it is systematically underpaying Medicare Advantage insurers. Certainly United has not given this Court any reason to reach that conclusion.

B. The payment system does not violate the requirement that the Secretary calculate “[t]he average risk factor” for traditional Medicare beneficiaries, “using the same methodology as is expected to be applied in making payments” to Medicare Advantage insurers.

The Secretary must annually “provide for the computation and publication” of “[t]he average risk factor for the . . . population” covered by “the original medicare fee-for-service program under parts A and B . . . using the same methodology as is expected to be applied in making payments under [Medicare Advantage].” 42 U.S.C. § 1395w-23(b)(4). He unquestionably does so: for both the traditional Medicare and Medicare Advantage populations, risk scores are calculated using the coefficients produced by the Medicare Advantage risk adjustment model. Quite literally the same methodology is applied in both cases.

United objects that the underlying quality of the diagnosis data differs between the traditional Medicare and Medicare Advantage populations, and says that difference in data quality amounts to a difference in methodology. But the diagnosis coding methodology employed in the two programs is identical: both traditional Medicare providers and Medicare Advantage insurers must follow the ICD-9-CM coding guidelines which, as discussed above, require medical record documentation for each diagnosis reported. 45 C.F.R. § 162.1002(a)(1), (b)(1) (adopting “The Official ICD–9–CM Guidelines for Coding and Reporting” as the official methodology for all diagnosis coding); *see* ICD-9-CM Coding Guidelines at 5 (AR 11385) (discussing medical record documentation). No one is authorized to submit diagnoses unsupported by medical record documentation,¹³ yet some traditional Medicare providers and some Medicare Advantage insurers do. Their failure to abide by the Secretary’s methodology for data submission does not transform that methodology into something else.

United suggests that erroneous diagnoses in the fee-for-service data set lead to systematic underpayment through the benchmarking process, Opp. & Reply at 11–14, but the insurer makes the same error here as above, and tacitly assumes that a “corrected” fee-for-service data set would only remove unsupported diagnoses, without adding unreported diagnoses. There is, again, no reason to make that assumption, and no reason to conclude that insurers are underpaid.

¹³ *See* Medicare Program Integrity Manual, § 3.3.2.1 (“For Medicare to consider coverage and payment for any item or service” provided through fee-for-service Medicare, “the information submitted by the supplier or provider must corroborate the documentation in the beneficiary’s medical documentation. . . .”), *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf>.

V. The Secretary’s interpretation of “identified” is lawful.

The Overpayment Rule says that an “identified overpayment” exists whenever a Medicare Advantage insurer “should have determined through the exercise of reasonable diligence, that [it] has received an overpayment.” 42 C.F.R. § 422.326(c). As one district court has recognized, when Congress enacted 42 U.S.C. § 1320a-7k(d), it intended “to subject willful ignorance of Medi[care] overpayments to the [False Claims Act’s] stringent penalty scheme.” *United States ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 391 (S.D.N.Y. 2015). This interpretation of “identified” does that, and no more. As the Ninth Circuit put it, “CMS has long made clear that . . . Medicare Advantage organizations have ‘an obligation to undertake “due diligence” to ensure the accuracy, completeness, and truthfulness’ of the [diagnosis] data they submit to CMS and ‘will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness’ of these data.” *Swoben*, 848 F.3d at 1167 (quoting 2000 Rule, 65 Fed. Reg. at 40268 (AR 2006)); *see id.* at 1174.

The Overpayment Rule’s requirement that insurers “exercise . . . reasonable diligence” in identifying overpayments, 42 C.F.R. § 422.326(c), is simply a restatement of their pre-existing obligation to undertake “due diligence” to ensure the “accuracy” and “truthfulness” of the diagnosis data they submit. The Overpayment Rule merely continues the Secretary’s established practice, and should be upheld.

CONCLUSION

Before the Overpayment Rule, Medicare Advantage insurers were entitled to payment for the marginal costs associated with diseases documented in the medical records of their beneficiaries, as calculated by the Secretary’s risk adjustment model. The Overpayment Rule did not alter those terms of entitlement, and this Court should not do so here.

Respectfully submitted,

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EXHIBIT 41

Medicare Managed Care Manual

Department of Health and
Human Services (DHHS)
Centers for Medicare and
Medicaid Services (CMS)

Transmittal No 1

Date: JULY 2, 2001

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
7		10 - 230	---
12		10 - 30	---
14		10 - 20	---

**NEW/REVISED MATERIAL --EFFECTIVE DATE: Not Applicable
IMPLEMENTATION DATE: Not Applicable**

The Medicare Managed Care Manual (MMCM) is a new vehicle for instructions for Medicare managed care organizations.

This transmittal includes the following:

- An overall Table of Contents which includes the chapters being issued by this transmittal, and anticipates future chapters that will be added to this manual.
- Additional chapters will be published as updated information is available. It is anticipated that eventually most or all material in the Operation Policy Letters that become permanent will be included.
- This initial issuance consists of three chapters. They are:

Chapter 7, Payments to Medicare+Choice (M+C) Organizations, this chapter provides the policies and the methods the Center for Medicare and Medicaid Services follows to determine the amount of payment a Medicare+Choice organization will receive for Medicare beneficiaries enrolled in an M+C plan offered by the organization.

Chapter 12, Effect of Change of Ownership and Leasing, this chapter outlines the effect of a change in ownership on a M+C contract when the contract can be transferred to a new entity, the type of documentation, required, and a Model Novation Agreement than can be used by a contracting entity undergoing a change in ownership.

Chapter 14, Contract Determinations and Appeals, this chapter provides procedures for making and reviewing contract determinations and the appeals process.

The MMCM is an Internet document and may be accessed from the CMS Web site:
<http://www.hcfa.gov/pubforms/progman.htm>.

These instructions should be implemented within your current operating budget.

NOTE: Normally red italicized font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

Medicare Managed Care Manual

Table of Contents

Manual Transmittals through Transmittal Number 1 are included in this update. As new transmittals are included they will be identified on this page. To review individual transmittal cover pages click [here](#).

Chapter 1	General Administration of the Managed Care/Medicare Plus Choice Program - not yet available
Chapter 2	Enrollment and Disenrollment - not yet available
Chapter 3	Marketing - not yet available
Chapter 4	Benefits and Beneficiary Protection - not yet available
Chapter 5	Quality Assurance - not yet available
Chapter 6	Relationships With Providers - not yet available
Chapter 7	Payments To Medicare+Choice Organizations
Chapter 8	Premiums and Cost Sharing – not yet available
Chapter 9	Provider-Sponsored Organizations - not yet available
Chapter 10	Organization Compliance With State Law and Pre-emption By Federal Law - not yet available
Chapter 11	Contracts With Medicare+Choice Organizations - not yet available
Chapter 12	Effect Of Change Of Ownership Or Leasing Of Facilities During Term Of Contract
Chapter 13	Grievances Organization Determinations and Appeals - not yet available
Chapter 14	Medicare Contract Determinations and Appeals
Chapter 15	Intermediate Sanctions - not yet available
Chapter 16	Private Fee For Service Medicare+Choice Plans - not yet available
Chapter 17	Cost Based HMOs and CMPs - not yet available
Chapter 18	Health Care Prepayment Plans - not yet available

Chapter 19 Managed Care and M+C Systems Requirements - not yet available

Chapter 20 Managed Care and M+C Systems' Business Requirements - not yet available

each beneficiary. (See §90.4.3.) CMS may also use the data for other purposes, such as “recalibration” of diagnosis weights in the risk-adjustment payment model to account, for example, for adoption of new technology or for changes in the average use of resources for enrollees in a particular category.

Accordingly, the BBA requires each M+C organization, as well as eligible organizations with risk-sharing contracts under §1876 of the Act, to submit to CMS, in accordance with CMS instructions, all data necessary to characterize the context and purposes of each encounter between a Medicare enrollee and a provider, supplier, physician, or other practitioner. Requirements concerning collection of encounter data apply to M+C organizations with respect to all their M+C plans, including private fee-for-service plans, with the exception of certain demonstration projects discussed in §90.5.

To the extent required by CMS, encounter data must account for services covered under the original Medicare program, for Medicare covered services for which Medicare is not the primary payer, or for other additional or supplemental benefits that the organization must provide.

M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate encounter data that conforms to the format used under original Medicare. These provisions may include financial penalties, including withholding payment, for failure to submit complete and accurate data, or for failure to submit data that conform to the requirements for submission.

Upon enrollment, M+C organizations may obtain permission from the beneficiary to have access to past medical records of their enrollees. However, diagnostic information cannot be passed from CMS to the M+C organizations because of privacy concerns.

NOTE: The policy discussed in §110.2 is current; however, CMS is conducting a review of policy pertaining to certification.

110.2 - Certification of Data Accuracy, Completeness, and Truthfulness

(Rev. 1, 07-02-01)

As a condition for receiving a monthly payment under the M+C program, the M+C organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers and who reports directly to such officer, must make a certification on Attachment B of the M+C contract, based on best knowledge, information, and belief, that the encounter data the M+CO submits to CMS are accurate, complete, and truthful. If such encounter data are generated by a related entity, contractor, or subcontractor of the M+C organization, such entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data. (See 42 CFR 422.502(l).)

CMS expects M+C organizations to design and implement effective systems to monitor the accuracy, completeness, and truthfulness of encounter data and to exercise due diligence in reviewing the information provided to CMS. The Department of Justice, the Office of Inspector General, and CMS acknowledge that the volume and variety of data make some inaccuracies inevitable, and they will take into account any legitimate difficulties M+C organizations may have with provider compliance. However, this certification standard does not relieve M+C

organizations of their obligation to comply fully with the M+C program's encounter data requirements.

110.3 - Validation of Data

(Rev. 1, 07-02-01)

M+C organizations and their providers and practitioners are required to submit medical records for validating encounter data, as prescribed by CMS. Medical record reviews of a sample of hospital encounters may be audited to ensure the accuracy of diagnostic information. Independent contractors will conduct the reviews.

110.4 - Hospital Inpatient Encounter Data Requirements

(Rev. 1, 07-02-01)

As discussed in §70, the timing of encounter data collection set forth in the BBA signaled to CMS that the initial risk adjustment method should be based only on data from inpatient hospital stays, with later implementation of a method based on data from additional sites of care. CMS selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method under which payments are made, beginning January 1, 2000. In this model, diagnoses from hospitalizations are used to identify a particularly ill and high cost subset of beneficiaries for whom higher payments will be made in the next year.

The hospital inpatient encounter data requirements entail submission of data for discharges from inpatient hospitals, including facilities reimbursed under the prospective payment system (PPS), long stay hospitals, psychiatric and rehabilitation hospitals, and psychiatric/rehabilitation distinct parts of hospitals. Encounter data are not currently required for discharges from skilled nursing facilities (SNFs).

NOTE: In order to participate as a Medicare provider, a hospital must meet certain conditions specified in the Medicare regulations at 42 CFR 482.12. Generally, these conditions pertain to issues such as compliance with applicable Federal, State, and local laws, make-up of the medical staff, and quality assurance plans.

All discharges reflecting inpatient stays should be submitted. If a patient moves from a one-day hospital stay to a swing bed or skilled nursing facility bed, then this is simply a one-day stay (see §90.2.1). If the patient is transferred to a rehabilitation facility, then the diagnoses from the rehabilitation facility stay may be used to determine the risk adjustment payment.

Contracted and Non-contracted Facilities - The M+C organization must ensure that CMS receives a record of each hospital discharge for each managed care enrollee, regardless of whether the hospital is a contracted or non-contracted facility. M+C organizations may need to modify their contracts with hospitals to ensure that all managed care discharges are identified.

Coding Guidance - The records that M+C organizations submit should reflect the original diagnosis that the provider submitted to the M+C organization. M+C organizations should not modify, supplement, or re-sequence diagnosis codes received from hospitals.

Encounter data should be substantiated by the hospital's medical record. If the M+C organization receives a record from a provider that contains an incorrect code in a critical field

EXHIBIT 42



FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 417, 422, et al.

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 409, 417, 422, 423, and 424**

[CMS-4159-P]

RIN 0938-AR37

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

SUMMARY: The proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. The proposed rule also includes several provisions designed to improve payment accuracy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 7, 2014.

ADDRESSES: In commenting, please refer to file code CMS-4159-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4159-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4159-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier)

your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.) b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Christopher McClintick, (410) 786-4682, Part C issues. Marie Manteuffel, (410) 786-3447, Part D issues. Kristy Nishimoto, (206) 615-2367, Part C and D enrollment and appeals issues. Whitney Johnson, (410) 786-0490, Part C and D payment issues. Clarisse Owens, (410) 786-0880, Part C and D compliance issues. Frank Whelan, (410) 786-1302, Part D improper prescribing issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication

of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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sponsors report the gap discount amounts to CMS, and through a contractor, CMS invoices the manufacturers on a quarterly basis for the applicable discount amounts. The manufacturers repay each Part D sponsor directly for the invoiced amounts under the Medicare Coverage Gap Discount Program Agreement (Agreement) described at § 423.2315. Under § 423.2320(b), CMS reconciles the interim payments with amounts invoiced to manufacturers.

In the event that a manufacturer fails to provide the applicable discounts in accordance with the Agreement, we must impose civil money penalties (CMPs) equal to the sum of the applicable discount the manufacturer would have paid under the Agreement and 25 percent of that amount. The CMP that is equal to the sum of the applicable discount the manufacturer would have paid under the agreement is used to pay the applicable discount that the manufacturer had failed to provide.

In our final rule describing the payment process for Part D sponsors under the Coverage Gap Discount Program, we did not contemplate a payment process in the event that a manufacturer becomes bankrupt and does not pay the Part D sponsors for quarterly invoiced amounts under the Agreement. Even though we will impose a CMP on a bankrupt manufacturer in an effort to collect the unpaid invoiced amounts, the bankruptcy settlements will likely result in the CMP being modified or reduced. In order to ensure that the Part D sponsors have the funds available to advance the gap discounts at the point-of-sale, as required under section 1860D-14A(c)(1)(A)(ii) of the Act, we now propose to amend § 423.2320 such that we will assume financial liability for the applicable discount by covering the costs of the quarterly invoices that go unpaid by a bankrupt manufacturer at the time of the Coverage Gap Discount Reconciliation described at § 423.2320(b). We would then file a proof of claim with the bankruptcy court to recover those costs from the bankrupt manufacturer.

The proposed policy that CMS assume financial liability for the applicable discounts in the event of a manufacturer bankruptcy is consistent with CMS' payment processes for Part D sponsors under the Medicare Coverage Gap Discount Program. Under § 423.2320 (a), CMS provides interim payments to ensure that Part D sponsors have the funds available to advance the coverage gap discount to beneficiaries at point of sale. Under § 423.2320 (b), CMS reconciles the interim payments with the invoiced manufacturer discount

amounts in order make the PDP sponsor whole for the gap discount amount provided to the beneficiaries at point of sale. (For more information on these provisions, see October 11, 2011 final rule (76 FR 63017, 63027).) In order to remain consistent with the intent of the Coverage Gap Discount Reconciliation to make the Part D sponsor whole for the gap discounts amounts advanced at point of sale, CMS must provide payments to the Part D sponsor to cover the cost of the applicable discount in the event that the manufacturer cannot pay the quarterly invoices due to a bankruptcy. We propose to cover the costs of unpaid quarterly invoices only in the event that a manufacturer becomes bankrupt. We would not cover the cost of unpaid quarterly invoices for any other reasons because, in the event that a manufacturer fails to pay the quarterly invoices, we will impose CMPs that will cover the cost of the unpaid invoices. In the event that a manufacturer becomes bankrupt, we are concerned that the court will either modify or reduce the amount of the CMP, making the CMP process ineffective for covering the cost of the invoices and leaving the Part D sponsor in the position of having to cover the costs of the gap discount.

We propose to implement this policy by adjusting the Coverage Gap Discount Reconciliation to account for quarterly invoices that go unpaid as a result of a manufacturer becoming bankrupt. This adjustment will only occur for manufacturer discount amounts as they are reported on PDEs submitted by the submission deadline for the Part D reconciliation.

Based on the preceding, we propose to add a new paragraph (c) to § 423.2320 to describe a process for accounting for quarterly invoiced amounts that go unpaid by a bankrupt manufacturer.

6. Risk Adjustment Data Requirements (§ 422.310)

We propose to strengthen existing regulations related to the accuracy of risk adjustment data by amending § 422.310 on risk adjustment data validation. First, we propose to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under § 422.308(c)(1) and § 422.310(g)(2). (Paragraph § 422.308(c)(1) addresses adjustments to payments for health status, and paragraph § 422.310(g)(2) addresses deadlines for risk adjustment data submission, including the final risk

adjustment data submission deadline prior to CMS' calculation of the final risk factors for a payment year.) Under our proposal, medical record reviews conducted by an MA organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the MA organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments. This proposed amendment furthers our goals of improving payment accuracy and reducing payment errors.

We also propose to amend § 422.310(g) regarding deadlines for submission of risk adjustment data. Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. We propose to revise the regulation to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment.

Finally, we propose to align this regulation with proposed § 422.326 by making two additional changes in paragraph (g). First, we propose the deletion of the January 31 deadline in subparagraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. This means that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, as discussed in section II.B.1.b. of this proposed rule. Second, we propose to add subparagraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

7. RADV Appeals

a. Background

We published Risk Adjustment Data Validation (RADV) appeals regulations in the April 15, 2010 **Federal Register**. These rules were proposed and finalized under CMS's authority to establish Medicare Advantage (MA) program standards by regulation at section 1856(b)(1) of the Act and are found at § 422.311 et seq.

As explained in the preamble of that final rule, Subpart G of the MA regulations at part 422 describes how

EXHIBIT 43

April 7, 2008

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for 2009, and the risk and other factors to be used in adjusting such rates. Attached is a spreadsheet containing the capitation rate tables for CY 2009. Also included is a spreadsheet which shows the statutory component of the regional benchmarks. The rates are posted on the Centers for Medicare & Medicaid Services (CMS) web site at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/> under Ratebooks and Supporting Data.

Attachment I shows the final estimates of the increase in the National Per Capita MA Growth Percentage for 2009. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 4.24 percent. These growth rates will be used as the minimum update percentage in calculating the 2009 rates, except for the ESRD State rates, which are subject to a 2 percent minimum increase under Section 1853(a)(1)(H). The county fee-for-service (FFS) rates for 2009 were rebased. Under section 1853(c)(1) of the Act, MA capitation rates in 2009 will be based on the higher of the county FFS per capita amount or a minimum percent increase over the 2008 rate.

Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentage.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2006 is being posted on the above website at this time as well.

We received comments from 30 organizations in response to CMS' request for comments on the Advance Notice of Methodological Changes for CY 2009 MA Capitation Rates and Part D Payment Policies (Advance Notice), published on February 22, 2008. Six comments were from Associations, 23 comments were from plans, and one comment was from the Congress. Attachment III summarizes key policy changes from the approaches proposed in the Advance Notice, the key policies adopted as proposed in the Advance Notice, and then presents responses to comments on Part C and Part D issues in the Advance Notice. Attachment IV contains tables with the 2009 CMS-HCC risk adjustment factors, Part D benefit parameters, and other information. The CMS-HCC factors are also available in Excel files on the CMS website at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/RSD/list.asp#TopOfPage>.

Questions can be directed to:

Paul Spitalnic (410-786-2328) for Attachments I and II

Anne Hornsby (410) 786-1181 and Rebecca Paul at (410) 786-0852 for Attachments III and IV.

/ s /

Abby L. Block

Director

Center for Beneficiary Choices

/ s /

Paul Spitalnic, A.S.A., M.A.A.A.

Director

Parts C & D Actuarial Group

Office of the Actuary

Attachments

commenters disagreed that CMS had taken into full account the degree of “catch up” and felt that a number of MA organizations would face the possibility of being penalized for these efforts.

Response. We appreciate commenters’ concerns about the methodology of our approach to calculating and applying an MA coding differences adjustment. Because we are not making an adjustment for 2009, these comments are moot for this year.

Comment. One commenter suggested that CMS identify strategies for improving coding accuracy in FFS to reduce the variance in coding patterns directly related to differences in financial incentives between MA and FFS – strategies such as risk-adjusting FFS payments.

Response. CMS does make adjustments to FFS payments for diagnosis coding that is not in synchronization with a provider’s case mix. We have applied an adjustment to long term hospitals that is projected to total \$430 million over five years (FY 2009-FY 2013) and to home health providers that is projected to total \$6.53 billion from 2008-2012.

Section F. CMS Audits

In CY 2007, CMS’ payments to MA plans were 100 percent risk-adjusted for the first time because the transition from demographic-only to risk-adjusted payments was completed. Given this milestone, CMS has determined that our Risk Adjustment Data Validation, starting with CY 2007 payments, will be conducted using a sampling frame that generates statistically valid plan-level payment error estimates for those plans selected for review.

CMS will audit a subset of MA plans each year. The audit will include randomly-selected plans and targeted plans. Targeted plans will be selected based on how their risk score growth compared to FFS.

Findings from our validation studies from CY 2007 onward may inform CMS why plan average risk scores did or did not grow rapidly. This analysis will allow us to further refine our MA coding intensity adjustment. In addition, because we will have statistically-valid plan-level error estimates, we will make plan-level payment adjustments rather than adjustments to payments for specific beneficiaries whose risk scores were not supported by the medical record reviews, as we have done previously.

Section G. Adjustment to FFS Capitation Rates for VA-DOD Costs

In the Advance Notice, CMS proposed to adjust to the extent appropriate the 2009 FFS rates to reflect CMS’ “estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.” Specifically, the Office of the Actuary (OACT) proposed to compare the risk-adjusted Medicare reimbursements of dual-eligible individuals — those entitled to benefits under this title and entitled to benefits from the Department of Defense (e.g., DoD TRICARE for Life and DoD US Family Health Plan) or the Department of Veterans Affairs (VA) — with individuals entitled only under this title. In cases where groupings of dual-eligible individuals

EXHIBIT 44

1 UNITED STATES DEPARTMENT OF JUSTICE
2 WASHINGTON, D.C. 20530
3 CIVIL INVESTIGATIVE DEMAND NO. 16-13
4

5 - - - - - x

6 IN RE:

7 CIVIL INVESTIGATIVE DEMAND

8 OF

9 LARRY RENFRO

10 - - - - - x

11

12 TESTIMONY OF LARRY RENFRO

13 Friday, May 6, 2016

14 9:00 a.m.

15 Latham & Watkins

16 200 Clarendon Street

17 Boston, Massachusetts

18 Michelle Keegan, Court Reporter

19

20

21

22

23

24 Job No.: WDC-081985

1 So I did that for M&R, and I would do that
2 for C&S if they needed that. So I was the
3 relationship person.

4 Q. I see. So Jon Blum was the point of
5 contact at CMS and you were the point of contact
6 at United?

7 A. Yes.

8 Q. Got it. Sitting here today, do you
9 believe that great conversation did not relate to
10 RADV?

11 A. I do not believe it related to RADV.

12 Q. Okay. And you don't recall what it
13 related to?

14 A. No.

15 Q. Prior to April of 2014, had you had
16 conversations with anyone at CMS about the claims
17 verification program?

18 A. Say that again, please.

19 Q. Sure. Prior to April of 2014, had you had
20 conversations with anyone at --

21 A. Yes.

22 Q. -- CMS about the claims verification
23 program?

24 A. Yes.

<http://www.yeslaw.net/help>

1 Q. Who?

2 A. John Blank.

3 Q. And when was your conversation with him?

4 A. Around March 27th.

5 Q. And was it by phone or in person?

6 A. In person.

7 Q. And where did it take place?

8 A. Holiday Inn right behind HHS.

9 Q. In Washington, D.C.?

10 A. Uh-hmm.

11 Q. And was anyone else present?

12 A. No.

13 Q. Okay. And who initiated the conversation
14 on claims verification?

15 A. I did.

16 Q. And what did you ask him or what did you
17 tell him?

18 A. I told him that I had been told that there
19 was a proposed rule that put claims verification
20 into effect January 1, 2015. And we had been
21 doing claims verification since 2012.

22 Q. Did you tell him anything else?

23 A. And I asked him, "What does that mean?"

24 And he said: Well, you shouldn't have

<http://www.yeslaw.net/help>

1 been doing it yet, but we're not discussing 2012.
2 That's a closed period. So 2013 and '14 would
3 be -- "Why are you doing it?" is basically what he
4 said.

5 And I probably asked him, "What should we
6 do?"

7 And he said, "Well, let me get back to
8 you."

9 Q. Did he get back to you?

10 A. He did. I don't remember when. I would
11 say in the next couple of days. And he told me
12 that at this point in time it's not in effect. As
13 a result of not being in effect, we shouldn't be
14 doing it.

15 Now, I'd been told about this discrepancy
16 by Karen Erickson. So she had told me and
17 explained the claims verification in terms of that
18 we had a discrepancy the way that I explained it
19 to John and talked about, you know, that we would
20 need clarification.

21 So again, this, Carol, is what we look at
22 in terms of wanting clarification and not being
23 afraid to go and ask our customer about this. And
24 John gave me his opinion.

<http://www.yeslaw.net/help>

1 Q. So what was the date of the first
2 conversation you had with him?

3 A. 27th of March.

4 Q. Did you follow that up with an e-mail to
5 him?

6 A. No.

7 Q. Did you report that conversation in an
8 e-mail to anyone?

9 A. No.

10 Q. Did you orally report that conversation to
11 anyone?

12 A. I did.

13 Q. To whom?

14 A. To Marianne Short and Steve Hemsley.

15 Q. Who is Marianne Short?

16 A. General counsel for UHG.

17 Q. And when did you tell them about that
18 conversation?

19 A. It would have been right after the
20 conversation. I don't know the date on that. I
21 just know -- I'd say a couple of days after
22 the 27th.

23 Q. And then you said a couple of days later
24 Jon Blum -- you spoke with him?

<http://www.yeslaw.net/help>

1 A. Came back to me and said that the rule
2 would go in effect January 1, 2015.

3 Q. So then did he do that by e-mail?

4 A. Phone.

5 Q. By phone?

6 A. Phone call.

7 Q. And did you follow that up with an e-mail
8 to him?

9 A. No.

10 Q. Why not?

11 A. I had to go to my client. This was not an
12 Optum -- this was not an Optum CMS situation.
13 This is an M&R CMS situation. So all I was doing
14 was trying to give clarification so I could give
15 that information to my client.

16 Q. So did you give that information to your
17 client?

18 A. I gave the information to Marianne Short,
19 who's the general counsel, and she gave it to the
20 client.

21 Q. How do you remember that it was
22 March 27th, 2014, that you first spoke to Jon
23 Blum?

24 A. Because I knew -- well, let me put it this

<http://www.yeslaw.net/help>

1 way: We're going to go through some more here.
2 We're going to talk about some more conversations.
3 And as I did those conversations, I thought that I
4 should remember those dates and conversations
5 because I was setting up the meetings and having
6 the conversations. So that's why I remembered
7 those dates.

8 Q. Before you came here today, did you do
9 anything to refresh your recollection to remember
10 those dates?

11 A. I did not have to.

12 Q. You have since then in the last two years
13 remembered that date?

14 A. I sure do.

15 Q. Because that conversation was very
16 important to you?

17 A. Well, it was very important that I
18 understood how this process needed to work because
19 I was going through other people to my client. I
20 wasn't dealing directly with my client on this,
21 and I wanted to remember how this worked.

22 Q. So after your conversation with Jon Blum,
23 was a decision made to terminate the CV program?

24 A. The process, M&R finds out about it. They

<http://www.yeslaw.net/help>

1 want more clarity. And the more clarity was that
2 they wanted me to have the conversation with
3 Marilyn Tavenner.

4 Q. Why did they want more clarity?

5 A. Because I think -- going back to the thing
6 that I always keep talking about is we're trying
7 to do this right. We just wanted more
8 clarification to make sure that we were doing it
9 right.

10 One reason it's easy to remember this is
11 because of the certification deadline that was
12 coming up on the 30th. And so I just believed
13 that they wanted to be really clear what this
14 meant and wanted Marilyn to weigh in on it.

15 Now, during HealthCare.gov, they had split
16 the baby, so to speak. And Marilyn was in charge
17 of HealthCare.gov and Jon was in charge of policy.

18 So Jon was really the person, I believed,
19 and he was my contact. That's why I went to him
20 and asked the question. And then when Marianne
21 went to my client and they came back and said they
22 wanted more clarity. That's why we went to
23 Marilyn.

24 Q. Did you explain to Jon on March 27th what

<http://www.yeslaw.net/help>

1 the claims verification program was?

2 A. I think -- I did not explain that in terms
3 of the detail of the program. What I knew was he
4 clearly understood what I was asking because he
5 talked about the due date, the go-live date of
6 January 1, 2015, and that he had received other
7 inquiries from the industry.

8 Q. Did he clearly know all about the claims
9 verification program that United had?

10 A. We did not get into detail about the
11 claims verification.

12 Q. When you say he clearly knew, he knew
13 about the proposed regulation?

14 A. Yes.

15 Q. I see. Okay. Did he know that the claims
16 verification that was being done was part of a
17 chart review program?

18 A. I don't know.

19 Q. Did he know that the chart reviews that
20 United performed were blind chart reviews?

21 A. I don't know.

22 Q. Did he know the -- how many the number of
23 deletes that United had previously made based on
24 its claims verification program?

<http://www.yeslaw.net/help>

1 A. I don't know.

2 Q. Did he know of the monetary value of the
3 overpayments that had already been made by United
4 based on the claims verification program?

5 A. I don't know.

6 Q. Did he know about any other compliance
7 efforts that United was undertaking to determine
8 if the risk adjustment data that it submitted to
9 CMS was validated by medical records?

10 A. I don't know.

11 Q. Did you know anything about that?

12 A. I did not know.

13 Q. Did he in his conversations with you --
14 Let me just back up.

15 You said two conversations with Jon Blum.
16 Is that the only conversations that you had with
17 him about claims verification?

18 A. Yes.

19 Q. Okay. And did he say during those
20 conversations that United had no affirmative
21 compliance obligations to ensure that the data
22 they were submitting to CMS for risk adjustment
23 payments was accurate?

24 A. He did not state that.

<http://www.yeslaw.net/help>

1 Q. So based on your conversation with Jon
2 Blum, was it clear to you that the proposed
3 regulation was not retroactive?

4 A. Yes.

5 Q. Did he say anything else about -- anything
6 else about any compliance obligations that United
7 had or didn't have with respect to the accuracy of
8 the risk adjustment data?

9 A. No.

10 Q. Did Jon Blum leave a week or two after you
11 had a conversation with him?

12 A. I don't know the timing. I know he's
13 gone, but I don't know the timing. Sorry.

14 Q. Well, soon after you had this conversation
15 with him, was he no longer your contact? Did
16 someone else become your contact?

17 A. My contact would have been Marilyn
18 Tavenner after Jon.

19 Q. How long had you known Marilyn Tavenner
20 for?

21 A. I met her mid October in the
22 HealthCare.gov crisis.

23 Q. In October 2013?

24 A. So I never had met her before.

<http://www.yeslaw.net/help>

1 Q. And did you start working closely with her
2 at that time, October 2013?

3 A. I'd say I don't have the date, off the top
4 of my head. When we started HealthCare.gov, it
5 was on a Friday, Saturday. There was an
6 additional person, Jeff Zients, who came in to
7 work on HealthCare.gov.

8 So we started working with them on a
9 Saturday. I just know that's the day the system
10 went down for about a week.

11 But regardless of that, I'd never met
12 Marilyn. Steve Hemsley had been the contact with
13 Marilyn. And then I went in and positioned what
14 we could do to help with HealthCare.gov.

15 To rephrase the question, you asked me how
16 did I know her. That's how I met her. That's how
17 I started working with her.

18 Q. I see. And did you work with her on a
19 daily basis during this time period, late 2013?

20 A. That would be an understatement, but yes.

21 Q. On an hourly basis?

22 A. It was probably close to that.

23 Q. So you got to know her quite well, quite
24 quickly?

<http://www.yeslaw.net/help>

1 A. Marilyn was running the -- as I think I
2 mentioned, Jon was doing policy and Marilyn was
3 doing HealthCare.gov.

4 So we came in, and I would say I worked
5 equally with Jeff Zients and with Marilyn
6 Tavenner. And so routine calls every day, routine
7 meetings every day, seven days a week. And yes,
8 we talked.

9 But Jeff Zients would have played a
10 similar role, as he was brought in by the White
11 House.

12 Q. And Jon Blum was not involved in the
13 HealthCare.gov. Is that correct?

14 A. Not at all.

15 Q. When you spoke to Jon Blum in March
16 of 2014, did you know he was on his way out of
17 CMS?

18 A. I did not.

19 Q. Did you find that out soon thereafter?

20 A. The answer to that would be yes. I don't
21 know the timing, but yes, I did find out after
22 that.

23 Q. Since Jon Blum has left CMS, have you had
24 any contact with him?

<http://www.yeslaw.net/help>

1 A. I have not.

2 (Exhibit 19 marked for identification)

3 Q. I'm going to hand you what's been marked
4 as Renfro Exhibit 19. It's a one page e-mail,
5 MARA1296260.

6 A. Right.

7 Q. This is an e-mail that you sent to Marilyn
8 Tavenner on April 27, 2014. Did you write this
9 e-mail?

10 A. I did not.

11 Q. Who wrote the e-mail?

12 A. Dave Johnson.

13 Q. Who is he?

14 A. M&R's general counsel or UHC's general
15 counsel, I should say.

16 Q. Did you review it before you sent it?

17 A. Yes.

18 Q. At the time that you sent this, was Jon
19 Blum gone?

20 A. I don't know.

21 Q. And who is Aryana Khalid?

22 A. Chief of staff to Marilyn.

23 Q. Did you know her?

24 A. I did.

<http://www.yeslaw.net/help>

1 Q. And the subject is "Followup meeting."
2 And it says, "Based on CMS's proposed rule that
3 would add requirements to medical chart reviews by
4 Medicare Advantage plans and in light of the
5 annual risk adjustment data certification due
6 April 30th, we wanted to confirm our understanding
7 of how we should be addressing 2012 dates of
8 service."

9 What is it your understanding that the
10 annual risk adjustment data certification says?

11 A. I read that statement as meaning that we
12 had a deadline on April 30th.

13 Q. I'm sorry. Have you ever read the annual
14 risk adjustment data certification?

15 A. I have not.

16 Q. Do you know what it says?

17 A. No.

18 Q. And then it says, "Because the proposed
19 rule would obviously not be effective for 2012
20 dates of service and the fact that other Medicare
21 Advantage plans do not look for possible deletions
22 when reviewing medical records, we are considering
23 stopping our review of medical records to identify
24 potential deletes for 2012 and not deleting any

<http://www.yeslaw.net/help>

1 diagnosis codes that we may have previously
2 identified as potential deletes but not yet
3 submitted."

4 Do you see that?

5 A. Yes.

6 Q. And then you go on to say, "Prior to
7 submitting our attestation this Wednesday, we
8 would like to confirm that our understanding is
9 appropriate."

10 If it was obvious that the rule was not
11 retroactive, why did you need to confirm that?

12 A. Let's go back to the conversation with the
13 customer, being M&R. So they wanted more clarity
14 and they asked me to talk to Marilyn. And I
15 talked to Marilyn.

16 And then I'd go back and I'd tell Marianne
17 what Marilyn said. And M&R asked to have
18 additional clarity. And I'd go back to Marilyn.
19 And her suggestion was that she would put a
20 committee together.

21 Q. A committee?

22 A. A committee, meaning Sean Cavanaugh and
23 Cheri Rice.

24 And that was because we had the discussion

<http://www.yeslaw.net/help>

1 internally. M&R, the client, wanted to talk
2 directly to CMS.

3 Q. Do you know if it was so obvious that the
4 rule wasn't retroactive why they wanted to do
5 that?

6 A. I don't know.

7 Q. Was the thought that in addition to
8 getting confirmation of the obvious thing that the
9 rule wasn't retroactive to also get from CMS a
10 statement that United had no responsibility to
11 ensure -- to do any compliance efforts to ensure
12 the accuracy of the risk adjustment data that it
13 submitted to CMS?

14 A. I don't know.

15 Q. So Marilyn -- you had an earlier
16 conversation with Marilyn. Is that correct?

17 A. Meaning?

18 Q. With Marilyn Tavenner before April 27th.
19 You say "Based on our" -- You say here, "Based on
20 our conversation, I believe the appropriate people
21 for this conversation would be Sean Cavanaugh and
22 Cheri Rice."

23 A. I talked to her the morning of the 26th
24 and told her that the client wanted to talk

<http://www.yeslaw.net/help>

1 directly to CMS, that M&R wanted to talk to CMS.

2 Q. So you talked to her on Saturday,
3 April 26th?

4 A. And she asked for me to put that in, the
5 request.

6 Q. The request for the meeting with her
7 staff?

8 A. Right.

9 Q. How do you remember that that was the
10 26th?

11 A. Explain that.

12 Q. Is it on your calendar? How do you
13 remember that you called her on Saturday morning,
14 the 26th of April 2014?

15 A. Because I remember getting the call on the
16 25th in the evening from M&R or from our lawyer
17 asking me to arrange it.

18 Q. Which lawyer is that?

19 A. Marianne Short.

20 Q. Was Mr. Shores involved in those calls
21 too?

22 A. Short.

23 No.

24 Q. It says here, "The fact that other

1 Medicare Advantage plans do not look for possible
2 deletions when reviewing medical records."

3 You didn't know whether that was correct
4 or not, that statement, when you sent it. Is that
5 true? You didn't know --

6 A. I was relying on the customer to tell me.

7 Q. You personally had no knowledge --

8 A. No, I did not.

9 Q. Okay. And the customer is?

10 A. M&R.

11 Q. And who particularly were you relying on
12 for that fact from M&R?

13 A. The general counsel.

14 Q. Is that Johnson?

15 A. Right.

16 Q. I see. And isn't it correct that prior to
17 your sending this e-mail you had already -- M&R
18 had already suspended the claims verification
19 process?

20 A. I don't know.

21 Q. So when was your first conversation with
22 Marilyn Tavenner about this? Was that April 26th?

23 A. April 8th.

24 Q. And how do you remember that?

<http://www.yeslaw.net/help>

1 A. I had documented that.

2 Q. So what led you to -- Is that the first
3 call that you had with Marilyn Tavenner about this
4 issue, April 8th?

5 A. I had had a conversation to tell her that
6 I'd like to set up a call and that she should
7 probably talk to Jonathan Blank because I had
8 already talked to him.

9 Q. Okay. So that was before April 8th?

10 A. Uh-hmm.

11 Q. When was that?

12 A. I don't know.

13 Q. And what did she do? Do you know?

14 A. I don't know.

15 Q. Do you know if she ever talked to Jonathan
16 Blank?

17 A. I don't know.

18 MR. MERON: Wait for the question.

19 A. I think she did.

20 Q. Why do you think she did?

21 A. Because on the 8th when we had the
22 conversation, she referenced she talked to John.

23 Q. So what led you to making contact with her
24 about this issue?

<http://www.yeslaw.net/help>

1 A. The fact that M&R wanted her to opine on
2 what I'd learned from John in her opinion.

3 Q. Why did they want her opinion?

4 A. They were looking for just another point
5 of clarification.

6 Q. Do you know why?

7 A. I don't.

8 Q. And do you know who it was at M&R who
9 wanted that?

10 A. I don't.

11 Q. Was it Ben Johnson?

12 A. I don't know.

13 Q. Did anyone provide you with any speaking
14 points for the call with Marilyn Tavenner on
15 April 8th?

16 A. No.

17 Q. Did you ask anyone for speaking points?

18 A. No.

19 Q. Prior to making that call to Marilyn
20 Tavenner on April 8th, did you get any information
21 or direction or guidance or advice from anyone
22 about what to say to her on the call?

23 A. Yes.

24 Q. And who did you get --

1 A. Marianne Short.

2 Q. Anyone else?

3 A. No.

4 Q. Did you speak to Mr. Hemsley about the
5 call before you made it?

6 A. Yes.

7 Q. And what did you discuss with Mr. Hemsley?

8 A. I just informed him --

9 MR. MERON: Excuse me. Is that a separate
10 call from the one with Marianne or was it one call
11 they were both on?

12 THE WITNESS: They would have been both on
13 it.

14 Q. So Marianne Short was with you when you
15 had the conversation with Mr. Hemsley?

16 A. She was with Steve. She was with
17 Mr. Hemsley. And it was a call.

18 Q. Do you have -- Prior to making the call to
19 Marilyn Tavenner, did you have a call to
20 Mr. Hemsley without attorneys present?

21 A. No.

22 Q. And prior to making the call to Marilyn
23 Tavenner, did you have a discussion with anyone
24 else other than Mr. Hemsley and Marianne Short

<http://www.yeslaw.net/help>

1 about the call?

2 A. No.

3 Q. Did anyone else know you were going to be
4 making the call?

5 A. Not that I know of.

6 Q. So prior to making the call to Marilyn
7 Tavenner on April 8th, you had never seen the
8 compliance regulation that I showed you earlier
9 today. Correct?

10 A. No, I had not seen it.

11 Q. Where did you make the call from? Where
12 were you?

13 A. I'm not sure. I'm not sure.

14 Q. Was anyone with you when you made the
15 call?

16 A. No.

17 Q. Did you tape-record it?

18 A. No.

19 Q. Did you record it somehow?

20 A. I documented it.

21 Q. But you didn't make a recording of any
22 sort?

23 A. No.

24 Q. Did you have any goals or objectives in

<http://www.yeslaw.net/help>

1 mind when you made the call or before you made the
2 call to Marilyn Tavenner about what you wanted to
3 accomplish during the call?

4 A. No, other than doing the right thing.

5 Q. What do you mean by "doing the right
6 thing"?

7 A. We wanted to get the right clarification
8 so that my customer would do the right thing.

9 Q. Does that mean comply with all existing
10 regulations?

11 A. With regard to claims verification? Is
12 that the question?

13 Q. No. Regarding to compliance obligations.

14 A. We were only talking about claims
15 verification.

16 Q. The proposed rule, had you ever read it
17 before you made the call?

18 A. No.

19 Q. Have you ever read it since?

20 A. No.

21 Q. Is your understanding that the proposed
22 rule uses the terms "claims verification"?

23 A. I don't know.

24 Q. Do you know what the proposed rule says?

<http://www.yeslaw.net/help>

1 A. No.

2 Q. Do you know whether Marilyn Tavenner even
3 knew what the proposed rule was when you talked to
4 her?

5 A. I don't know.

6 Q. Would you be surprised to hear that
7 perhaps, just like you, maybe she also didn't know
8 what the proposed rule was?

9 A. I don't know.

10 Q. So two of you could have been speaking
11 about a rule that neither one of you ever read.
12 Is that correct?

13 A. I don't know.

14 Q. So what did Marilyn Tavenner know, if
15 anything, about the claims verification program at
16 United when you talked to her on April 8th?

17 A. I don't know.

18 Q. Did you tell her anything about it? I
19 guess it would have been hard because you didn't
20 really know anything about it. Right?

21 A. I'd asked her to talk to John.

22 Q. But you don't really know what John knows
23 about it. Right?

24 A. Right.

<http://www.yeslaw.net/help>

1 Q. Did someone tell you to take notes of the
2 call you made to Marilyn Tavenner on April 8th?

3 A. They did.

4 Q. I'm sorry?

5 A. They did.

6 Q. Who told you?

7 A. Marianne Short.

8 MR. MERON: Sorry. I didn't know that was
9 going to be his answer. Let's not discuss
10 communications with lawyers.

11 MS. WALLACK: I don't think that counts as
12 legal advice, really. But if you wanted to define
13 that as legal advice, go for it.

14 Q. Do you know if anyone from Latham &
15 Watkins knew you were going to make the call
16 before you made it?

17 A. I don't know.

18 Q. Did Dave Wichmann know about the call
19 before you made it?

20 A. No.

21 Q. Is it your practice to take notes during
22 calls?

23 A. No.

24 Q. Did you after the call with Marilyn

<http://www.yeslaw.net/help>

1 Tavenner send anyone an e-mail about the call?

2 A. No.

3 Q. So the call on April 8th that you made to
4 Marilyn Tavenner, you didn't send her an e-mail
5 confirming what you discussed with her during the
6 call. Is that correct?

7 A. That's correct.

8 Q. Why not?

9 A. It's up to my client to do this. I was
10 working from a relationship standpoint doing what
11 my client was asking me to do.

12 So my feeling was the relationship terms
13 of the contract and so forth between them, not
14 Optum. So I was just trying to have the
15 relationship of Optum to M&R.

16 I was trying to do what they asked me to
17 do. So I'm trying to understand what Marilyn and
18 her clarification, portray that, explain that to
19 my client through Marianne Short. They wanted
20 more clarification.

21 Q. So you documented the call, but you didn't
22 send Marilyn Tavenner a confirming e-mail about
23 your discussion?

24 A. Did not.

<http://www.yeslaw.net/help>

1 Q. And that's because you weren't asked to.
2 And you were only going to do what you were asked
3 to do. Correct?

4 A. As long my client is not doing anything
5 illegal, I will do what they ask me to do.

6 Q. Or jump off a bridge or something like
7 that.

8 So after you had this call with Marilyn
9 Tavenner on April 8th, did you send any e-mails to
10 anyone about the call?

11 A. No.

12 Q. Did you talk to anyone about the call?

13 A. Yes.

14 Q. And who did you speak with?

15 A. Marianne Short, Steve Hemsley.

16 Q. So you talked to them both before and
17 after the call?

18 A. Yes, together both times.

19 Q. Do you know why it was such a big issue
20 that Mr. Hemsley was involved?

21 A. No.

22 Q. Was it a lot of money involved in this
23 issue?

24 A. I don't know.

<http://www.yeslaw.net/help>

1 Q. Is it generally when Mr. Hemsley becomes
2 involved when there's a lot of money around an
3 issue?

4 A. He picks things to get involved in. I
5 don't know why.

6 Q. I guess I have to ask him. Is that
7 correct?

8 A. (No verbal response)

9 Q. So what specifically did you say to
10 Marilyn Tavenner on the call on April 8th?

11 A. I asked her did she have the same
12 understanding on claims verification as John.

13 She said if the proposed rule goes into
14 effect -- and I'm paraphrasing now. If the
15 proposed rule goes into effect January 1, 2015,
16 you should be doing normal business, which means
17 you do not have to be doing claims verification.

18 And then I think I asked her and she might
19 have mentioned something about the written
20 language and so forth.

21 And so then I asked her, "Are you the
22 final decision-maker on this?"

23 And she said, "Yes."

24 Or I may have put it a different way.

<http://www.yeslaw.net/help>

1 Maybe I said, "Do I need to go to anybody else to
2 make my client feel comfortable with the clarity
3 of this?"

4 And she said she was decision-maker.

5 Q. Okay. So you asked her if you had to do
6 claims verification, but you don't -- did you
7 explain to her what claims verification was?

8 A. No.

9 Q. And so you're not sure, sitting here
10 today, that she even know what claims verification
11 was. Correct?

12 A. She knew about the proposed rule, and I
13 believe she had discussed it with Jonathan Blum.

14 Q. And so when she was talking about what you
15 had or had not to do, was she talking about the
16 retroactivity of the proposed rule? Do you know?

17 A. That's the way I read it.

18 Q. Okay. And she was saying that -- she
19 opined to you that the rule was not retroactive?

20 A. We did not talk about the rule. We talked
21 more about the situation that it would go into
22 effect January 1, 2015. It wasn't in effect right
23 now. That's how we discussed it.

24 Q. And she -- who used the words "normal

<http://www.yeslaw.net/help>

1 business practices"?

2 A. She did.

3 Q. Do you know what she meant by "normal

4 business practices"?

5 A. I took that to mean that it's not in
6 effect, and you should be just doing what you're
7 normally doing with claims verification.

8 Q. Isn't what you normally did claims
9 verification? Wasn't that the normal practice for
10 several years?

11 A. She was -- I assume she was speaking from
12 the standpoint that it doesn't exist because it
13 hasn't gone into effect yet.

14 Q. Did she say "claims verification doesn't
15 exist"?

16 A. She said "the proposed rule."

17 Q. Right. Okay. So do you know whether when
18 you made the call to Marilyn Tavenner on April 8th
19 whether she knew anything about what exactly this
20 proposal said?

21 A. I don't.

22 Q. And you didn't tell her because you didn't
23 know. Right?

24 A. Right.

<http://www.yeslaw.net/help>

1 Q. Okay. On this call on April 8th, did you
2 tell her that the rule -- that in United's
3 opinion, the rule was obviously not retroactive?

4 A. I probably didn't say it like that. I
5 probably said: How could the rule be in effect if
6 the proposed rule goes into effect January 1,
7 2015? That's my question.

8 Q. So you asked a question rather than made a
9 statement?

10 A. I probably made a statement.

11 Q. Okay. So you made a statement because it
12 was United's position by this point, right, on
13 April 8th that the proposed rule was obviously not
14 retroactive?

15 A. It was not United's position because
16 that's why we were asking her the question. We
17 were seeking clarity.

18 Q. So on April 8th, United's position was not
19 that the rule was obviously not retroactive, but
20 by April 27th that was United's position.
21 Correct?

22 A. By April 27th, we were positioning ourself
23 to go and have another meeting with CMS to have
24 more clarity.

<http://www.yeslaw.net/help>

1 C E R T I F I C A T E

2

3 I, Michelle Keegan, Registered Merit Reporter
4 and Notary Public in and for the Commonwealth of
5 Massachusetts, do hereby certify that the
6 foregoing transcript, Volume I, is a true and
7 accurate transcription, to the best of my ability,
8 of my stenographic notes taken on Friday, May 6,
9 2016.

10

11

12

13

14 Michelle Keegan

15 Notary Public

16 My commission expires:

17 May 16, 2019

18

19

20

21

22

23

24

EXHIBIT 45



4/8/2014, 3:30pm CST

Larry Renfro
Chief Executive Officer
19025 Technology Drive
Eden Prairie, MN 55344
T 952.935.7203
F 952.935.0644
larry.renfro@optum.com

MARILYN TAVENNER INDICATED THAT
WE MAY PROCEED AS IF THE CLAIMS
VERIFICATION PROCESS DID NOT EXIST
FOR 2012, 2013, AND 2014 DUE TO THE
LACK OF REGULATORY LANGUAGE
PERTAINING TO CHART VERIFICATION.

SHE STATED THAT WE SHOULD NOT
BE TREATED DIFFERENTLY THAN OTHER
HEALTH PLANS AND WE SHOULD DO
BUSINESS AS WE NORMALLY DO.

WHEN ASKED IF WE NEED ANY OTHER
APPROVAL ON THIS ISSUE, TAVENNER
SAID, "NO, YOU ARE FINE TO HANDLE AS
NORMAL BUSINESS PROCESS."

EXHIBIT 46

Message

From: Renfro, Larry C [larry.renfro@optum.com]
Sent: 4/28/2014 6:48:40 AM
To: Leafgren, Janis A [janis_a_leafgren@uhg.com]
Subject: Fw: Follow Up Meeting

Could you coordinate?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.
From: Cavanaugh, Sean (CMS/CMMI) <Sean.Cavanaugh@cms.hhs.gov>
Sent: Monday, April 28, 2014 7:46 AM
To: Renfro, Larry C
Cc: Simpkins, Alyson R. (CMS/CM)
Subject: RE: Follow Up Meeting

Alyson - This one is time sensitive.

From: Cavanaugh, Sean (CMS/CMMI)
Sent: Monday, April 28, 2014 7:34 AM
To: 'larry.renfro@optum.com'
Cc: Simpkins, Alyson R. (CMS/CM)
Subject: RE: Follow Up Meeting

Larry - I am copying Alyson Simpkins who handles my calendar to help arrange a time to meet.

From: Tavenner, Marilyn (CMS/OA)
Sent: Sunday, April 27, 2014 2:00 PM
To: 'larry.renfro@optum.com'
Cc: Blum, Jonathan D. (CMS/CM); Khalid, Aryana C. (CMS/OA); Cavanaugh, Sean (CMS/CMMI)
Subject: Re: Follow Up Meeting

I agree. I am looping in Sean to set up time with you guys this week.

From: Renfro, Larry C [mailto:larry.renfro@optum.com]
Sent: Sunday, April 27, 2014 12:44 PM
To: Tavenner, Marilyn (CMS/OA)
Cc: Blum, Jonathan D. (CMS/CM); Khalid, Aryana C. (CMS/OA)
Subject: Follow Up Meeting

Marilyn:

Based on CMS' proposed rule that would add requirements to medical chart reviews by Medicare Advantage plans and in light of the annual risk adjustment data certification due April 30, we wanted to confirm our understanding of how we should be addressing 2012 dates of service. Because the proposed rule would obviously not be effective for 2012 dates of service and the fact that other Medicare Advantage plans do not look for possible deletions when reviewing medical records, we are considering stopping our review of medical records to identify potential deletes for 2012 and not deleting any diagnosis codes that we may have previously identified as potential deletes but not yet submitted. Prior to submitting our attestation this Wednesday, we would like to confirm that our understanding is appropriate. Based on our conversation, I believe the appropriate people for this conversation would be Sean Cavanaugh and Cheri Rice.

Thanks for your time.

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EXHIBIT 47

*Privileged and Confidential
Attorney Work Product
Attorney/Client Communication
April 29, 2014*

CMS MEETING NOTES

Meeting Date

- April 29, 2014
- Approximate start time was 12:45 eastern time

Attendees

- CMS: Sean Cavanaugh, Cynthia Tudor, Cheri Rice, Dan [Farmer], Julie Grover
- UnitedHealth Group (UHG): Dan Schumacher, Steve Nelson, Karen Erickson, Thad Johnson

Location

- UHG attendees: HHS offices in Washington DC
- CMS attendees: CMS offices in Baltimore, MD

Topic

- Medical records review requirements; Notice of Proposed Rulemaking (NPR or “proposed rule”) issued in January 2014; 2012 annual risk adjustment data certification

Meeting Summary

- CMS and UHG representatives began the meeting by introducing themselves. UHG representatives explained the reason for requesting the meeting and asked whether the CMS attendees had seen the email to Marilyn Tavenner sent by Larry Renfro on April 27 requesting the meeting (see exhibit A hereto). CMS attendees acknowledged that they had read the email and inquired as to UHG’s specific ask.
- UHG representatives explained their understanding that CMS’ proposed rule relates to future periods and wanted to confirm any potential impact to 2012 dates of service in light of the annual risk adjustment data certification for 2012 dates of service due on April 30.
- CMS had a number of clarifying questions relating to UHG’s current processes as they relate to medical records review
- UHG representatives provided a general overview of UHG’s claim verification process and explained that UHC had already submitted a number of deletes for 2012 dates of services as a result of that process. (Later in the meeting, UHG representatives informed CMS that the number of new and unique diagnosis code deletes already submitted was approximately 13,000.) UHG representatives also indicated that, in light of the proposed rule and other discussions with CMS, UHC had suspended its claims verification process pending a decision by the Company of whether it was appropriate to submit additional deletes to CMS that have been identified through the Company’s claims verification process; and also whether the Company should continue with, make changes to, or stop, its current process to identify any additional potential deletes relating to 2012 dates of service.
- Cheri Rice of CMS indicated that until the proposed rule relating to medical records review was finalized, MA plans do not have any proactive responsibility to confirm whether diagnoses submitted by physicians are correct. She also said, however, that if a plan has knowledge that specific codes submitted through medical claims are not supported by medical charts appropriate deletes should be submitted. She summarized this by saying that if a plan has knowledge of an overpayment it should submit appropriate deletes.

- There was then a more detailed discussion of UHG's claim verification process, including the last step of the process being a review by an external expert. Cheri Rice asked for a quantification of the number of codes at various steps in the process. UHG's representatives informed CMS of the number of new and unique codes that had previously been submitted for deletion for 2012 dates of services (approximately 13,000); the number of new and unique codes for which all steps of the claims verification process had been completed, including external review, but which had not been submitted as deletes due to the Company suspending its claims verification process in light of (1) CMS' proposed rule, (2) prior conversations with CMS and (3) the inherent FFS error rate (approximately 8,000); and the number of codes that the Company estimated might be deleted if the Company were to continue its claims verification process to conclusion, including external review, for all codes that were still under review in the claims verification process (i.e., codes for which the claims verification process had not been completed) (approximately 40,000). Cheri Rice requested clarification of the last group and was informed that these codes were at various stages of the process including not having been through external review.
- Cheri Rice then asked some follow-up questions on the general state of the submission of deletes relating to 2012 dates of service based on a call other CMS employees had with OptumInsight the week of April 21, and whether our inquiry was related to the deletes discussed on that call. UHG representatives explained that the prior call related to a number of other deletes that were still in the process of being completed, including finalization of the Q/A process relating to chart review and completion of the Company's process for obtaining attestations for medical charts that may not have included signatures. UHG further explained in response to CMS questions that the Q/A process for chart review was separate from the claims verification process and was a quality control procedure for codes added as a part of chart review. As part of this discussion, CMS representatives reiterated that, under CMS regulations, MA plans were not required to design their chart review programs for overall accuracy until the proposed rule is finalized. Sean Cavanaugh stated that, under current rules, if UHG doesn't know codes are inaccurate the Company would not have to delete them. He went on to state that if UHC does not know until the end of its claims verification process that a code is incorrect then there is no requirement to delete the code until the effective date of CMS' final rule. Cheri Rice added that there is a false claims act requirement that plans not knowingly keep overpayments so if you do not know that there is an overpayment you do not need to delete a code.
- UHC representatives then informed CMS that, due to the new electronic certification methodology and the resultant inability to footnote the certification as UHG had done previously, UHG would be submitting a letter from Steve Nelson explaining UHG's understandings regarding the certification. CMS representatives indicated they were working with other plans on similar concerns.
- UHG inquired whether CMS could provide any guidance into assumptions the Company should make about chart review requirements in preparing its bids for 2015. After conferring among themselves, CMS representatives acknowledged the issues created by the proposed rule, but stated they could not provide any guidance into assumptions UHG should make in preparing its 2015 bids.
- UHG representatives thanked CMS attendees for their time and the meeting concluded.

EXHIBIT 48

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE CENTRAL DISTRICT OF CALIFORNIA

3	- - - - -	+
4	UNITED STATES OF AMERICA,	
5	Plaintiff,	Civil Action No.
6	vs.	2:16-cv-08697-
7	UNITEDHEALTH GROUP, INC.,	MWF-SS
8	et al,	
9	Defendants.	
10	- - - - -	+

11 Videotaped Deposition of Marilyn B. Tavenner
12 Washington, D.C.
13 Wednesday, February 28, 2018
14 9:06 a.m.

15
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17
18
19
20
21
22
23
24 Reported by: Laurie Donovan, RPR, CRR, CSR
25 Job No: 137792

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1 rule was never finalized? 11:15AM

2 A I do. 11:15AM

3 Q Now, do you recall that in April of 11:15AM

4 2014, you were approached by Larry Renfro of 11:15AM

5 United to discuss whether or not MA plans were 11:15AM

6 required to conduct reviews that would look not 11:15AM

7 only for diagnosis codes to add but for diagnosis 11:15AM

8 codes to be deleted? 11:16AM

9 MR. FREEBORNE: Objection to form. 11:16AM

10 THE WITNESS: I remember being 11:16AM

11 approached by Larry to discuss a concern he 11:16AM

12 had about the process that involved review of 11:16AM

13 charts. 11:16AM

14 BY MR. SCHINDLER: 11:16AM

15 Q And tell me what you recall about that. 11:16AM

16 A That he was asking me about something 11:16AM

17 that was in the proposed rule that related to 11:16AM

18 chart review, and giving me his ideas on what he 11:16AM

19 thought it meant, and I listened to him, and then 11:16AM

20 I referred him to our staff. 11:16AM

21 Q Do you recall telling Mr. Renfro that 11:16AM

22 because this proposed rule was not yet in effect, 11:16AM

23 that there was no requirement for United to go 11:17AM

24 back to look at charts in order to look for codes 11:17AM

25 to delete? 11:17AM

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1 A No.

11:17AM

2 Q Okay. Do you recall telling him that

11:17AM

3 two-way looks were not required because this

11:17AM

4 proposed rule was not yet in effect?

11:17AM

5 A No. I recall sending him to the staff

11:17AM

6 to ask that question.

11:17AM

7 Q Okay. Well, as you sit here, do you

11:17AM

8 recall whether he, in fact, went to the staff or

11:17AM

9 whether the staff met with Mr. Renfro or anybody

11:17AM

10 at United to discuss this question?

11:17AM

11 MR. FREEBORNE: Objection to form.

11:17AM

12 You can answer.

11:17AM

13 THE WITNESS: So I recall that I

11:18AM

14 recommended that he meet with the staff and

11:18AM

15 ask the staff to make that happen.

11:18AM

16 BY MR. SCHINDLER:

11:18AM

17 Q That you asked the staff to meet with

11:18AM

18 him, okay, and when you asked the staff to make

11:18AM

19 that happen, did they follow your instructions?

11:18AM

20 A I don't know the answer to that, because

11:18AM

21 I handed it off to them to manage, which is the

11:18AM

22 way I handled everything in the agency.

11:18AM

23 Q Okay.

11:18AM

24 (Exhibit 1007 was marked for

11:18AM

25 identification.)

11:18AM

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1 BY MR. SCHINDLER:

11:18AM

2 Q Showing you what's been marked as

11:18AM

3 Exhibit 1007, and it's a double-sided, two-page

11:18AM

4 exhibit, and it appears to be an email chain that

11:19AM

5 begins in April 27 of 2014 with an email from

11:19AM

6 Mr. Renfro to you, copied to Mr. Blum and someone

11:19AM

7 named Aryana Khalid.

11:19AM

8 Do you see that? It begins, "Marilyn."

11:19AM

9 A I do.

11:19AM

10 Q And Mr. Renfro wrote to you, "Based on

11:19AM

11 CMS' proposed rule that would add requirements to

11:19AM

12 medical chart reviews by Medicare Advantage plans,

11:19AM

13 and in light of the annual risk adjustment data

11:19AM

14 certification due April 30, we wanted to confirm

11:19AM

15 our understanding of how we should be addressing

11:19AM

16 2012 dates of service. Because the proposed rule

11:19AM

17 would obviously not be effective for 2012 dates of

11:19AM

18 service, and the fact that other Medicare

11:19AM

19 Advantage plans do not look for possible deletions

11:19AM

20 when reviewing medical records, we are considering

11:19AM

21 stopping our review of medical records to identify

11:19AM

22 potential deletes for 2012 and not deleting any

11:19AM

23 diagnosis codes that we may have previously

11:20AM

24 identified as potential deletes but not yet

11:20AM

25 submitted. Prior to submitting our attestation

11:20AM

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1 this Wednesday, we would like to confirm that our 11:20AM
2 understanding is appropriate. Based on our 11:20AM
3 conversation" -- and that's his reference to the 11:20AM
4 conversation he had with you, correct? 11:20AM

5 A Yes. 11:20AM

6 Q And that conversation pertained to the 11:20AM
7 topic he had outlined in this paragraph, the 11:20AM
8 proposition of whether or not United was required 11:20AM
9 to look for possible deletions, correct? 11:20AM

10 MR. FREEBORNE: Objection to form. 11:20AM

11 THE WITNESS: He's outlining his 11:20AM
12 opinion, and then he's saying he believes the 11:20AM
13 appropriate people for this conversation 11:20AM
14 would be Sean and Cheri Rice, which is what 11:20AM
15 we talked about on the phone. 11:20AM

16 BY MR. SCHINDLER: 11:20AM

17 Q But my question was different, 11:20AM
18 Ms. Tavenner, so if you'd listen carefully, I'd 11:20AM
19 appreciate it. 11:20AM

20 He writes to you, "Based on our 11:20AM
21 conversation," and that's a reference to the 11:20AM
22 conversation that you had with Mr. Renfro prior to 11:20AM
23 the date of this email, correct? 11:21AM

24 A First of all, you're stopping 11:21AM
25 mid-sentence. The entire sentence says, "Based on 11:21AM

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1 our conversation, I believe the appropriate people 11:21AM
2 for this conversation would be Sean Cavanaugh and 11:21AM
3 Cheri Rice" -- 11:21AM

4 Q I understand. 11:21AM

5 A -- and that was based on our 11:21AM
6 conversation. I instructed him to go meet with 11:21AM
7 the staff. 11:21AM

8 Q I understand. 11:21AM

9 MR. FREEBORNE: Counsel, I ask that 11:21AM
10 you allow the witness to complete her answer. 11:21AM

11 BY MR. SCHINDLER: 11:21AM

12 Q Based on the conversation you had with 11:21AM
13 Mr. Renfro previously, you had indicated that he 11:21AM
14 should go talk with Mr. Cavanaugh and Ms. Rice, 11:21AM
15 correct? 11:21AM

16 A With Mr. Cavanaugh and Ms. Rice, yes. 11:21AM

17 Q Right, but my question is a little 11:21AM
18 different. It's in terms of his description of 11:21AM
19 this issue that precedes the notion of going to 11:21AM
20 talk to Mr. Cavanaugh and Ms. Rice. You with me? 11:21AM
21 His description of that conversation relates to 11:21AM
22 this idea of whether or not United is required to 11:21AM
23 delete codes based upon the proposed rule, 11:21AM
24 correct? 11:22AM

25 MR. FREEBORNE: Objection to form. 11:22AM

1 THE WITNESS: Again, I'm not sure 11:22AM

2 what you're asking. 11:22AM

3 BY MR. SCHINDLER: 11:22AM

4 Q If you look at the entirety of the 11:22AM

5 paragraph that Mr. Renfro writes to you, his 11:22AM

6 description of what the issue is, whether or not 11:22AM

7 United is required to delete codes; given that 11:22AM

8 this proposed rule is not yet in effect, his 11:22AM

9 description of what the issue is, is that an 11:22AM

10 accurate description of what it was he was asking 11:22AM

11 you? 11:22AM

12 MR. FREEBORNE: Objection to form. 11:22AM

13 THE WITNESS: He wasn't asking me. 11:22AM

14 He was giving me his impression of what he 11:22AM

15 could do under the proposed rule, and when he 11:22AM

16 gave me that impression, I suggested that he 11:22AM

17 sit down with the staff, because it would be 11:22AM

18 up to the staff to decide that. 11:22AM

19 BY MR. SCHINDLER: 11:22AM

20 Q To decide -- 11:22AM

21 A And I sent him to the staff that is 11:22AM

22 responsible for the Medicare Advantage program, 11:22AM

23 the same way I would do anyone who came with a 11:23AM

24 question. You send them to the subject matter 11:23AM

25 expert and to the management in that area, and you 11:23AM

1 get them to tell you what they can and cannot do. 11:23AM

2 Q Okay, and on the first page of this 11:23AM

3 exhibit, you write, "I agree. I'm looping in Sean 11:23AM

4 to set up time with you guys this week," and then 11:23AM

5 Mr. Cavanaugh tells you that he'll reach out to 11:23AM

6 Mr. Renfro and take care of it, and Ms. Khalid 11:23AM

7 writes, "They need to meet ASAP, Sean, due to some 11:23AM

8 timing issues." 11:23AM

9 Do you see that? 11:23AM

10 MR. FREEBORNE: Objection to form. 11:23AM

11 THE WITNESS: Yes. 11:23AM

12 MR. FREEBORNE: And compound. 11:23AM

13 BY MR. SCHINDLER: 11:23AM

14 Q And I want to ask you: With respect to 11:23AM

15 the conversation you had with Mr. Renfro, if his 11:23AM

16 recollection of that conversation he had with you 11:23AM

17 was that you told him that United was not required 11:23AM

18 to delete -- to look for deletions because the 11:24AM

19 proposed rule was not yet in effect, would he be 11:24AM

20 inaccurate? 11:24AM

21 MR. FREEBORNE: Objection to form. 11:24AM

22 THE WITNESS: I told him that I 11:24AM

23 could not make that decision, that that 11:24AM

24 decision would be something he would have to 11:24AM

25 discuss with the staff and Medicare 11:24AM

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1 Advantage, and I sent him to those people. 11:24AM

2 BY MR. SCHINDLER: 11:24AM

3 Q Okay, and I think I asked you earlier, 11:24AM

4 and I apologize, but do you recall whether 11:24AM

5 Ms. Rice or Mr. Cavanaugh reported back to you 11:24AM

6 after their meeting with United? 11:24AM

7 MR. FREEBORNE: Objection to form. 11:24AM

8 THE WITNESS: I don't recall. 11:24AM

9 BY MR. SCHINDLER: 11:24AM

10 Q Go ahead. I'm sorry. You don't recall? 11:24AM

11 A No. 11:24AM

12 Q Is that they could have and you don't 11:24AM

13 recall, or you don't know one way or the other? 11:24AM

14 A I just -- 11:24AM

15 MR. FREEBORNE: Same objection. Go 11:24AM

16 ahead. 11:25AM

17 THE WITNESS: I don't recall. I 11:25AM

18 frequently handed off issues to the 11:25AM

19 appropriate management and subject matter 11:25AM

20 expert for them to handle. 11:25AM

21 BY MR. SCHINDLER: 11:25AM

22 Q Were you aware that Ms. Rice confirmed 11:25AM

23 that until that proposed rule relating to medical 11:25AM

24 records review was finalized, that Medicare 11:25AM

25 Advantage plans did not have any proactive 11:25AM

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1 responsibility to confirm whether diagnoses 11:25AM

2 submitted by physicians were correct? 11:25AM

3 MR. FREEBORNE: Objection to form. 11:25AM

4 THE WITNESS: I am not aware of 11:25AM

5 what Ms. Rice said on this issue. 11:25AM

6 BY MR. SCHINDLER: 11:25AM

7 Q And if she had provided that information 11:25AM

8 to members of United, would that have been 11:25AM

9 inconsistent with what you had told Mr. Renfro? 11:25AM

10 MR. FREEBORNE: Objection to form. 11:25AM

11 THE WITNESS: I told Mr. Renfro he 11:25AM

12 was to go meet with the appropriate staff. 11:25AM

13 BY MR. SCHINDLER: 11:26AM

14 Q As of 2014, you understood that United 11:26AM

15 was, in fact, not performing additional searches 11:26AM

16 to look for codes to delete, correct? 11:26AM

17 MR. FREEBORNE: Objection to form. 11:26AM

18 THE WITNESS: I'm not sure United 11:26AM

19 ever told me what they were or were not 11:26AM

20 doing. 11:26AM

21 BY MR. SCHINDLER: 11:26AM

22 Q But as indicated in the email that 11:26AM

23 Mr. Renfro indicated to you here, the one that we 11:26AM

24 just looked at, he tells you "we are considering 11:26AM

25 stopping our review of medical records to identify 11:26AM

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1 potential deletes for 2012 and not deleting any 11:26AM
2 diagnosis codes," right? That's something he 11:26AM
3 wrote to you on April 27, 2014, correct? 11:26AM

4 A He wrote that he was considering that 11:26AM
5 based on what he believed was in the proposed 11:26AM
6 rule. I told him I could not answer that. I 11:27AM
7 understood his question, I could refer him to 11:27AM
8 subject matter experts, so I referred him to the 11:27AM
9 administrator for the Medicare Advantage program 11:27AM
10 and asked that they meet with him. 11:27AM

11 Q Aside from this proposed rule that never 11:27AM
12 went into effect, you were unaware of any other 11:27AM
13 CMS regulation that required United or any MA plan 11:27AM
14 to go look for additional codes to delete, were 11:27AM
15 you? 11:27AM

16 MR. FREEBORNE: Objection to form. 11:27AM

17 THE WITNESS: I don't know the 11:27AM
18 answer to that. I was not at that level of 11:27AM
19 detail. 11:27AM

20 BY MR. SCHINDLER: 11:27AM

21 Q Is it fair to say, Ms. Tavenner, that 11:27AM
22 during the entire time that you were at CMS -- so 11:27AM
23 from 2010 until 2015 -- that CMS never made a 11:27AM
24 decision to stop making payments to United based 11:27AM
25 upon the fact that United was not conducting 11:28AM

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1 medical records review to look for codes to 11:28AM

2 delete? 11:28AM

3 MR. FREEBORNE: Objection to form. 11:28AM

4 THE WITNESS: I can't answer that 11:28AM

5 question. 11:28AM

6 BY MR. SCHINDLER: 11:28AM

7 Q Well, do you ever -- 11:28AM

8 A I do not know the answer to that 11:28AM

9 question. 11:28AM

10 Q I'm asking: During the time that you 11:28AM

11 were administrator, you have no recollection of 11:28AM

12 anybody at CMS -- I'm sorry, strike that -- of 11:28AM

13 CMS, the agency itself, refusing to make payments 11:28AM

14 to United based upon United's failure to look for 11:28AM

15 additional codes to delete? 11:28AM

16 MR. FREEBORNE: Objection to form. 11:28AM

17 THE WITNESS: I still can't answer 11:28AM

18 that question. I don't remember. I cannot 11:28AM

19 answer that question. 11:28AM

20 BY MR. SCHINDLER: 11:28AM

21 Q You don't remember whether CMS made a 11:28AM

22 decision to stop paying United? Is that, is that 11:28AM

23 your testimony? I want to make sure I'm asking 11:28AM

24 the question correctly. 11:28AM

25 MR. FREEBORNE: Objection to form. 11:28AM

1 THE WITNESS: I don't remember. I 11:28AM

2 don't know. 11:28AM

3 BY MR. SCHINDLER: 11:28AM

4 Q Well, you don't have any recollection of 11:28AM

5 that happening, do you? 11:28AM

6 MR. FREEBORNE: Objection to form. 11:29AM

7 THE WITNESS: I have told you I 11:29AM

8 cannot answer that question. I do not know 11:29AM

9 the answer to that question. 11:29AM

10 BY MR. SCHINDLER: 11:29AM

11 Q But you never made the decision, as you 11:29AM

12 sit here, to tell anybody at CMS we should stop 11:29AM

13 paying United because they're not performing a 11:29AM

14 search for codes to delete in medical records? 11:29AM

15 MR. FREEBORNE: Objection to form. 11:29AM

16 THE WITNESS: Are you asking me the 11:29AM

17 question did I direct the staff to stop 11:29AM

18 paying United? 11:29AM

19 BY MR. SCHINDLER: 11:29AM

20 Q Correct. 11:29AM

21 A I did not. 11:29AM

22 Q And as you sit here, you don't remember 11:29AM

23 anybody of the staff coming to you to ask you 11:29AM

24 whether they could stop paying United? 11:29AM

25 MR. FREEBORNE: That may implicate 11:29AM

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1 deliberative process.

11:29AM

2 BY MR. SCHINDLER:

11:29AM

3 Q Well, I'm just asking the foundational
4 question.

11:29AM

11:29AM

5 Do you have any memory of anybody of the
6 staff coming to you to ask whether CMS could stop
7 paying United based upon the fact that United was
8 not looking for additional codes to delete; yes or
9 no?

11:29AM

11:29AM

11:29AM

11:29AM

11:29AM

10 MR. FREEBORNE: As phrased -- as
11 phrased, we'll need to take a break.

11:29AM

11:29AM

12 MR. SCHINDLER: I just want the
13 foundational yes or no. I'm not asking
14 anything more, just do you recall whether you
15 were asked that question.

11:29AM

11:29AM

11:30AM

11:30AM

16 MR. FREEBORNE: But the problem is
17 that embedded in the question is sort of a
18 deliberation, and, and if it can be
19 rephrased, we can move on.

11:30AM

11:30AM

11:30AM

11:30AM

20 MR. SCHINDLER: I'm just -- if you
21 want to propose a way to rephrase it to me,
22 there's no need to rephrase it. It's a
23 yes-or-no question whether somebody came to
24 her. The follow-on questions may elicit
25 deliberative privilege, Mr. Freeborne, but

11:30AM

11:30AM

11:30AM

11:30AM

11:30AM

11:30AM

1 I'm just asking a yes-or-no question whether 11:30AM
2 that -- she has any memory of that occurring, 11:30AM
3 and if the answer is no, then there's no 11:30AM
4 deliberation. 11:30AM

5 MR. FREEBORNE: Let me just take a 11:30AM
6 break just to be careful. 11:30AM

7 THE VIDEOGRAPHER: The time is now 11:30AM
8 11:30. We are going off the record. 11:30AM

9 (Whereupon, a short recess was 11:33AM
10 taken.) 11:33AM

11 THE VIDEOGRAPHER: The time is now 11:33AM
12 11:35. We are on the record. 11:33AM

13 MR. FREEBORNE: Counsel, you had 11:34AM
14 asked that I propose a rephrasing. As I hear 11:34AM
15 it, the core of your question is whether or 11:34AM
16 not Ms. Tavenner had any discussions with 11:34AM
17 staff regarding stopping payment to United. 11:34AM
18 If that's the question, she has no 11:34AM
19 recollection of that, and she can so testify. 11:34AM

20 If it seeks to go into 11:34AM
21 deliberations with the staff, you know, I 11:34AM
22 think we can obviate that issue since she 11:34AM
23 doesn't have any recollection of discussing 11:34AM
24 this topic whatsoever. 11:34AM

25

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1 BY MR. SCHINDLER:

11:34AM

2 Q So just so the record is clear, the 11:34AM
3 answer to my question then would be no? Because I 11:34AM
4 want to make sure that the question of whether you 11:34AM
5 have any recollection of anybody coming to -- and 11:34AM
6 we can read the question back, but I need a -- I 11:34AM
7 need an answer apart from Mr. Freeborne. 11:34AM

8 So can you read back the question? 11:34AM

9 THE REPORTER: Yes. 11:34AM

10 (Whereupon, reporter reads 11:35AM
11 requested material.) 11:35AM

12 MR. FREEBORNE: Objection to form, 11:35AM
13 and as I said, I proposed a rephrasing to 11:35AM
14 obviate a privilege issue. 11:35AM

15 If you can answer the question 11:35AM
16 without divulging deliberative process, go 11:35AM
17 ahead. 11:35AM

18 THE WITNESS: I do not remember any 11:35AM
19 discussions by the staff on the issue of 11:35AM
20 stopping payment on United. 11:35AM

21 BY MR. SCHINDLER:

11:35AM

22 Q Can I just go back for one moment to the 11:35AM
23 conversation you had with Mr. Renfro? You, you 11:35AM
24 testified that Mr. Renfro came to you to express a 11:35AM
25 concern, and can you tell me, what was his 11:35AM

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1 concern?

11:35AM

2 MR. FREEBORNE: Objection to form.

11:35AM

3 This is just to clarify what he said, or are

11:35AM

4 you asking her to read his mind? What is the

11:35AM

5 question?

11:35AM

6 MR. SCHINDLER: You've made your

11:35AM

7 objection to form. The question is pending.

11:36AM

8 She testified that he had a concern.

11:36AM

9 BY MR. SCHINDLER:

11:36AM

10 Q And my question is: What was the

11:36AM

11 concern he expressed to you?

11:36AM

12 A It seems the concern he expressed was

11:36AM

13 what he put in writing.

11:36AM

14 Q Okay, so just so we're clear, you're

11:36AM

15 referring back to Exhibit --

11:36AM

16 A 1007.

11:36AM

17 Q And the concern --

11:36AM

18 A At the top of page 2.

11:36AM

19 Q Just so we're looking at the same thing,

11:36AM

20 you're referring to his email to you?

11:36AM

21 A Yes.

11:36AM

22 Q So the, the discussion at his initial

11:36AM

23 email to you of April 27, 2014, that description

11:36AM

24 in that email accurately reflects what he told you

11:36AM

25 during his conversation with you?

11:36AM

1 MR. FREEBORNE: Objection to form. 11:36AM

2 THE WITNESS: Again, what he said 11:36AM

3 to me was he was talking about chart review 11:36AM

4 and a proposed rule. It probably wasn't 11:37AM

5 quite as eloquent as this, but either way I 11:37AM

6 said I understand your concerns. I'm going 11:37AM

7 to get you to sit down with the staff. I 11:37AM

8 can't answer your question. I'll have to 11:37AM

9 refer it to the staff, and the staff can give 11:37AM

10 you their decision. 11:37AM

11 BY MR. SCHINDLER: 11:37AM

12 Q Got it, and you have some recollection 11:37AM

13 of this conversation, Ms. Tavenner, so my question 11:37AM

14 is: What was the concern that -- strike that. 11:37AM

15 You testified a moment ago you said "I 11:37AM

16 understand your concern," okay? What was the 11:37AM

17 concern that you understood Mr. Renfro to be 11:37AM

18 expressing to you? 11:37AM

19 A It's basically what's written here. He 11:37AM

20 was getting ready to sign an attestation. He was 11:37AM

21 unclear about what to do with the records that he 11:37AM

22 had reviewed, and it didn't really get into as 11:37AM

23 much detail as was in this email, but it was 11:37AM

24 enough where the proposed rule, the fact that he 11:37AM

25 wanted to sign for validation, he needed an 11:38AM

1 answer. I referred him to the staff. 11:38AM

2 Q And he needed an answer about whether it 11:38AM

3 was appropriate for United to cease looking for 11:38AM

4 diagnosis codes to delete, correct? 11:38AM

5 MR. FREEBORNE: Objection to form. 11:38AM

6 THE WITNESS: He was looking for an 11:38AM

7 answer about what he was supposed to do with 11:38AM

8 the records he had reviewed, because he 11:38AM

9 wanted to sign the attestation, and he wanted 11:38AM

10 to make sure he did it correctly. 11:38AM

11 BY MR. SCHINDLER: 11:38AM

12 Q And as you sit here, your testimony is 11:38AM

13 that the only thing you told him was go check with 11:38AM

14 staff or I will arrange a meeting with staff? Is 11:38AM

15 that the sum total of your recollection of what 11:38AM

16 you told him? 11:38AM

17 MR. FREEBORNE: Objection to form. 11:38AM

18 THE WITNESS: The sum total of my 11:38AM

19 recollection is I said I hear your problem. 11:38AM

20 I can't answer the question. I've got to 11:38AM

21 refer you to the staff, because they're going 11:38AM

22 to be the experts on this. 11:38AM

23 BY MR. SCHINDLER: 11:38AM

24 Q And so it's because you didn't know 11:38AM

25 whether or not United was required to look for 11:39AM

EXHIBIT 49

**FILED UNDER SEAL
IN ITS ENTIRETY**

EXHIBIT 50

**FILED UNDER SEAL
IN ITS ENTIRETY**

EXHIBIT 51

OMB Approved # 0938-0944

INSTRUCTIONS FOR COMPLETING
THE MEDICARE ADVANTAGE
BID PRICING TOOLS
FOR CONTRACT YEAR 2014

April 5, 2013

IV. APPENDICES

APPENDIX A – ACTUARIAL CERTIFICATION

CMS requires an actuarial certification to accompany every bid submitted to HPMS. A qualified actuary who is a member of the American Academy of Actuaries (MAAA) must complete the certification. The objective of obtaining an actuarial certification is to place greater responsibility on the actuary's professional judgment and to hold him/her accountable for the reasonableness of the assumptions and projections.

Actuarial Standards of Practice and Other Considerations

In the actuarial certification, the actuary must certify that the actuarial work supporting the bid conforms to the current Actuarial Standards of Practice (ASOP), as promulgated by the Actuarial Standards Board. While other ASOPs apply, particular emphasis is placed on the following:

- ASOP No. 5, *Incurred Health and Disability Claims*.
- ASOP No. 8, *Regulatory Filings for Health Plan Entities*.
- ASOP No. 23, *Data Quality*.
- ASOP No. 25, *Credibility Procedures Applicable to Accident and Health, Group Term Life, and Property/Casualty Coverages*.
- ASOP No. 41, *Actuarial Communications*.
- ASOP No. 45, *The Use of Health Status Based Risk Adjustment Methodologies*.

The certifying actuary must also certify that the actuarial work supporting the bid complies with applicable laws, rules, CY2014 bid instructions, and current CMS guidance. In addition, he/she must consider whether the actuarial work supporting the bid is consistent and reasonable with respect to the plan benefit package and the organization's current business plan.

Certification Module

The certification module contains the following features:

- Standardized required language. (The required elements are described in a subsequent section of this appendix.)
- The ability to append free-form text language to the required standardized language.
- A summary of key information from the submitted bids.
- Links to additional information regarding the bid package such as the PBP, BPT, and supporting documentation.
- The ability to certify multiple bids/contracts.
- The ability to print and save the submitted certification.

An initial actuarial certification must be submitted via the HPMS certification module in June. The actuary must also certify the final bid (that is, pending CMS approval) via the certification module in August following the CMS publication of the Part D national average monthly bid amount, the Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the MA regional benchmarks. Actuaries are not required to certify every intermittent resubmission throughout the bid review process, but they may do so if they wish.

APPENDIX A

Note that in the event that the PBP changes after the “final” bid is certified, the bid that is uploaded into HPMS with the revised PBP must be recertified whether or not the BPT changes.

Material changes to the certification language (after the initial June certification submission) are not allowed without prior written permission from the CMS Office of the Actuary.

Plan sponsors may have multiple actuaries assigned to one contract to perform the certifications. For example, a consulting actuary may certify the Part D portion of a bid, while an internal plan staff actuary may certify the MA portion of the bid. Also, one actuary may certify plan Hxxxx-001, while a different actuary may certify plan Hxxxx-002. The instructions contained in this appendix must be followed by all actuaries who will be certifying CY2014 bids.

If a certification is not submitted via the HPMS certification module, the bid will not be considered for CMS review and approval.

Every MA BPT requires a certification. Likewise, every PD BPT requires a certification. Since Part D BPTs are not submitted for “800-series” EGWP employer bids, a Part D actuarial certification is not required for EGWPs. However, a certification is still required for the MA portion of “800-series” employer bids.

Additional information regarding the actuarial certification process (including technical instructions for completing the HPMS certification module) will be included in the initial actuarial certification deadline memorandum issued in June 2013.

Required Certification Elements

The certification module contains the following information, as part of the standardized language:

- The certifying actuary’s name/user ID and the date, “stamped” when the certification is submitted.
- Attestation that the actuary submitting the certification is a member of the American Academy of Actuaries (MAAA). As such, the actuary is familiar with the requirements for preparing Medicare Advantage and Prescription Drug bid submissions and meets the Academy’s qualification standards for doing so.
- The specific contract, Plan ID, and segment ID of the bid associated with the certification.
- The contract year of the bid contained in the certification.
- Indication of whether the certification applies to the Medicare Advantage bid, the Part D bid, or both.
- Attestation that the certification complies with the applicable laws,¹ rules,² CY2014 bid instructions, and current CMS guidance.

¹ Social Security Act sections 1851 through 1859; and Social Security Act sections 1860D-1 through 1860D-42.

² 42 CFR Parts 400, 403, 411, 417, 422, and 423.

APPENDIX A

- Attestation that, in accordance with federal law, the bid is based on the “average revenue requirements in the payment area for a Medicare Advantage/Prescription Drug enrollee with a national average risk profile.”
- Attestation that the data and assumptions used in the development of the bid are reasonable for the plan’s benefit package (PBP).
- Attestation that the data and assumptions used in the development of the bid are consistent with the organization’s current business plan.
- Attestation that the bid was prepared in compliance with the current standards of practice, as promulgated by the Actuarial Standards Board of the American Academy of Actuaries, and that the bid complies with the appropriate ASOPs.
- A statement that, in compliance with ASOP No. 23, any data and assumptions provided by reliances were reviewed for reasonableness and consistency and that supporting documentation for the reliance on information provided by others is uploaded with the bid.

Please refer to ASOP No. 23, *Data Quality*, and ASOP No. 41, *Actuarial Communications*, for additional details regarding reliances.

Certification Module Access

Detailed instructions regarding how to apply for access to the CY2014 certification module were released via an HPMS memorandum about consultant access or electronic signature access to HPMS.

APPENDIX B – SUPPORTING DOCUMENTATION

GENERAL

In addition to the BPT and actuarial certification, Plan sponsors must provide CMS with supporting documentation for every bid, as described in these instructions.

Unless otherwise noted, Plan sponsors must upload all required supporting documentation at the time of the initial June bid submission. Additional supporting documentation, if requested, must be made available to CMS reviewers within 48 hours, as required by these instructions. Plan sponsors must upload supporting documentation consistent with the final certified bid.

Supporting documentation requirements apply regardless of the source of the assumption, whether it was developed by the actuary, the Plan sponsor, or a third party. If the actuary relied upon others for certain bid data and/or assumptions, those individuals are subject to the same documentation requirements. The actuary must be prepared to produce all substantiation pertaining to the bid, even if it was prepared by others or is based on a reliance.

In preparing supporting documentation, the actuary must consider ASOP No. 41, *Actuarial Communications*. In accordance with Section 3.2, “Actuarial Report,” the materials provided must be written “with sufficient clarity that another actuary qualified in the same practice area could make an objective appraisal of the reasonableness of the actuary’s work.”

All data submitted as part of the bid process are subject to review and audit by CMS or by any person or organization that CMS designates. Certifying actuaries must be available to respond to inquiries from CMS reviewers regarding the submitted bids.

Supporting documentation must be easily understood by CMS reviewers and must include the following:

- The rationale for the assumption, including quantitative support and details, rather than just narrative descriptions of assumptions.
- Plan-specific variations in addition to the overall pricing assumption or methodology.
- Values that match entries in the current BPT and tie to the PBP.
- Excel spreadsheets with working formulas, rather than pdf files.

Supporting documentation must be clearly labeled and include the following information:

- The bid ID. At a minimum, the contract number and organization name must appear on the first page. Specific plan numbers must be included where appropriate, such as on the first page, in a separate chart, or as an attachment.
- A reference to MA, Part D, or both.
- A hard-coded date.
- Contract/Plan number and topic in the beginning of the file name.
- The word “revised”, if any information in the file is revised or appended during bid review.

APPENDIX B

Acceptable forms of supporting documentation include, but are not limited to, the following items:

- Meeting minutes that include comprehensive documentation of discussions related to bid development.
- E-mail correspondence related to bid development.
- A complete description of data sources—for example, a report's official name/title, file name, date obtained, source file, etc.
- Intermediate calculations showing each step taken to calculate an assumption.
- A summary of contractual terms of administrative services agreements.
- A business plan.

Supporting documentation that is not acceptable or that may result in a request for additional information includes, but is not limited to, the following items:

- Materials that can be accessed only through a secure server link that requires a password.
- A reference to the supporting documentation for another plan, such as “the same as for plan Hxxxx-xxx,” and not the documentation itself. The supporting documentation for a plan must be self-contained.
- General descriptions of pricing that do not include plan-specific information.
- A statement that the source of a pricing assumption is “professional judgment” with no additional explanation of the data points underlying the assumptions—for example, supporting factors, studies, or public information.
- “Living worksheets” that are overwritten with current data. Supporting documentation must include the version of the worksheet that was used in bid preparation.
- Information obtained after the bids are submitted.
- A statement that a pricing assumption or methodology is assumed acceptable based on its inclusion in a bid that was approved by CMS in a prior contract year. Data, assumptions, methodologies, and projections must be determined to be reasonable and appropriate for the current bid, independent of prior bid filings.

SUBMITTING SUPPORTING DOCUMENTATION

Supporting materials must be in electronic format (Microsoft Excel, Microsoft Word, or Adobe Acrobat) and must be uploaded to HPMS. CMS will not accept paper copies of supporting documentation. Note that multiple substantiation files can be submitted to HPMS at one time by using “zip” files, which compress multiple files into one (.zip file extension). Also, one file can be uploaded to multiple plans in HPMS by using the CTRL key when plans are selected. However, documentation must not be uploaded to plans to which it does not pertain. It is not acceptable to upload to multiple plans materials specific to a Part D plan, MA plan, or certain contract ID.

Cover Sheet

To expedite the bid review process, Plan sponsors must upload a cover sheet that lists all of the supporting documentation that is uploaded or provided on the bid form. The filename must include the phrase “cover sheet.” A cover sheet is required for each upload of substantiation.

APPENDIX B

The cover sheet must include detailed information for each support item—such as the filename and the location within the file, if applicable—and must clearly identify the bid IDs and whether the substantiation is related to MA, Part D, or both.

Note that some documentation requirements apply to every bid (for example, every bid contains a risk score assumption), while other documentation requirements apply only to bids that contain certain assumptions (for example, manual rate documentation applies only if a bid's projection is based on manual rates). For documentation categories that apply to a subset of bids that contain a specified assumption, the cover sheet must not refer to a "range" of bid IDs (such as "plans 001 – 030" or "all plans under contract Hxxxx"). For these items, the cover sheet must contain the exact bid IDs (contract/plan/segment) to which the documentation applies.

For subsequent substantiation uploads, the cover sheet must summarize the additional documents uploaded at that time (that is, the cover sheet must not be maintained as a cumulative list). The subsequent cover sheets must also contain the exact bid IDs rather than a "range" of bid IDs.

Sample check lists and cover sheets for the initial June bid submission, and for subsequent substantiation uploads, are provided at the end of this appendix.

Timing

Plan sponsors and certifying actuaries must prepare all supporting documentation at the time of the initial June bid submission in order to be immediately available to CMS and reviewers at that time or be readily available upon request as explained below.

- The "Initial June Bid Submission" section in this appendix describes supporting documentation items that Plan sponsors must upload to HPMS with the initial June bid submission.
- The "Upon Request by CMS Reviewers" section of this appendix describes materials that Plan sponsors and certifying actuaries must provide within 48 hours of request by CMS reviewers and upload to HPMS prior to bid approval.
- When a BPT is resubmitted, the Plan sponsor must upload a summary of changes, including the cause and effect of each revision, authorized by CMS or CMS reviewers. If multiple BPTs are submitted at the same time, the supporting documentation must include a mapping of specific bid changes and bid IDs.
- Prior to bid approval,—
 - Plan sponsors and certifying actuaries must revise supporting documentation consistent with the final certified bid. Note that the upload of e-mail correspondence to HPMS alone does not satisfy this requirement.
 - Plan sponsors must upload revised supporting documentation and e-mail correspondence supporting bid resubmissions to HPMS.

Initial June Bid Submission

The following documentation requirements apply to all bids (as all bids contain these assumptions):

- A cover sheet outlining the documentation files, as described above.

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- A product narrative that offers relevant information about plan design, the product positioning in the market (such as high/low), enrollment shifts, service area changes, type of coverage, contractual arrangements, marketing approach, and any other pertinent information that would help expedite the bid review. For dual-eligible SNPs, include a statement indicating how the plan conforms to state and territorial Medicaid regulations for benefits, cost sharing, care management, and margins.
- A document titled “Related Party Declaration,” which states whether or not the Plan sponsor is in a related-party agreement (Worksheets 1 and 4).
- Support for the claims credibility assumptions (Worksheet 2), including—
 - A statement of the credibility approach used—for example, the CMS guideline or the CMS override.
 - A description of the credibility methodology used if it varies from the CMS guideline or the CMS override.
 - The method for blending differences between the credibility for utilization and that for unit cost into a composite PMPM credibility factor.
 - Justification for any variation in the credibility approach by line of business.
 - An explanation for a zero credibility percentage for a service category with credible data.
- A detailed description of the process used for adjusting cost sharing due to maximum OOP limits, including how the PMPM impact of the maximum OOP was determined. (Worksheet 3).
- Support for non-benefit expense assumptions. The required elements include—
 - A reconciliation of the base period non-benefit expenses reported in the BPT and auditable material such as corporate financials and plan-level operational data (Worksheet 1).
 - A description of the expenses included in each non-benefit expense category in the BPT. (Worksheet 4)
 - Detailed support for the development of projected non-benefit expenses (Worksheet 4). The required elements include—
 - A description of the methodology used to develop projected non-benefit expenses.
 - A description of the data source and its relationship to the base period non-benefit expenses reported in the BPT.
 - An explanation for significant differences between actual and expected non-benefit expenses for CY2010, CY2011 and CY2012, including a description of how that knowledge was incorporated into the CY projection.
 - A demonstration of the development of each line item using relevant data, assumptions, contracts, financial information, business plans, and other projections.
- Justification of the gain/loss margin (Worksheet 4). The required elements include—
 - Support for overall MA margin levels including—
 - The Plan sponsor’s margin requirement for all non-Medicare health insurance lines of business, including any change in such requirement in the prior two years, and identification of these lines of business.

APPENDIX B

- ▶ A description of the methodology used to develop the gain/loss margin assumption and the level at which the aggregate margins are determined.
- ▶ For Plan sponsors that choose to satisfy aggregate-level gain/loss requirements at the organization level, a list of the MA contract numbers offered by the organization.
- ▶ A demonstration of consistency of projected margins from year to year.
- ▶ A demonstration of consistency between the aggregate margin for general enrollment plans & I/C SNPs (or for other gain/loss margin categories, if applicable) and the applicable measure of the Plan sponsor's margin requirement, that is, (i) the Plan sponsor's margin requirement for all non-Medicare health insurance lines of business, or (ii) the Plan sponsor's capital and surplus requirement.
- ▶ A demonstration of consistency between the aggregate margin for general enrollment plans & I/C SNPs and other gain/loss margin categories, if applicable.
- ▶ A detailed justification for unique situations, in which the aggregate margin for D-SNPs is outside of the stated range of the aggregate margin for general enrollment plans & I/C SNPs combined, including a description of extenuating circumstances supporting an exception, evidence of the absence of anti-competitive practices and solvency issues, and actions taken to bring the margin differential into compliance with bid instructions.
- ▶ A demonstration of consistency between (projected) aggregate margins and actual aggregate returns over the long term. If historically these items have been inconsistent, provide an explanation for how this is addressed in the current bid submission, for example, how pricing assumptions have been set to make the projected margin more consistent with actual returns.
- Justification for bids with relatively large projected overall gains/losses including an explanation of how the PBP offers benefit value in relation to the margin level.
- Support for bids with negative margins, including one of the following items:
 - ▶ For a new plan, or a plan with a zero or positive projected gain/loss margin for the prior contract year, a bid-specific, year-by-year, numeric business plan that demonstrates profitability within 3 to 5 years.
 - ▶ For a plan with a negative projected gain/loss margin for the prior contract year, a numerical comparison of the gain/loss margin to the MA margin in the original business plan. The required elements include—
 - Details and sources of deviation from the original business plan.
 - An explanation and demonstration as to how the targeted margin in the original business plan will be met, if the plan is progressing towards a positive margin less rapidly than projected in the original business plan.
 - A copy of the original business plan uploaded to HPMS in a separate file.
 - ▶ A description of the MA product pairing, which includes the gain/loss margin for each plan and shows that the plans—
 - Have identical service areas,
 - Are all local coordinated care plans, or all RPPOs, or all PFFS plans,
 - Have the same SNP type (or are all non-SNPs), and

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- Have a positive combined gain/loss margin.
 - For MA-PD plans, a description of the approach for setting the Part D margin in relation to the MA margin.
 - A detailed explanation of the need for flexibility in the gain/loss margin requirements in order to satisfy other CMS requirements.
- A detailed description of the items included in NBE quality initiatives and taxes and fees (Worksheet 4).
- Detailed support for the development of projected risk scores (Worksheet 5). The required elements include—
 - A detailed description, and corresponding numerical demonstration, of the methodology used to develop projected CY2014 MA risk scores.
 - A description of the source data for the development of the projected CY2014 MA risk scores.
 - A description of all projection factors and the basis for the factors.
 - A statement about the consistency between the development of the projected risk scores for the plan population and the development of projected medical expenses.
 - A demonstration that the method used is consistent with the preferred development approach in these instructions, including an explanation for using an alternate approach, if applicable.
 - Justification for and a description of the credibility assumption for actual plan risk scores.

The following documentation requirements apply to all bids that contain the assumptions specified below:

- Detailed support for the development of base period experience (Worksheet 1). This documentation, which is based on regulatory authority for the review of materials that pertain to any aspect of services provided, is also required in cases in which medical services are provided under a capitated arrangement. The required elements include—
 - A description of the allocation of allowed costs by service category when the allocation method is not based on plan experience data (Worksheet 1).
 - Information regarding the base period member months, if for some reason more than eight plans constitute the base period data (see Worksheet 1, Section II, line 5).
 - Reconciliation of base period experience with the audited financial statements and bid-level operational data (Worksheet 1). The data are to be reported on an incurred, rather than an accounting or GAAP, basis, including claims paid, unloaded claim reserves, non-benefit expenses, and revenues. Because the results reflect an experience period versus accounting period, the data need not be based on an audited GAAP financial basis.
 - Justification for the lack of encounter data for services provided under capitated arrangements including—
 - An explanation for the deficiency.
 - A detailed description of the steps that the Plan sponsor has taken or is taking to obtain encounter data for subsequent year's bid submissions.

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- ▶ A description of the data source for utilization per 1,000 and the basis for any adjustments.
- Detailed qualitative and quantitative support for the development of each projection factor (Worksheet 1). The required elements include—
 - A description of the source data, including the data's relevance to the MA plan.
 - A summary of the Plan sponsor's historical trends including—
 - ▶ The percentage trends.
 - ▶ A description of the methodology used to analyze the data.
 - ▶ The numeric calculations.
 - Any applicable adjustments to the source data, such as considerations for—
 - ▶ Plan sponsor's experience, including an explanation for significant differences between actual and expected claims for CY2010, CY2011 and CY2012, and a description of how that knowledge was incorporated into the projection factors.
 - ▶ Industry and/or internal studies.
 - ▶ Benefit design analysis.
 - ▶ A change in the mix of services, including the rationale for the type of projection factor used to reflect such change.
 - ▶ A change in the mix of provider arrangements such as capitated and risk sharing arrangements.
 - Justification for combining data for multiple service categories.
- A detailed description of the NBE quality initiatives and taxes and fees reflected in base period data (Worksheet 1 Section VI).
- Support for the allocation of enrollment between DE# and non-DE# beneficiaries including the basis for classifying dual-eligible enrollees as DE# (Worksheets 1 and 5).
- Support for the pricing, including utilization and unit cost, of incentive programs for preventive services (Worksheets 1 and 2, line q).
- Support for claim costs for hospice enrollees for mandatory supplemental benefits when these costs are included in the projected allowed cost PMPM.
- Detailed support for the data and methodology used in the development of appropriate manual rates for the expected population (Worksheet 2). The required elements include—
 - A description of the source data, including the data's relevance to the MA plan and the precise name of any published tables used.
 - Credibility standards applied to the data and corresponding adjustments, if applicable.
 - Consideration of any adjustments made for annual volatility of the source data.
 - Any applicable adjustments to the source data, such as—
 - ▶ Approach and factors applied to account for incomplete claim run-out and/or expenditures that are not reflected in the source data.
 - ▶ Addition of Medicare-covered benefits not reflected in the source data.
 - ▶ Exclusion of non-covered benefits reflected in the source data.
 - ▶ Techniques and factors used to reflect differences between the underlying population and that expected of the MA plan.

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- Techniques and factors used to adjust for differences in health care delivery system and plan design of the source data as compared to the MA plan.
- Methodology and data used to gross up reimbursements to an allowed-cost basis.
- Data and methodology used to project the data from base period to CY2014.
- The reasonableness of allowed costs and projection factors for costs based on capitated payments to related parties.
- The allocation of projected allowed costs by service categories.
- All other applicable factors and/or adjustments.
- Support for non-DE# projected allowed costs (Worksheet 2).
- An explanation for a zero cost of a benefit that is included in the PBP.
- The rationale for including in non-benefit expenses the cost of a benefit that is included in the PBP.
- Support, at the benefit level, for non-covered services (Worksheet 2, lines l through q, column o), if any, including a breakdown of the PMPM value shown in the BPT. For example, a \$4.00 PMPM in column o of row p, "Health and Education," is to be shown in the supporting documentation as \$1.50 PMPM for a smoking cessation program and \$2.50 PMPM for nutritional counseling. (Detailed support for the pricing of each additional benefit is available upon request.)
- Disclosure of related-party medical and administrative service agreements (Worksheets 1 and 4).
 - A Plan sponsor in a related-party agreement must provide the following:
 - Disclosure of every related-party agreement.
 - A summary that explains the relationship in terms of the parties involved, and common ownership, control, or investment.
 - A summary of the contractual terms of each relationship, to include a description of the services provided, and money exchanged.
 - A description of the approach used to report the medical expense (if applicable), gain/loss margin, and non-benefit expense in the bid.
 - A Plan sponsor that chooses to demonstrate that the terms and fees associated with their administrative services agreement are comparable to those between the related party and unrelated parties of similar size and market position must—
 - Demonstrate and explain the manner in which the terms of one or more of the agreements between the related-party organization and other unrelated parties and the fees associated with the related party transaction are comparable.
 - A Plan sponsor that chooses to demonstrate that the terms and fees associated with their medical services agreement are comparable to those between the related party and unrelated MA organizations of similar size and market position must either—
 - Demonstrate and explain the manner in which the terms of one or more of the agreements between the related-party organization and other unrelated MA organizations and the fees associated with the related party transaction are comparable, or

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- Demonstrate that the fees associated with the related party contract are comparable to 100% FFS.
 - A Plan sponsor who chooses to enter 100% FFS cost in the BPT as net medical expenses must—
 - Document that: (i) it cannot demonstrate the fees associated with the related-party transaction are comparable to the fees between the related party and other unrelated MA organizations of similar size and market position, and (ii) the actual medical costs of the related party cannot be determined.
 - Demonstrate that fees associated with a related-party transaction for medical services are not comparable to 100% FFS costs.
- Support for the development of the contract year ESRD subsidy (Worksheet 4). This required documentation includes the following:
 - Base period (for example, 2012) revenues and medical expenditures for Medicare-covered benefits provided to enrollees in ESRD status.
 - The source for, and the development process of, any manual rates used.
 - Relevant base-to-contract year trend factors.
 - A short narrative on the credibility approach applied to the ESRD experience.
- Detailed support for the MSP adjustment (Worksheet 5).
- Support for zero projected DE# member months when there are DE# members in the base period (Worksheet 5).
- Support for the development of plan-provided ISAR factors (Worksheet 5), if used. (This requirement applies to RPPOs only.) A description of the methodology and data source(s) used to calculate the ISAR factor(s) must be included. The factors must reflect the requirements for medical expense, non-benefit expense, and gain/loss margin. Additionally, the support must illustrate the county-level medical costs (such as unit costs and/or utilization) and retention (that is, non-benefit expense and gain/loss margin) that were assumed in the development of the factors.
- Support for the benefit, projected non-benefit expense, and projected gain/loss margin for specific OSB packages (Worksheet 7).
- In accordance with Appendix D, support for actuarial swaps/equivalence customization allowable for employer and union groups enrolled in individual-market plans, when used (that is, when indicated in the “General Information” section of Worksheet 1).
- For EGWPs, an explanation of the consistency between the pricing in the bid and the expected underwriting assumptions for all groups, in aggregate. This documentation includes, but is not limited to, a description of the underwriting methodology.
- The input sheet(s) for the pricing model used in the development of the bid.
- An explanation of and detailed support for how CY2013 bid audit findings and observations were corrected in the current bid for the same plan. To the extent that an issue applies to other plans in the same contract or parent organization, the documentation for the audited plan must describe how the bids for all plans are treated consistently regarding that issue.
- Support for reliance on information supplied by others that—
 - Identifies the source(s) of the information—for example, name, position, company, date;
 - Identifies the information relied upon;

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- States the extent of the reliance—for example, whether or not checks as to reasonableness have been applied; and
- Indicates to which plan(s) the reliance information applies.

See the sample format at the end of Appendix B.

Upon Request by CMS Reviewers

It is not required that the items below be uploaded with the initial June bid submission, but they must be prepared at that time in order to be readily available for CMS reviewers upon request. If substantiation is requested by CMS reviewers, it must be provided within 48 hours. These materials will be reviewed at audit:

- Support for the pricing of the non-covered services, including utilization and unit cost (Worksheet 2, lines l through r, column o). (Support at the benefit level is required in the initial June bid submission.)
- Detailed support for cost-sharing utilization assumptions and plan-level deductible (Worksheet 3).
- Support for allocation of allowed costs and cost sharing between Medicare-covered and A/B mandatory supplemental benefits (Worksheet 4).
- Support for when the formulas provided in the BPT for DE# plan cost sharing (Worksheet 4, Section IIB, column f) are overwritten at the discretion of the certifying actuary.
- Copies of related-party agreements for a Plan sponsor who has entered into a related-party agreement with an organization that is providing services to unrelated parties.
- Support for the calculation of the “Medicaid Cost Sharing” in column k, including cost sharing required by state or territory Medicaid programs in the plan’s service area based on the eligibility rules for subsidized cost sharing for DE# beneficiaries (Worksheet 4).
- Justification for significant differences between the assumptions of corresponding employer-only group and individual-market products (such as the relationship of the bid to the benchmark). See Appendix D for more information.
- A letter supporting any information upon which the certifying actuary relied, if applicable. This letter must be signed by the person (source) who provided the information.
- Communication between CMS reviewers and the Plan sponsor throughout the bid review process (that is, e-mail communication) that was not uploaded to HPMS during bid review.
- An explanation as to how certain findings from the Office of Financial Management (OFM) audit were addressed in the current bid.

Additional information not specified in this list may be requested by CMS reviewers, as needed, at any point during the bid desk review process.

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MA CHECKLIST FOR REQUIRED SUPPORTING DOCUMENTATION

Initial June Bid Submission – Required for All Bids
Cover sheet
Product narrative
Related-party declaration
Claims credibility assumption
Adjustment to cost sharing for maximum OOP limit
Non-benefit expenses
Gain/loss margin
Projected NBE quality initiatives and taxes and fees
Projected risk scores

Initial June Bid Submission – Required for All Bids with Specified Assumptions
Base period experience and reconciliation
Projection factors
Base period NBE quality initiatives and taxes and fees
Enrollment allocation (DE#/non-DE#)
Preventive services incentive programs
Hospice claims costs for mandatory supplemental
Manual rate development
Non-DE# projected allowed costs
Zero cost benefit
Cost of benefit included in non-benefit expenses
Non-covered services benefit-level summary
Disclosure of related-party agreements
ESRD "subsidy"
MSP adjustment
Projected zero DE# member months
ISAR factors
Optional supplemental benefit (OSB) packages pricing assumptions
Actuarial swaps/equivalences
EGWP comparison of bid pricing and expected underwriting assumptions
Input sheets for pricing model
Bid audit results
Reliance information

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Upon Request by CMS Reviewers
Non-covered services pricing
Cost-sharing utilization and plan-level deductible
Allocation of allowed costs/cost sharing to Medicare-covered and non-covered
Override of formulas for DE# plan cost sharing
Related-party agreements
State and territory cost sharing requirements
Differences in EGWP and general market pricing assumptions
Reliance letter
Bid review communications
OFM audit results
Other

SAMPLE COVER SHEET – SUBMITTED WITH INITIAL BID UPLOAD IN JUNE

Supporting Documentation Cover Sheet #1

CY2014 Bid Submission

Organization Name: Health One

Contract(s): H1234, H9999, and S9999

Date: June 3, 2013

Documentation Requirement	Specific Bid ID(s) or N/A	File Name	Location within File (if Applicable)	Applies to: MA, PD, or Both
Cover sheet	All bids	Cover Sheet 6-1-2013.pdf	Page 1	both
Product narrative	All bids	Cover Sheet 6-1-2013.pdf	Pages 2-4	both
Credibility assumption	All bids	Cover Sheet 6-1-2013.pdf	Page 5	both
Cost sharing mapping	All bids	Cover Sheet 6-1-2013.pdf	Page 6	both
Non-benefit expenses	All bids	AdminProfit.xls	Sheet 1	both
Gain/loss margins	All bids	AdminProfit.xls	Sheet 2	both
Risk scores	All bids	Risk CY2014.xls	MA-Sheet 1 PD-Sheet 2	both
Manual rates	H1234-003-0 S9999-001-0	Manual.xls	Section II	PD
ESRD subsidy	H1234-001-0 H1234-004-0	Manual.xls	Section I	MA

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SAMPLE COVER SHEET – SUBMITTED AS A SUBSEQUENT SUBSTANTIATION UPLOAD

Supporting Documentation Cover Sheet #2

CY2014 Bid Submission

Organization Name: Health One

Contract(s): H1234, H9999, and S9999

Date: July 16, 2013

Documentation Requirement	Specific Bid ID(s) or N/A	File Name	Location within File (if Applicable)	Applies to: MA, PD, or Both
Cover sheet	H1234-001-0 H1234-003-0 H1234-004-0 H1234-801-0 H9999-001-0 S9999-001-0	Cover Sheet 7-16-2013.doc	n/a	both
E-mail communication with CMS bid reviewers	H1234-001-0 H1234-003-0 H1234-004-0 H9999-001-0	Email1.doc	n/a	MA
E-mail communication with CMS bid reviewers	H9999-001-0 S9999-001-0	Email2.doc	n/a	PD
E-mail communication with CMS bid reviewers	H9999-001-0 S9999-001-0	Email3.doc	n/a	PD

SAMPLE FORMAT FOR RELIANCE ON INFORMATION SUPPLIED BY OTHERS

Bid ID	MA or PD or Both	Source (Name, Position, Company)	Type of Information	Comments
H1234-002-00	MA and PD	Joe Smith, Director of Finance, ABC Health Plan	Administrative expenses, gain/loss margin	
H1234-002-00	MA and PD	Jane Doe, Medicare Analyst, ABC Health Plan	Claim modeling, risk score	I have not performed any independent audit or otherwise verified the accuracy of these data or information.

EXHIBIT 52

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Attorneys for United Defendants

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

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-MWF(SSx)

**DECLARATION OF JON BIRD IN
SUPPORT OF UNITED'S
OPPOSITION TO PLAINTIFFS'
MOTION FOR PARTIAL
SUMMARY JUDGMENT**

Date: September 17, 2018
Time: 10.00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

DECLARATION OF JON BIRD

I, Jon Bird, hereby declare as follows:

1. I am a Vice President, General Management at Optum, one of the UnitedHealth Defendants (hereinafter "Optum"). I make this declaration in support of United's Opposition to the Plaintiff's Motion for Partial Summary Judgment in this matter.

2. I have personal knowledge, information, or belief of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

3. I have held my current position of Vice President, General Management at Optum for approximately 2 years.

4. Prior to that role, I served as a Senior Vice President, Risk and Quality Analytics at Optum, where my responsibilities included leading risk adjustment and quality analytics across population covered by United, including Medicare Advantage, Medicaid, and commercial coverage. My work included developing logic supporting gaps in risk, revenue forecasting, sweep estimates and reconciliation, financial impact analysis, audit support, and Risk Adjustment Data Validation.

5. I have significant experience with, and extensive involvement in and knowledge of, UnitedHealthcare, Medicare & Retirement's ("United") Chart Review Program.

6. During the relevant time period of 2009 through 2017 (date of service years 2008 through 2016), United performed chart reviews covering significantly more than 25% of United's beneficiaries.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 23, 2018, in Coto de Caza, California.

By

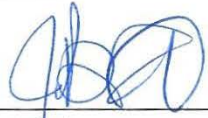

Jon Bird

EXHIBIT 53

March 28, 2003

NOTE TO: Medicare+Choice Organizations and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2004
Medicare+Choice (M+C) Payment Rates

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the M+C capitation rate methodology and risk adjustment methodology for CY 2004. Preliminary estimates of the various national per capita M+C growth percentages and the methodology changes for CY 2004 are also attached. For 2004 and 2005, CMS will announce the M+C rates on the second Monday in May before the calendar year concerned, in accordance with Section 532 of P.L. 107-188, the Public Health Security and Bioterrorism Response Act of 2002. This Advance Notice is published 45 days before that date.

Attachment I shows the preliminary estimates of the national per capita growth percentage for both the blend rates and the floor amount. Attachment II of this Notice includes a detailed discussion of the new CMS-HCC risk adjustment model that will be in effect for CY 2004, the new ESRD payment approach, and various implementation issues affecting CY 2004 payments.

We will continue paying M+C organizations in 2004 on a fee-for-service basis for covered clinical trial items and services provided to their members.

Comments or questions may be addressed to:

Ms. Anne Hornsby
Centers for Medicare & Medicaid Services
7500 Security Boulevard
C4-01-22
Baltimore, Maryland 21244

In order to receive consideration prior to the May 12, 2003 announcement of M+C capitation rates, comments must be received by April 14, 2003.

/ s /

Gail Pardue McGrath
Director
Center for Beneficiary Choices

/ s /

Solomon Mussey, A.S.A.
Director
Medicare and Medicaid Cost Estimates Group
Office of the Actuary
Attachments

Clinical Features of the CMS-HCC Model

HCCs are disease groups broadly organized into body systems, somewhat analogous to the ICD-9-CM major diagnostic categories. Unlike the ICD-9-CM categories, however, the diagnoses within each disease group are related clinically and in terms of cost to the Medicare program.

Whereas the PIP-DCG model places a person in only a single cost group based on his/her principal inpatient diagnosis with the greatest cost implications, the CMS-HCC model is structured so that each disease group contributes its incremental predicted cost to payment amounts. Conceptually, disease groups are not mutually exclusive because unrelated disease processes each contribute to the predicted costs of care. The CMS-HCC model uses diagnoses from physician visits and hospital inpatient and outpatient stays to assign each beneficiary to none, one, or more than one disease group. For example, an M+C enrollee with heart disease, cerebrovascular disease, and cancer would be assigned to three separate disease groups, and CMS's payment for this enrollee will reflect increments for each of these conditions. We refer to this as an additive model because, in general, each additional diagnosis results in an increased payment.

In some cases, however, an additional diagnosis does not trigger an additional payment increment because a more severe diagnosis supercedes a less serious one. That is, the CMS-HCC model also can characterize a beneficiary's illness level within a disease process. In some disease groups the diagnoses are clinically related and ranked by (cost) severity in a hierarchy, since the more severe manifestations of a disease process principally define the impact of that disease group on cost.

An example is the diabetes hierarchy. Diabetes diagnoses are organized into four severity groups, ranked from uncomplicated diabetes to diabetes with renal manifestations (highest cost implications). A person may be coded with diagnoses in any or all of the four severity groups, but only the highest code in the hierarchy is used to increment payment for diabetes. There are similar hierarchies among cancers and cardiac diseases. In short, costs are additive across hierarchies and disease groups, but not within hierarchies. (See **Exhibit 2** for a draft list of the disease groups that have hierarchies.)

CMS-HCC Model Refinement.

In the original HCC model developed by Health Economics Research, there were approximately 5,000 ICD-9 codes grouped into about 100 disease clusters used for payment, which is about a third of the approximately 15,000 possible codes in ICD-9-CM. The developers isolated and excluded codes that were vaguely defined, only represented signs or symptoms, and did not contribute significantly to the predictive power of the model. They made decisions about how to cluster codes and which to exclude in consultation with a panel of physicians using statistical information and clinical input.

CMS was able to reduce further the size of the original HCC model, with only a modest effect on the power of the model to predict costs, by taking into account the clinical and cost significance of various disease groups relative to the model's overall performance and clinical coherence. The CMS-HCC model categorizes a reduced set of ICD-9-CM diagnosis codes (approximately 3,300 codes grouped into a reduced set of about 800 codes) into approximately 64 disease groups

(HCCs). (The draft list of the reduced code set that triggers payment in the CMS-HCC model was published in April 2002 on the CMS website at <http://www.cms.hhs.gov/healthplans/riskadj/>. The final list of codes for 2004 will be published May 12, 2003 in the Announcement of M+C Payment Rates. Each year we will issue a list of required diagnoses to take into account new ICD-9 codes.) CMS analysts used both statistical information and clinical input from physicians to trim the original HCC model. The general principles for trimming the model included: retaining disease categories from each body system; not disrupting hierarchies; removing the categories with the smallest cost and predictive power implications; removing categories with very few people unless very costly; removing marginal categories that require a large number of codes; and including categories based on clinical judgment.

The clear structure of the original HCC model allowed us to associate diseases categories with incremental costs and construct tables to show how often certain disease groups occur in the Medicare population (based on a 5 percent fee-for-service sample of Medicare beneficiaries). We used stepwise regression, a technique that ranks the variables by their predictive power, to identify the disease groups that were weakest from a statistical point of view, i.e., the groups with the least predictive power.¹ Based on the results of this analysis, we produced a range of possible models from one with very few disease groups to a full comprehensive model, and discussed the advantages and disadvantages of each with a panel of physicians from within and outside CMS. Most of the panelists preferred the more comprehensive models because they were more clinically defensible and less subject to gaming. However, they found that a model such as the CMS-HCC version presented here was a reasonable compromise, given the need to balance improved payment accuracy with minimizing administrative data burden.

Since the initial selection of the CMS-HCC model, CMS has continued to refine the model, addressing concerns about coding practices and model performance. CMS contracted with an independent group to study issues of coding practice and its effect on how the model would perform when applied. Based on the findings, CMS modified the cancer and diabetes hierarchies. For example, metastatic (secondary site) cancer codes are not reported as frequently as they should be in fee-for-service claims data, so the distinction between multiple primary sites and metastases is poor in the Medicare data. Reflecting this, the secondary site codes have been merged with other costly primary cancers. For diabetes, further study of the costs and coding resulted in a reordering of the codes within the diabetes hierarchy. We will continue to assess the need for improvements in the model in 2004 and beyond.

CMS also incorporated some interactive terms in the model to capture the combined effects on cost of certain diseases. In most instances, simply adding the incremental costs of multiple diseases captures the combined effect that individual diseases have on costs. However, research

¹ Regression analysis is a technique used to predict outcomes, measure the strength of the association between independent variables (predictors, e.g., demographic variables) and the dependent variable (outcome, i.e. Medicare expenditures), and, to identify the subset of independent variables that are most effective for estimating the outcome. Stepwise regression is a form of this technique that is used to identify the subset of variables that is most effective for estimating the outcome. It works by eliminating those independent variables from the regression that contribute least to explaining the outcome.

has shown that some combinations of diseases are more or less costly to treat than the sum of the costs of individual diseases. Thus, interactive terms representing combined effects are in the model. The diseases involved are diabetes, congestive heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, renal failure, and coronary artery disease. There are also terms in the model that distinguish the costs of the disabled (under 65) from the aged for specific diseases. These are disorders that typically have more expensive treatment patterns in the younger population, e.g., drug and alcohol psychosis and dependence, opportunistic infections, and cystic fibrosis.

See the end of this section for information on another CMS refinement of the HCC model – the addition of an adjuster for long-term institutional status.

Estimation methods. The fee-for-service data used to calibrate the models are from 1999 and 2000. The diagnoses and Medicaid status are from 1999, and the total costs for each beneficiary are from 2000. ESRD patients were excluded from calibration of the CMS-HCC model. They will be paid under an alternative payment methodology to reflect their unique costs, described in Section B.

Decedents in 2000 are included and treated as they were in the previous payment models. First, their costs were annualized, i.e., inflated to correspond to a full 12-month period. Then, when the model was estimated, the decedents were assigned a weight according to the proportion of the year they were alive. M+C enrollees and hospice patients are treated similarly: their costs are included until they enter hospice or enroll in an M+C organization. All claim types were used to compute costs. Hospital inpatient, outpatient and clinical practitioner claims were used to collect diagnoses. Principal and secondary diagnoses were used from institutional bills and the diagnoses from claim headers were used from the practitioner bills. Fully denied claims were not used. However, diagnoses were accepted from claims that had Medicare Secondary Payer as the reason for denial.

The estimation was done using the weighted least squares method. The cost variable was annualized and weights were set to the fraction of the year in months that each person was alive and not in a hospice or M+C organization. Annualization and weighting was also done to reflect a beneficiary's time and expenditures in the community or institutionalized status category. The expenditures in each status were summed separately. Statistical formulations more elaborate than weighted linear regression have been researched but did not improve the performance of risk adjustment models significantly or consistently.

When models are estimated using the regression method, each characteristic (demographic or diagnostic) is estimated to determine its marginal costliness to the Medicare program. Use of the regression method produces a coefficient for each variable (characteristic), which represents the marginal (additional) effect of each variable in predicting program costs. These coefficients are then converted to relative cost factors, because in order to use the model as an adjuster to a base rate, costs must be converted to relative costs – i.e., risk adjustment factors. This is done by dividing the marginal costs by the average per capita costs in fee-for-service Medicare. For example, if the average per capita cost in Medicare is \$5000, a marginal cost of \$1000 for some characteristic becomes a relative risk factor of 0.2. To arrive at a beneficiary's total risk

adjustment factor, add the factors associated with each applicable demographic characteristic and each applicable disease group.

Adjustment for coding intensity and population changes. We believe that there have been sufficient changes in the national average predicted expenditures from 1997 to 2004 that it may not be appropriate to use the 1997 national average predicted expenditures to calculate the relative risk factors for the 2004 CMS-HCC model. These changes are related to changes in fee-for-service-population data attributable to changing demographics, average disease burdens, and coding patterns (i.e., later data tends to reflect more precise coding).

The CMS-HCC risk adjustment model is calibrated on expenditures and disease patterns for 1999 and 2000. When the coefficients from that calibration are used to predict expenditures from earlier or later periods, the model would predict the same mean were it not for the factors above. However, the predicted means from earlier years tend to be lower than those from later years. Fee-for-service coding intensity and specificity, particularly in physician claims, has increased over time. In other words, if we created relative risk factors for our 2004 CMS-HCC model using 2000 claims data on a sample of fee-for-service beneficiaries and then used these risk factors to calculate the risk scores for a 2004 sample fee-for-service beneficiaries with exactly the same demographic and actual disease profile as the 2000 sample, the 2004 group would still have higher risk scores than the 2000 group.

When calculating the ratebook for 1997, we are exploring using the national means from each of three years to compute the relative risk scores for the counties. This method would make the mean relative risk factor for fee-for-service equal to 1.0 for that period. It is desirable that the mean relative score stay at this value, so CMS will consider an actuarial adjustment to the national mean predicted expenditures used to calculate relative risk factors so that the mean relative risk factor in fee-for-service remains close to 1.0 for the payment period. Note that any changes in population demographics and rising coding intensity are happening in the fee-for-service population, which is the basis for the risk adjustment model.

Adjustment for long-term institutionalization. In the course of our research addressing other characteristics distinguishing cost among beneficiaries, we found further evidence for differences in cost between the community population and the long-term institutionalized (defined as those in institutions more than 90 days) within the same disease groups. The direct recognition of health status in the model results in a large overprediction for the long-term institutionalized if not controlled for in the model. We also found that the costs for the short-term institutionalized resemble the costs for beneficiaries with similar health status residing in the community.² These findings do not show that the long-term institutionalized are not expensive to Medicare. What we are recognizing is that people in the community are even more expensive to the program than equally ill people (in the same disease groups) who are long-term institutionalized.

Institutional status is recognized in the payment year, not the prior year. To implement an adjuster without creating burden for the M+C organizations, CMS is using the Minimum Data Set (MDS) collected routinely from nursing homes to identify the population of long-term

² Hereafter, the term “community” will be used to refer to community-based and short-term institutionalized populations.

institutionalized. MDS assessments are sent to the States and CMS on at least a quarterly basis. CMS is using the presence of a 90-day assessment in the payment year to identify the long-term residents for payment purposes. Payment at the long-term rate would start in the month following the assessment. Once persons are so identified, they remain in long-term status until discharged home for more than fourteen days. Note that this marker is different from the institutionalized marker used in the demographic system. That marker largely captured the higher costs of older and sicker people who go into skilled or unskilled levels of care. In the risk adjustment model, the health status markers capture most of these characteristics. We are concentrating on long-term residents and their cost patterns, after controlling for disease.

The CMS-HCC model has been calibrated separately for the community and long-term institutionalized populations. Disease-related incremental payments for the community population are generally higher than those for the institutionalized. The age/sex payments are higher for the institutionalized than the community population. The costs associated with high mortality rates in the long-term institutionalized group are all captured in this calibration, which included only the institutional months for this population. The CMS-HCC model for the institutionalized has been simplified even further than the community model. The same diseases are captured, but many disease groups have been merged to assure stable coefficients. The resulting model is similar to some of the reduced models that were researched for the whole population.

B. New payment methodology for M+C ESRD enrollees.

Simultaneous with the implementation of the CMS-HCC model for risk adjustment, we are implementing a new approach to improve payments on behalf of enrollees with End Stage Renal Disease (ESRD). Section 605 of BIPA required CMS to adjust our approach to computing ESRD payment rates to reflect the method used in the ESRD social HMO (S/HMO) demonstration then in place. We interpret this to mean that ESRD payments to M+C organizations should employ the same basic approach as under the ESRD demonstration referenced in section 605. To implement the BIPA provision for 2002, CMS increased the base rates by three percent and began adjusting payments with age and sex factors, while continuing to review other options. Effective January 2004, M+C enrollees with ESRD will be incorporated into diagnosis-based risk adjustment using a different version of the CMS-HCC model. (See **Exhibit 3** for a draft list of coefficients for each disease group.) The new ESRD payment model will align us further with the method used in the ESRD S/HMO demonstration by allowing us to capture co-morbidity information in addition to demographic information and basic disease markers for ESRD beneficiaries. ESRD status is recognized in the payment year. The data for 100 percent of ESRD beneficiaries were used to develop the model. The three parts of the ESRD CMS-HCC model are:

1. A full risk adjustment model for people on dialysis that is calibrated only on this population, so the payment weights are unique to these beneficiaries. A rescaled state-level ratebook will be created to reflect this population's program costs.
2. A series of lump-sum payments to reflect costs associated with transplant procedures. Transplant costs associated with the month of transplant and two following months are carved out of expenditures for the ESRD population to allow CMS to make larger

transplant-specific payments (outside of the risk adjustment model) over a three-month window.

3. A modified version of the regular CMS-HCC model for people who have successful kidney transplants. The model has an additional term to recognize the extra costs of immunosuppressive drugs and higher intensity of care for this group.

We developed this three-part model in response to our findings on expenditures patterns for ESRD beneficiaries. Dialysis patients have high ongoing costs, while transplant patients incur a very high one-time cost. Functioning graft patients are much more similar to the general population than they are to dialysis patients. Using the same payment weights for all three groups would lead to over- or underpayments to M+C organizations that do not have enough ESRD enrollees to have an average mix. To address this problem, CMS developed separate payment approaches for these three populations.

Risk adjustment model for dialysis patients. The dialysis model has the same HCC categories as the CMS-HCC model for the non-ESRD population, except that HCCs with kidney disease diagnoses are excluded (HCC128 to HCC132). The model is calibrated only on dialysis patients, so the disease weights used for payment recognize disease and expenditure patterns unique to this population.

The data used for calibrating the ESRD models were 1999 (diagnostic) and 2000 (cost) data on fee-for-service ESRD beneficiaries. For example, expenditures for a fee-for-service beneficiary on dialysis from January through August 2000 who received a transplant in September 2000 are included in the dialysis group for eight months, but then are excluded. From September through November 2000, this beneficiary's costs are included in the transplant data to determine estimated average transplant costs. As of December 2000, this beneficiary is included in the functioning graft model.

Transplant patients. To pay more accurately for the high costs of kidney transplants, CMS will make transplant-specific payments to M+C organizations for three months for each member who received a transplant, beginning in the month of transplant. CMS calculated a national average cost for three months (the transplant month and two subsequent months) and divided the average for the three months by three to get the average monthly cost. CMS converted the average monthly cost to a relative factor. The ratio of this monthly cost to the national average monthly cost for dialysis patients is the factor. This factor multiplies the rates in the dialysis ratebook to determine payment. No additional ratebook is needed, as this method produces a payment that is the national rate, geographically adjusted.

For example, assuming that the national average three-month program cost for a transplant is \$40,000 and that the national average monthly cost for a dialysis patient is \$3,500, the relative factor would be 3.81 (i.e., $[40,000/3]/3500$). Payments for a transplant for a resident of a nationally average county would be $3.81 \times 3,500 = \$13,335$ for each of three months. Payments in higher or lower cost counties would vary.

See Section D.6 for information on a new option M+C organizations may choose to adopt for reporting dialysis and transplant status of members.

Functioning graft beneficiaries. The model for functioning graft enrollees is based on the model for the general population, except that HCCs for kidney transplant status, dialysis status and renal failure are excluded. This means that for their members with functioning grafts, M+C organizations will be paid in 2004 based on the diseases reported for functioning graft members recorded in 2003 (the reporting year for 2004). However, CMS also will make an add-on payment for each functioning graft enrollee to recognize the extra costs associated with immunosuppressive drugs and additional intensity of services for this population. The payment model is a slight modification of the regular model; all the coefficients are the same (with the exclusions above) but a term with a factor for the average additional costs of these beneficiaries is included.

The functioning graft payment automatically begins the month after the third transplant payment unless CMS hears from the M+C organization or the CMS data system that the member has returned to dialysis. Anytime a functioning graft patient returns to dialysis, payment is made using that model.

Since Section 605 of BIPA required CMS to adjust our approach to computing ESRD payment rates to reflect the method used in the ESRD social HMO (S/HMO) demonstration then in place, we interpret this to mean that the new three-part model will be implemented at 100 percent of payments for 2004, just as the 2002 changes to the ESRD methodology per BIPA were implemented at 100 percent. See Section E for a discussion of Medicare Secondary Payer status.

C. Changes in Methodology for PACE and certain Demonstrations

Background.

Overview: CMS has developed a Medicare payment approach that adjusts the payment to an organization according to the frailty of an organization's enrollees. The frailty adjustment approach will be applied to the PACE program in 2004. The current PACE demonstrations are expected to transition to PACE program status during 2003. New PACE demonstrations will be paid under the same approach as the PACE program in 2004.

The current social HMO (S/HMO) demonstration is scheduled to end by December 31, 2003. In the absence of a legislative extension, we plan to continue the S/HMO demonstration with the risk adjusted payment methodology incorporating the frailty adjustment approach. The current waiver for the Wisconsin Partnership Program (WPP) demonstration expires on December 31, 2003. Pending a decision on the extension of the waivers, we intend to apply the frailty adjustment approach to the WPP demonstration in 2004. The adjustment approach will also apply to the Minnesota Senior Health Options (MSHO) and the Minnesota Disability Health Options (MnDHO) demonstrations in 2004.

The Balanced Budget Act of 1997 (BBA) mandated that Medicare capitated payments to PACE organizations be based on M+C payment rates, adjusted to account for the comparative frailty of PACE enrollees. The payment approach described herein is a further refinement to risk

adjustment to ensure that capitated payments to organizations that serve frail community-based populations are accurate.

The frailty adjustment approach is to be applied in conjunction with the CMS-HCC risk adjustment model. As mentioned above, the CMS-HCC model has been designed to pay appropriately for the long-term institutionalized population. Therefore, the frailty adjustment approach will apply only to community-based and short-term institutionalized enrollees³ (i.e., the frailty adjustment for long-term institutionalized enrollees is zero). Risk adjustment predicts (or explains) the future Medicare expenditures of individuals based on diagnoses and demographics. But risk adjustment may not explain all of the variation in expenditures for frail community populations. The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functionally impairments that are unexplained by risk adjustment.

Basic Approach: The first step in the estimation of an adjuster was determining the measures that were candidates for frailty adjustment. Certain measures of functional impairment (such as activities of daily living (ADLs)) were considered to be the most meaningful for purposes of payment. Beneficiary characteristics (such as age and gender) were also considered. In order to develop the frailty adjustor, CMS needed a database that linked measures of functional impairment to Medicare expenditures at the individual level. The Medicare Current Beneficiary Survey (MCBS) included the necessary linked information. Therefore, the candidate functional impairment measures were selected from among those collected by MCBS.

The next step was finding the relationship between the above measures or characteristics and the Medicare expenditures that were unexplained by risk adjustment. For example, the actual Medicare expenditures for each group of people with similar functional impairments were compared to the expenditures predicted by the CMS-HCC model for that group. As described below, the frailty adjustor was designed to explain (or adjust for) the average difference between the predicted and actual expenditures for each group.

The final step in the estimation was to select the appropriate measures from among the candidates. The selection process considered a number of criteria such as face validity, reliability, appropriate incentives, fairness, simplicity, and gameability. The measure(s) that best met the criteria were to be included in the frailty approach. The frailty model was to consist of a set of factors (one factor for each group) for the measure(s) that were selected.

Consistent with the way diagnosis data are used in risk adjustment, the frailty adjuster was designed to be prospective. That is, prior-year functional impairment data were used to predict the next-year's payment adjustment.

Estimating the Frailty Model

Calibration of Frailty Factors: The draft frailty factors were developed using the MCBS cost and use files for 1994 through 1997. Since the model was prospective, information from the "base year" was used to predict payment in the following year. Prior-year diagnosis and functional impairment information were linked to next-year Medicare expenditures to create

³ Hereafter, the term "community" will be used to refer to community-based and short-term institutionalized populations.

three data sets with person-year observations: 1994-95, 1995-96, and 1996-97. These data sets were pooled, and Medicare payments were predicted for these person-years using the CMS-HCC model. The difference of actual payments and predicted payments for each person-year (residual expenditures) was then related to beneficiary functional and institutional status using regression modeling. The frailty factors were derived from these regression coefficients and reflect the mean Medicare payments related to functional status that are not explained by the CMS-HCC model.

The residual expenditures for the MCBS institutionalized population were virtually zero. That is, the CMS-HCC model accurately predicted the average expenditures for this population. Therefore, the frailty adjuster applies only to the community population.

The frailty model was based on Activities of Daily Living (ADLs) as the core measure of functional impairment. Individuals were grouped according to their difficulty with 0 ADLs, 1 to 2 ADLs, 3 to 4 ADLs, and 5 to 6 ADLs. CMS considered whether the frailty model could be improved by including other measures and characteristics interacting with ADLs. Among other things, these included demographics, self-reported health status, chronic conditions, needing help or special equipment with ADLs, and physical measures of impairment (such as walking 2-3 blocks). In general, adding other measures did not appear to improve the frailty model. Some interaction terms were not statistically significant. That is, they did not improve the explanatory power of the model once ADLs were taken into account. Some measures lacked face validity, i.e., greater functional impairment failed to be associated with greater expenditures. Others were not considered reliable in that they could potentially suffer from a large degree of random variation due to small sample sizes. And still others were potentially gameable or provided incentives for inappropriate utilization. Therefore, CMS decided to base the frailty model on ADL groupings only.

Frailty Factor for the Under-55 Disabled: CMS analyzed the residual expenditures for the Medicare disabled population in MCBS. For the 55-and-over population, the residuals were significantly different from zero for all ADL groups. But for the under-55 population, the residuals were not significantly different from zero regardless of the degree of functional impairment. That is, the CMS-HCC model appears to adequately predict the expenditures of the under-55 population without the need for an additional frailty adjuster. Therefore, the frailty factor for this population is zero.

Mortality: The MCBS observations included persons who died in the payment year. The higher expenditures of these persons were included in the frailty model, using the same approach for treating the deceased as was used for the CMS-HCC model. Each ADL group in MCBS has an inherent mortality rate. To test whether the inherent mortality rates were reasonable, CMS investigated whether these mortality rates were representative of the mortality rates for the PACE program. The MCBS mortality rates for each ADL group were applied to the distribution of PACE enrollees by ADL group. This yielded a predicted mortality rate for PACE (i.e., the mortality rate that PACE would have experienced if it had the same rate of mortality as the MCBS population). The predicted mortality was similar to the actual mortality rate across all PACE organizations. That is, once ADLs were accounted for, the PACE mortality rate was

similar to the MCBS mortality rate. Frailty adjustment appears to adequately account for the rate of mortality for frail populations.

Draft Frailty Factors: The draft frailty factors for the 55-and-over community populations are as follows:

<u>Difficulty in ADLs</u>	<u>Frailty Factors</u>
0	-0.14
1-2	0.17
3-4	0.34
5-6	1.09

The final factors will be published in the May 12, 2003 Announcement of M+C Payment Rates.

D. CMS-HCC Model Implementation Issues

CMS will implement the CMS-HCC risk adjustment model following the approach used to estimate the model (as described above). The model will apply to M+C organizations and PACE organizations. The Evercare Demonstration is currently scheduled to end December 31, 2003. Pending a decision on the extension of the waivers, we intend to implement the CMS-HCC model for Evercare in 2004. The CMS-HCC model will also apply to the S/HMOs, WPP, MSHO, and MnDHO demonstrations, as mentioned in Section C. In determining a risk score for a beneficiary, we will determine the status of each variable included in the model based on the same definitions used to estimate the model. For example, in determining a beneficiary's Medicaid status, we will determine whether the beneficiary was eligible for Medicaid for at least one month during the data collection period. Then, the beneficiary's status on each variable in the model (i.e., age, sex, original reason for entitlement, Medicaid eligibility, institutional status (long-term versus community and short-term), and diagnoses) will be used to determine his/her risk factor. The risk factor (and frailty factor, if applicable) is then multiplied by the correct rate book amount to determine the risk adjusted payment. The demographic portion of the payment will continue to incorporate demographic variables such as age, sex, Medicaid eligibility, and institutional status. The final step is to implement the correct transition blend (see section D.7).

1. New Enrollee Factor.

If a beneficiary has less than 12 months of enrollment in Part A and Part B during the data collection period, then he/she will be assigned a new enrollee factor. During the payment year, a new enrollee factor will also be assigned to any beneficiary whose risk score is not available. In this case, the beneficiary's correct risk score will be determined during the next reconciliation. For ESRD payments, the dialysis and functioning graft models will have new enrollee factors for enrollees whose risk scores are not available.

2. Addressing Age Weights

In the past, CMS has recognized that people have birthdays that put them into age groups during a given year by either switching the payment group during the year in the demographic payment model or by paying a weighted average of the 2 groups each month to avoid having to switch age

EXHIBIT 54

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE)
COMPANY, *et al.*,)
)
Plaintiffs,)
)
v.)
)
THOMAS E. PRICE, M.D.,)
Secretary of Health and Human Services,)
et al.,)
)
Defendants.)
_____)

Case No. 16-cv-157

MOTION TO STAY

The Secretary of Health and Human Services respectfully moves for a stay of proceedings in this case during the pendency of two previously-filed False Claims Act cases in which the United States has intervened to bring claims against UnitedHealthCare Insurance Company (“UnitedHealth”), the lead plaintiff in this action, and its affiliates. In both suits, the United States alleges that UnitedHealth submitted false claims for and false statements relating to risk adjustment payments under Parts C and D of the Medicare program, and wrongly retained overpayments arising from those false or fraudulent claims and false statements. UnitedHealth has indicated that a central defense in both false claims actions will be that the Medicare statute’s use of the term “actuarial equivalence,” *see* 42 U.S.C. § 1395w-23(a)(1)(C)(i), permits the company to submit a certain percentage of invalid diagnoses or false claims to the Medicare program each year, and to retain the payments based on those invalid diagnoses and false claims.

UnitedHealth’s “actuarial equivalence” theory plays a central role in this case, too. Here, UnitedHealth challenges a regulation recently promulgated by the Centers for Medicare & Medicaid Services (“CMS”) that governs the time in which overpayments must be repaid, 42

C.F.R. § 422.326. UnitedHealth contends that this regulation is invalid because CMS declined to endorse UnitedHealth's "actuarial equivalence" theory.

The Secretary strongly disputes that theory on the merits; the Medicare statute does not permit UnitedHealth to submit a certain percentage of false claims before False Claims Act liability kicks in. But the merits of the theory can be saved for another day. For present purposes, what is relevant is that UnitedHealth seeks to present the identical arguments at the same time in parallel litigation with the same adversary, the federal government. Duplicative litigation of this nature is strongly disfavored in the federal courts. This Court accordingly should stay its hand, so as to allow the relevant issues to be adjudicated in the forum that will receive the richer factual record, that is, the court hearing the pending false claims actions.¹

BACKGROUND

I. The Pending Actions under the False Claims Act

Two *qui tam* actions brought by relators are pending in the Central District of California. They allege that UnitedHealth and its affiliates violated the False Claims Act by submitting false claims for and false statements relating to risk adjustment payments under Parts C and D of the Medicare program, and by wrongly retaining overpayments arising from those false or fraudulent claims and false statements. Declaration of Jessica E. Krieg, ¶ 2. The United States has intervened in both actions. *See* Notice of United States of Election to Intervene in Part at 2, *United States ex rel. Poehling v. UnitedHealth Group*, No. 2:16-cv-08697 (C.D. Cal. filed Feb.

¹ The Secretary also respectfully requests that his obligation to file an answer to the complaint, which would otherwise be due by April 14, 2017, be deferred during the pendency of this motion for a stay. The Secretary has been working diligently to compile the administrative record with respect to UnitedHealth's challenge to 42 C.F.R. § 422.326, and will continue to do so while this motion is being decided. The Secretary would require 90 days, however, to complete the compilation of the record. Counsel for the Secretary has consulted with counsel for the plaintiffs regarding this motion, and counsel for the plaintiffs state that they oppose this motion.

14, 2017), ECF No. 78 (Krieg Decl., Exh. A); Notice of Election of the United States to Partially Intervene in Action at 2, *United States ex rel. Swoben v. Secure Horizons*, No. 2:09-cv-05013 (C.D. Cal. filed Mar. 24, 2017), ECF No. 270 (Krieg Decl., Exh. B). The United States has been accorded until May 1, 2017 to file its complaint-in-intervention in the *Swoben* action and until May 16, 2017 to file its complaint-in-intervention in the *Poehling* action. Krieg Decl., ¶ 5. The United States has moved to consolidate the *Poehling* and *Swoben* actions. *Id.*, ¶ 6.

In the *Poehling* action, the United States contends that UnitedHealth conducted biased one-sided medical record reviews (also known as “chart reviews”), by which it distorted the information provided to the Medicare program about the health status of Medicare beneficiaries in United’s Medicare Advantage plans in order to obtain inflated payments from the Medicare program. Krieg Decl., ¶ 7. In the *Swoben* action, the United States contends that UnitedHealth caused at least one of its large provider groups in California to conduct similarly biased reviews. *Id.*, ¶ 8. The United States contends that, under CMS regulations in place since 2000, UnitedHealth had an obligation to undertake due diligence to ensure the accuracy, completeness, and truthfulness of the risk adjustment data that it submitted to the United States for payments for its Medicare Part C plans. *Id.*, ¶ 9; *see* 42 C.F.R. § 422.504(*l*). The United States claims, among other things, that UnitedHealth violated this obligation, and incurred False Claims Act liability, by engaging in its one-sided chart reviews. Krieg Decl., ¶ 10. In both the *Poehling* and *Swoben* actions, UnitedHealth has represented that it will contend that its actions were permitted under its interpretation of the Medicare statute’s “actuarial equivalence” provision, 42 U.S.C. § 1395w-23(a)(1)(C)(i). *Id.*, ¶ 11.

A *qui tam* relator filed the *Swoben* action on July 13, 2009, and amended his complaint to add allegations against UnitedHealth on September 30, 2009. Krieg Decl., ¶ 12. Another *qui*

tam relator filed the *Poehling* action on March 24, 2011. *Id.*, ¶ 13. The district court initially dismissed *Swoben* for failure to state a claim. The relator appealed, and the United States filed an amicus brief explaining that the relator’s allegations of one-sided chart reviews, if taken to be true, would state a claim under the False Claims Act. *Id.*, ¶ 14. The Ninth Circuit agreed that the relator’s allegations stated a claim, and reversed the dismissal of the complaint. *United States ex rel. Swoben v. UnitedHealthCare Ins. Co.*, 848 F.3d 1161, 1172–76 (9th Cir. 2016).

UnitedHealth has been aware of the *Swoben* action since that action was unsealed and the relator’s complaint was served on it in 2013. Krieg Decl., ¶ 15. Since at least 2012, UnitedHealth has known that the other relator, Benjamin Poehling, made allegations against it and that the United States was investigating those allegations. *Id.*, ¶ 16. Starting in 2013, UnitedHealth produced approximately 600,000 documents to the government in connection with the government’s investigation of Poehling’s allegations and, starting in 2015, UnitedHealth employees have provided testimony to the government as part of that same investigation. *Id.*, ¶ 17. Since 2012, UnitedHealth has been aware of the investigation’s focus on its large national chart review program. *Id.*, ¶ 18. In government counsel’s discussions with counsel for UnitedHealth, it became apparent that the company intended to rely on a defense centered on its broad (and, the government argues, wholly inaccurate) interpretation of “actuarial equivalence.” *Id.*, ¶ 19.

II. This Action

UnitedHealth and its affiliates filed this action under the Administrative Procedure Act on January 29, 2016, nearly four years after it first became aware of the pending False Claims Act matters. Compl., ECF No. 1. UnitedHealth challenges the validity of a regulation that CMS issued in 2014 to implement a provision of the Affordable Care Act, 42 C.F.R. § 422.326. The

regulation governs the timing according to which a party is required to report and repay an overpayment that it identifies. The 2014 regulation is not at issue in *Poehling* or *Swoben*—neither of those actions involves any allegations about the mistiming of repayments—but in this case, as in the false claims actions, UnitedHealth relies on its “actuarial equivalence” theory, under which, the company posits, UnitedHealth is entitled to retain certain payments that CMS would define to be overpayments. *See* Compl. ¶ 92.

The Secretary moved to dismiss the complaint for lack of jurisdiction. ECF No. 12. This Court denied the motion to dismiss on March 31, 2017. ECF No. 26.

DISCUSSION

Duplicative litigation among federal courts is strongly disfavored. *See Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976) (“As between federal district courts, . . . though no precise rule has evolved, the general principle is to avoid duplicative litigation.”); *see also Abbott Labs., Inc. v. Gardner*, 387 U.S. 136, 155 (1967) (noting that an APA pre-enforcement challenge may be stayed if it raises issues duplicative with other litigation). The reasons for this practice are “manifest . . . ‘Sound judicial administration counsels against separate proceedings, and the wasteful expenditure of energy and money incidental to separate litigation of identical issues should be avoided.’” *UtahAmerican Energy, Inc. v. Dep’t of Labor*, 685 F.3d 1118, 1124 (D.C. Cir. 2012) (quoting *Handy v. Shaw, Bransford, Veilleux & Roth*, 325 F.3d 346, 349 (D.C. Cir. 2003) (footnotes omitted)). Thus, a stay is appropriate where the same parties are litigating identical issues in separate forums because, if both suits were to proceed at the same time, “the respective district courts would be required to duplicate their efforts,” and “the twin claims could generate contradictory results that could, in turn, generate dueling appeals.” *UtahAmerican Energy*, 685 F.3d at 1124.

“The usual rule in this circuit has been that where two cases between the same parties on the same cause of action are commenced in two different Federal courts, the one which is commenced first is to be allowed to proceed to its conclusion first.” *Id.* (internal alterations omitted). This first-filed rule is not followed rigidly, however, and the court of appeals has recognized that in some cases the second-filed action deserves priority. *See Columbia Plaza Corp. v. Sec. Nat’l Bank*, 525 F.2d 620, 627 (D.C. Cir. 1975). In other words, “the decisions recognizing the first-in-time rule note that ‘equitable considerations’ may weigh against applying it in particular cases.” *UtahAmerican Energy*, 685 F.3d at 1124 (citations omitted).

In this case, absent a stay, UnitedHealth and the federal government will be litigating identical issues at the same time in two separate federal courts. In particular, the parties would litigate, both in this Court and in the false claims actions, the extent of UnitedHealth’s obligations under CMS regulations dating back to 2000 to accurately certify its risk adjustment data. *See* 42 C.F.R. § 422.504(*l*). The parties would also litigate in both actions the validity of UnitedHealth’s “actuarial equivalence” theory, under which the company asserts that it is entitled to retain certain payments that the United States alleges to be overpayments. Moreover, as UnitedHealth has put this issue in a recent filing in the *Swoben* action, this case involves “the legal underpinnings of *the very same arguments* the government” intends to assert there—“namely, that UnitedHealth was required to review and analyze the accuracy of codes submitted by providers under a ‘due diligence’ standard.” Defendant UnitedHealth’s Opposition to United States’s Motion for Order Consolidating Actions at 8, *United States ex rel. Swoben v. Secure Horizons*, No. 2:09-cv-05013 (C.D. Cal. filed Apr. 6, 2017), ECF No. 277 (Wallack Decl., Exh. C) (emphasis added). Given the overlapping nature of the issues that would be central to both

actions, a stay is appropriate to avoid “the wasteful expenditure of energy and money incidental to separate litigation of identical issues.” *Columbia Plaza*, 525 F.2d at 626.

Sound principles of judicial administration also dictate that this action be stayed during the pendency of the False Claims Act cases. The *Poehling* and *Swoben* actions were both filed more than four years before UnitedHealth brought this pre-enforcement APA challenge. The general principle that the first-filed case should take precedence would counsel in favor of a stay here: the *Swoben* case was filed seven years before this one. See *UtahAmerican Energy*, 685 F.3d at 1124. Moreover, additional considerations also counsel in favor of a stay of this action while the False Claims Act actions proceed. UnitedHealth has been aware of the *Swoben* and *Poehling* actions since at least 2013, and it has been aware that the federal government was investigating its Chart Review Program since at least 2012. UnitedHealth’s institution of this pre-enforcement action, in the face of an impending enforcement suit, provides strong reason for this Court to defer to the courts where the enforcement actions are pending. See *Stone & Webster, Inc. v. Georgia Power Co.*, 965 F. Supp. 2d 56, 60–61 (D.D.C. 2013), *aff’d*, 779 F.3d 614 (D.C. Cir. 2015). And, perhaps most importantly, cases involving concrete factual settings should take precedence over more abstract challenges. The court hearing the False Claims Act cases will benefit from a full factual record, including evidence that the government believes will show UnitedHealth’s knowledge of its due diligence obligations, its implementation of compliance programs relating to ensuring the validity of the diagnoses it submitted to Medicare for risk adjustment payments, and its decision to terminate those compliance efforts in early 2014. Wallack Decl., ¶ ___. In this APA action, by contrast, this Court would only have the administrative record to guide its analysis. The false claims actions therefore afford the

opportunity for a fuller, more complete, and more efficient adjudication of the issues in dispute between the two parties. *See Stone & Webster*, 965 F. Supp. 2d at 60-61.

CONCLUSION

To conserve the resources of the federal courts and the parties by avoiding needless duplication, the Secretary respectfully requests that this action be stayed during the pendency of the proceedings in the *Poehling* and *Swoben* actions. The Secretary also respectfully requests that his obligation to file an answer to the complaint be deferred during the pendency of this motion for a stay.

Dated: April 14, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of April, 2017, I caused the foregoing document to be filed electronically with the Clerk of Court through the CM/ECF System for filing, and served on counsel registered to receive CM/ECF notifications in this case.

/s/ James Bickford
James Bickford

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE)
COMPANY, *et al.*,)
)
Plaintiffs,)
)
v.)
)
THOMAS E. PRICE, M.D.,)
Secretary of Health and Human Services,)
et al.,)
)
Defendants.)
_____)

Case No. 16-cv-157

[PROPOSED] ORDER

Defendants' motion to stay is hereby **GRANTED** and this case is **STAYED** pending the resolution of *United States ex rel. Swoben v. Secure Horizons*, No. 2:09-cv-05013 (C.D. Cal.) and *United States ex rel. Poehling v. UnitedHealth Group*, No. 2:16-cv-08697 (C.D. Cal.).

SO ORDERED this _____ day of _____, 20____.

Rosemary M. Collyer
United States District Judge

EXHIBIT 55

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE
COMPANY, *et al.*,

Plaintiffs,

v.

THOMAS E. PRICE, M.D., in his official
capacity as Secretary of the Department of Health
and Human Services, *et al.*,

Defendants.

No. 1:16-cv-00157-RMC

**UNITED’S OPPOSITION TO DEFENDANTS’ MOTION TO STAY
AND MOTION FOR EXTENSION OF TIME**

This is the second time the government has tried to delay or avoid a ruling on the merits of United’s legal challenge to the “Overpayment Rule.” The government first argued that this Court lacks jurisdiction, and that United should be forced to defend itself in enforcement proceedings before challenging the rule. This Court rejected that argument. Undaunted, the government argues in this motion that the Court should indefinitely stay United’s challenge pending resolution of two cases filed under the False Claims Act (FCA) in which the government only recently intervened. But this Court already decided that United should not be required to undergo enforcement proceedings—and incur potentially draconian penalties—before bringing this challenge. That decision applies equally here.

In truth, the government’s request has nothing to do with any genuine concern with avoiding duplicative litigation. Instead, the government hopes that the leverage created by these FCA cases will cause United to capitulate before ever obtaining a ruling on the merits of this challenge to the Overpayment Rule—precisely the kind of *in terrorem* effect this Court already

held does not bar pre-enforcement review. This tactical purpose is apparent because *all* of the factors this Court should consider in deciding whether to enter a stay weigh overwhelmingly against the government. The FCA cases are only beginning, and will require substantial discovery before any possible ruling on the merits. Even then, these cases may never address any common legal issues, because United has many other dispositive defenses and the conduct at issue in both private relators' complaints predates the Overpayment Rule itself. In fact, the government asserts in this motion that the Overpayment Rule will *not* be at issue in these cases even once it files its own complaints. Thus, there is no reason to stay this case pending resolution of the FCA cases.

There is, however, every reason to proceed here without further delay. This case can be resolved expeditiously on the existing administrative record without any discovery. The risk of potential penalties and the burdens on United grow every day that the unlawful rule remains in effect. Prompt resolution, which is paramount to United and the entire industry, will create clarity (rather than inefficiency) as the FCA cases proceed through discovery, and poses no serious risk of any duplicative litigation. Indeed, the *Swoben* court just yesterday observed that the legal underpinnings of the government's FCA theories will be resolved by this Court's ruling on United's APA challenge. Finally, in stark contrast with the harm United will suffer if this case is stayed indefinitely, the government faces no hardship by this case pressing forward today. The merits of this case are ripe for review here and now.

BACKGROUND

The government seeks to stay these proceedings pending the resolution of two FCA cases pending in the U.S. District Court for the Central District of California (one of which was recently transferred there following *ex parte* proceedings) on the grounds that all three matters involve common issues concerning the obligations of Medicare Advantage (MA) plans.

A. The Swoben Action

In 2009, James Swoben filed an initial complaint under seal in the Central District of California, alleging violations of the FCA arising from unrelated billing practices by two defendants who are unaffiliated with United and no longer in the case. *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal.) (*Swoben*), ECF No. 1 at 3-7 (Exhibit A). In an amended complaint, Swoben added allegations against United concerning its chart review program. *See Swoben*, ECF No. 37 at 23-27 (Exhibit B). The government has acknowledged that Swoben's claims against United extend only to United's alleged involvement in chart reviews conducted by certain physician groups in California. *See Swoben*, ECF No. 271-1 at 20 n.13 (Exhibit C); *id.*, ECF No. 259 ¶ 4 (Exhibit D). The government also has acknowledged that, because *Swoben* concerns conduct that predates the 2014 Overpayment Rule, that rule does not apply in the case. *See* U.S. Br. 21 n.6, *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746 (9th Cir.) (CA9 *Swoben*) (Exhibit E). *Swoben* thus provides no opportunity for United to test the validity of the Overpayment Rule.

The government initially declined to intervene as to Swoben's claims against United. *See Swoben*, ECF No. 133 at 2 (Exhibit F). Swoben's complaint against United was unsealed, and United successfully moved to dismiss his suit with prejudice. *Id.* at 2, 10. Swoben appealed, and the parties briefed and argued the case before the Ninth Circuit. After argument, the Ninth Circuit requested supplemental briefing from the parties about the significance of a certification under 42 C.F.R. § 422.504(l) regarding the accuracy of claims data. In April 2016, the government filed an amicus brief arguing that the certification required United to exercise "due diligence" to identify and delete from its claims data diagnostic codes there were not supported in underlying medical charts. *See* Exhibit E at 6-7. The government filed its brief—its first

participation in the *Swoben* case—nearly three months *after* United brought this suit challenging the Overpayment Rule.

In August 2016, the Ninth Circuit reversed the district court’s pleading-stage dismissal of Swoben’s claims against United. *See United States ex rel. Swoben v. United Healthcare Ins. Co.*, 832 F.3d 1084, *amended by* 848 F.3d 1161 (9th Cir. 2016). In March 2017, the government finally sought leave to intervene in the case. *Swoben*, ECF No. 243 (Exhibit G). The district court ordered the government to file its complaint by May 1, 2017. *See Swoben*, ECF No. 254 at 2 (Exhibit H). The government asserts here that, even after its complaint-in-intervention is filed, the Overpayment Rule will not be at issue in *Swoben*. Mot. 5.

B. The Poehling Action

The second relevant FCA action was unsealed in February 2017—more than a year after United filed this APA suit. In that case, Benjamin Poehling, a former United employee, filed his complaint under seal in the Western District of New York in 2011, alleging in part that the national Chart Review Program he had helped develop and operate for United starting in 2007 had resulted in the submission of false claims. *See, e.g., Swoben*, ECF No. 271-2 at Ex. 3 (Compl. ¶¶ 16-17, 109, 114-66, *United States ex rel. Poehling v. UnitedHealth Group*, No. 11-cv-258 (W.D.N.Y.)) (Exhibit I). Poehling’s complaint remained under seal in the Western District of New York for years while the government investigated his claims. Like *Swoben*, Poehling’s now-unsealed complaint, amended most recently in 2011, only concerns conduct predating the 2014 Overpayment Rule and thus likewise provides United no opportunity to test the rule’s validity.

In November 2016, more than five years after Poehling’s complaint was filed, the government apparently decided that Poehling’s claims concerning federal MA program rules and the national operations of a Minnesota-based company actually belonged in California—and so

moved to transfer the action to the Central District, where, if it remains there, it might be subject to the Ninth Circuit's August 2016 *Swoben* decision. *United States ex rel. Poehling v. UnitedHealth Group Inc.*, No. 16-08697 (C.D. Cal.), ECF No. 50 (Exhibit J). In an effort to prevent United from objecting to this blatant forum shopping, the government filed its motion *ex parte*. After that motion was granted, the government moved to intervene in the case in February 2017. *See id.*, ECF No. 78 (Exhibit K). The district court ordered the government to file its complaint-in-intervention in that case by May 16, 2017. *Id.*, ECF No. 93 (Exhibit L). As with *Swoben*, the government asserts that the Overpayment Rule still will not be at issue in *Poehling* even after its complaint-in-intervention is filed. Mot. 5.

C. This Action

United's prosecution of this action is far more straightforward. In January 2016—more than a year before the government's intervention in either FCA case—United filed this suit challenging the Overpayment Rule's validity. *See* ECF No. 1. As the Court knows, United contends here that the Overpayment Rule violates the Medicare Act's requirement that the Centers for Medicare and Medicaid Services (CMS) “‘ensure actuarial equivalence’ between traditional Medicare and Medicare Advantage plans” by requiring MA plans to identify and delete diagnostic codes that are unsupported by underlying medical charts, without accounting for the fact that CMS does not similarly attempt to identify and delete unsupported diagnostic codes from the data for its own beneficiaries that CMS uses to set MA payments. *Id.* ¶ 92 (quoting 42 U.S.C. § 1395w-23(a)(1)(C)(i)). United requested that the Overpayment Rule be set aside, and that the Court grant a declaratory judgment that United is not required to undertake the efforts the government now claims are required from MA plans (but refuses to replicate itself) unless and until CMS imposes the same validation standard on its own data or accounts for that difference in some manner that maintains “actuarial equivalence” between CMS and MA plans.

The government moved to dismiss the case on the ground that United lacked standing to challenge the regulation and that, in any event, United should be required to await an enforcement action to vindicate its claims. Despite its years-long ongoing investigation in *Poehling*, the government asserted to the Court in moving to dismiss the case that United could not demonstrate an “‘imminent threat’ of prosecution” and that the Court therefore lacked jurisdiction. ECF No. 17 at 8 (citation omitted).

On March 31, 2017, the Court denied the government’s motion to dismiss, holding that United had standing to challenge the Overpayment Rule, which “imposes (for good reason or not) new obligations” that did not previously exist in any other regulation or statute. ECF No. 25 at 13. It further held that no other proceeding could provide an opportunity for judicial review of the Overpayment Rule, and that, even if it could, the associated penalties that might accrue to United while it waited for that opportunity would “render such a path practicably foreclosed.” *Id.* at 18. The government responded by filing this motion to stay.

ARGUMENT

The government cannot come close to meeting its burden of showing that a stay is necessary or appropriate. In exercising its discretion to issue a stay, a district court “must weigh competing interests and maintain an even balance.” *Landis v. N. Am. Co.*, 299 U.S. 248, 254-55 (1936); *see Dellinger v. Mitchell*, 442 F.2d 782, 786 (D.C. Cir. 1971). It is the proponent’s burden to establish that a stay is warranted. *Clinton v. Jones*, 520 U.S. 681, 708 (1997). Where there is “even a fair possibility that [a] stay . . . will work damage to some one else,” the movant “must make out a clear case of hardship or inequity in being required to go forward.” *Landis*, 299 U.S. at 255. And, regardless of any harm to the opposing party or public, courts may not

enter “a stay of indefinite duration in the absence of a pressing need.” *Id.*¹ The competing interests and equities in this case weigh overwhelmingly against the indefinite stay the government requests here.

A. United Has Compelling Interests In The Prompt Resolution Of This Case

This Court already has recognized United’s obvious and compelling interests in a prompt resolution of this case. Contrary to the government’s description of the regulation as a “timing” rule, Mot. 4-5, the Overpayment Rule “requires Medicare Advantage insurers [like United] to engage in ‘proactive compliance activities’” to validate and delete diagnostic codes from their risk adjustment data. ECF No. 25 at 11 (citation omitted). Although the scope of the rule is anything but clear, it is a “new” and “active obligation” that directly affects United’s core business of administering MA plans to roughly 4.6 million individuals nationwide. *Id.* at 10, 13.² The Overpayment Rule causes “systemic unlawful and unfair underpayment of Medicare Advantage plans.” ECF No. 1 ¶ 10.

These interests make this case a textbook one for immediate review. As the Supreme Court has explained, “[w]here the legal issue presented is fit for judicial resolution, and where a regulation requires an immediate and significant change in the plaintiffs’ conduct of their affairs with serious penalties attached to noncompliance, access to the courts under the Administrative Procedure Act and the Declaratory Judgment Act *must* be permitted, absent a statutory bar or some other unusual circumstance.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967) (emphasis added), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). This

¹ See, e.g., *Landis*, 299 U.S. at 256-57 (holding that the district court abused its discretion by issuing a stay that could last two years or more).

² The government’s promise to continue to litigate “the extent of [United’s] obligations under CMS regulations dating back to 2000” (Mot. 6), despite this Court’s holding that the Overpayment Rule imposes “new” obligations, further demonstrates the government’s intent to have these issues resolved in a forum of its choosing.

Court already has decided that the Overpayment Rule requires a change in the conduct of United's affairs, and that there are serious penalties attached to noncompliance. *See* ECF No. 25 at 6-7, 18-19 (listing potential penalties). Accordingly, as this Court has recognized, denying immediate access to a judicial forum to determine the legality of the Overpayment Rule would not simply delay judicial review, as a practical matter it could foreclose it. *Id.* at 18.

The government nevertheless insists that “[s]ound principles of judicial administration” require further, indefinite delay. Mot. 7. But there is nothing “sound” about imposing through a stay the very barrier to judicial review that the Supreme Court has held must not be imposed as a general matter, and that this Court specifically held should not be imposed here. On the contrary, “sound principles of judicial administration” warrant immediate review.

B. The Government Has No Legitimate Interest In Delaying Resolution

Far from imposing any unfair burden on the government, the government only stands to benefit from an order requiring this case to proceed. United is the largest provider of MA plans in the country, serving nearly a quarter of MA beneficiaries. “If the Government prevails [in this case], a large part of the industry is bound by the decree; if the Government loses, it can more quickly revise its regulation” to comply with the governing law. *Abbott Labs.*, 387 U.S. at 154. Either way, the government should welcome this opportunity to clarify the legal issues here.³ At any rate, there is no need to delay the resolution of those issues.

The government's principal argument is that a stay will avoid duplicative and wasteful litigation of “identical issues” in multiple forums. Mot. 5 (citation omitted). That is not only wrong, it is precisely backwards. Unlike this case, which concerns only pure questions of law based on a fixed administrative record, the FCA cases will involve full-blown civil litigation

³ *See Indep. Bankers Ass'n of Am. v. Smith*, 534 F.2d 921, 929-30 (D.C. Cir. 1976) (agencies “only profit from an early determination that eliminates . . . uncertainty” about their authority).

after the government files its complaints-in-intervention next month. In *Swoben*, for example, a discovery cut-off is currently scheduled for July 17, 2018. *Swoben*, ECF No. 293 at 33 (Exhibit M). Each side will then be permitted just one dispositive motion to be heard by August 27, 2018. *Id.* at 8, 33. (That is assuming that the current deadlines are not extended.) Trial will not begin before November 27, 2018. *Id.* at 10. As for *Poehling*, the district court has not yet set a schedule, but there is no reasonable prospect that that case, which concerns not just United's operations in California, but nationwide, will be resolved any sooner. In fact, the United States already has reserved the right to request additional discovery for the "much larger *Poehling* action." *Swoben*, ECF No. 287 at 7 (Exhibit N).⁴

By contrast, absent a stay, this case could be resolved in months rather than years. Notwithstanding the government's repeated attempts to delay these proceedings, United is prepared to file its summary judgment brief within 45 days of the resolution of the government's motion to stay—with or without the government's answer. Assuming the government compiles the administrative record and its summary judgment brief in a similar period (as the Court may order it to do), the case would be fully briefed and ripe for resolution by this Court before discovery in the FCA cases even gets far off the ground.

Moreover, even after discovery is complete, the FCA cases may not resolve *any* questions common to this case. The government contends here that the Overpayment Rule itself will not be "at issue" in the FCA cases (Mot. 5), so the fundamental issue of this case will *not* be resolved in the FCA cases. Neither might any other potentially common underlying legal issues. United intends to move for summary judgment on a number of grounds that would constitute

⁴ If post-trial motions or appeals are included in the government's request that this case be stayed for "the pendency of the proceedings in the *Poehling* and *Swoben* actions," Mot. 8, the indefinite delay will be even longer.

complete and independent defenses to those actions, including whether any actual evidence supports the relators' factual allegations, United's consistent transparency with the government regarding its risk adjustment processes, United's state of mind concerning compliance with the Medicare Act and relevant regulations, and the government's inability to prove the materiality of any allegedly false claim or establish any resulting harm, to name only a few defenses. Exhibit N at 2-4. If United prevails at summary judgment on any one of those issues, there will be no need to reach *any* legal issues common to all three cases.

On the other hand, proceeding now to the merits of this case necessarily will resolve a fundamental issue that is common to all three cases. The only issue before this Court is the government's legal justification for the Overpayment Rule—*i.e.*, whether it can lawfully require United to identify and delete unsupported diagnostic codes in United's risk adjustment data, despite its failure to do so in its own data used to set MA payments. Once this Court resolves that common issue, there would be no need (and no opportunity under preclusion principles) to relitigate it in the FCA cases.⁵ For that reason, United consistently has argued that this Court is the proper forum to resolve these issues and is simply preserving these legal arguments in the FCA cases to assert after they have been resolved here. *See* Defendants' Suppl. Br. 8 n.4, CA9 *Swoben* (Exhibit O); Exhibit N at 3. Indeed, just yesterday, the *Swoben* court observed that this Court "will soon be hearing UnitedHealth's challenge to the legal underpinnings of the Government's arguments." *Swoben*, ECF No. 295 at 4 (Exhibit P). It is not unfair or inefficient

⁵ *See* 18A Charles Alan Wright et al., *Federal Practice & Procedure* § 4446 (2d ed. online 2017) ("The very purpose of [a declaratory judgment] is to establish a binding adjudication that enables the parties to enjoy the benefits of reliance and repose secured by *res judicata*. . . . Matters actually litigated by the parties and determined by a declaratory judgment are thus precluded from further litigation"); *see also* *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 402-03 (1940) ("There is privity between officers of the same government so that a judgment in a suit between a party and a representative of the United States is *res judicata* in relitigation of the same issue between that party and another officer of the government.").

for this Court to proceed expeditiously here and thereby provide guidance as the FCA cases proceed through discovery.

C. Even If The First-Filed Rule Applies, It Weighs Against A Stay

The government also relies on the “usual rule” that “where two cases between the *same parties* on the *same cause of action* are commenced in two different Federal courts, the one which is commenced first is to be allowed to proceed to its conclusion first.” Mot. 6 (emphasis added) (quoting *UtahAmerican Energy, Inc. v. Dep’t of Labor*, 685 F.3d 1118, 1124 (D.C. Cir. 2012)). That rule does not help the government for several reasons. In the first place, the first-filed rule does not even apply here because this case and the FCA cases do not involve the same cause of action. Even if it did, this *is* the first case raising these issues between these parties. In any event, the first-filed rule is not categorical, and should yield to the overwhelming equities favoring United here.

The first-filed rule applies only if two cases concern the “same cause of action.” *UtahAmerican*, 685 F.3d at 1124 (citation omitted). Two cases concern the same cause of action only if they arise “out of the same ‘transaction.’” *Handy v. Shaw, Bransford, Veilleux & Roth*, 325 F.3d 346, 348, 350 (D.C. Cir. 2003).⁶ And, according to the government itself, the FCA actions and this action do not. It is beyond dispute that all of the conduct alleged in the current operative complaints in the FCA cases predates the Overpayment Rule by a number of years. And, although we will not know precisely what conduct will be at issue after the government files its complaints-in-intervention, the government itself asserts that the Overpayment Rule will still not be implicated in either case. Mot. 5. Applying the first-filed rule here would drastically

⁶ See also *Stone & Webster, Inc. v. Georgia Power Co.*, 965 F. Supp. 2d 56, 61 (D.D.C. 2013) (*Stone & Webster I*) (“[T]here is no question that the parties’ claims arise out of the same transaction such that they should—for judicial economy—be resolved in a single forum.”), *aff’d*, 779 F.3d 614 (D.C. Cir. 2015).

expand it, well beyond its purpose of providing a “comprehensive disposition of litigation” of the same cause of action. *Stone & Webster, Inc. v. Georgia Power Co.*, 779 F.3d 614, 617 (D.C. Cir. 2015) (*Stone & Webster II*) (quoting *Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183 (1952)).

Even if the rule did apply, it would weigh *against* a stay here. This is the first case between these “same parties” to raise the common legal issues. *UtahAmerican*, 685 F.3d at 1124 (citation omitted). Before the government’s interventions in February and March 2017—more than a year *after* this suit was filed—the only parties in Swoben’s unsealed and Poehling’s sealed complaints were United and two *private* individuals. “The United States . . . is a ‘party’ to a privately filed FCA action only if it intervenes in accordance with the procedures established by federal law.” *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009)). If the legal questions had been presented and resolved in United’s favor in either of the privately filed FCA cases before the government intervened, the government would undoubtedly have argued that collateral estoppel could not operate against it as a non-party to the suit. *See* 18A Wright et al., *Federal Practice & Procedure* § 4449 (“The basic premise of preclusion is that parties to a prior action are bound and nonparties are not bound.”). It should not be permitted to take the opposite view of its “party” status where it arguably works in its favor here.

Finally, the government admits that the first-filed rule “is not followed rigidly.” Mot. 6. “[C]ountervailing equitable considerations, where present, cannot be ignored.” *Stone & Webster II*, 779 F.3d at 617 (quoting *Columbia Plaza Corp. v. Sec. Nat’l Bank*, 525 F.2d 620, 627 (D.C. Cir. 1975)).⁷ “[I]n a good many cases proceedings in an earlier-filed action have been stayed to

⁷ *See also Handy*, 325 F.3d at 350 (when applying the “so-called ‘first-to-file’ rule, we have emphasized that the district court must balance equitable considerations rather than using . . . ‘a mechanical “rule of thumb”” (citations omitted)).

enable the court later acquiring jurisdiction to proceed to judgment first,” when, as here, there are “countervailing equitable considerations.” *Columbia Plaza*, 525 F.2d at 627. The inequity of allowing the government to pick and choose its forum through strategically timed intervention, venue transfer, and unsealing decisions, along with the onerous hardships faced by United while review of the Overpayment Rule is delayed, would thus warrant a discretionary departure from the first-filed rule even if it applied.

D. The Validity Of The Overpayment Rule Must Be Decided On The Administrative Record Alone

The government also argues that “cases involving concrete factual settings should take precedence over more abstract challenges.” Mot. 7. It further insists that the “full factual record” that will be developed in the FCA cases will allow for a “fuller, more complete, and more efficient adjudication of the issues in dispute,” than the “administrative record” that will (eventually) be before this Court. *Id.* at 7-8. The government cites no authority for this purported preference to adjudicate purely legal questions of administrative law on a robust factual record, because there is none. “Judicial review of an administrative action is confined to ‘[t]he grounds . . . upon which the record discloses that [the] action was based.’” *Steffan v. Cheney*, 920 F.2d 74, 76 (D.C. Cir. 1990) (per curiam) (alterations in original) (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)).⁸ A reviewing court “should have before it neither more nor less information than did the agency when it made its decision.” *Steffan*, 920 F.2d at 76 (citation omitted).

This Court already has held that the complaint here alleges sufficient facts to establish United’s standing and that this case is ripe for review. *See* ECF No. 25 at 13 & 9 n.2. There are

⁸ *See also Tabor v. Joint Bd. for the Enrollment of Actuaries*, 566 F.2d 705, 709-10 (D.C. Cir. 1977) (“[A]gency action cannot be sustained on *post hoc* rationalizations supplied during judicial review.”).

no additional facts required. It is not a drawback that the lawfulness of the Overpayment Rule will be decided based solely on the record before the agency when it promulgated the rule because that is the law.

E. The Court Should Order The Government To Answer The Complaint Immediately

The government moves for an administrative stay of its obligation to answer on the grounds that “[t]he Secretary would require 90 days . . . to complete the compilation of the record.” Mot. for Extension of Time 1. The government further contends that this delay “is necessary for the preparation of an answer.” *Id.* This request is extraordinary. The Court’s rules require that, “[i]n cases involving judicial review of administrative agency actions, unless otherwise ordered by the Court, the agency *must* file a certified list of the contents of the administrative record with the Court within 30 days following service of the answer to the complaint or simultaneously with the filing of a dispositive motion, whichever occurs first.” Local Rule 7(n)(1) (emphasis added). United filed its complaint in January 2016. The government filed its motion to dismiss the case, in its entirety, on constitutional and statutory grounds on May 11, 2016. Under the plain language of the local rules, the Secretary was therefore required to file a certified list of the administrative record with the Court no later than June 10 *of last year*—30 days after it filed a motion requesting that the Court entirely “dispos[e]” of this case. It defies belief that nearly a year has passed since then, yet without any order extending the default rule, the Secretary is still “working diligently to compile the administrative record” (the bulk of which is publically accessible at Regulation.gov) and requires another 90 days to finish the job. United respectfully submits that the Court should order the government to file its answer and the certified list of the record immediately, and set an expedited briefing schedule to resolve this important case without any further delay.

CONCLUSION

The government's motion to stay proceedings in this case and its motion for an extension of time should be denied. The government should be required to answer United's complaint immediately, and the Court should set an expedited briefing for summary judgment to resolve this matter without any further delay.

April 28, 2017

Respectfully submitted,

/s/ Daniel Meron

Daniel Meron (D.C. Bar No. 450419)
Jonathan Y. Ellis (D.C. Bar No. 1020074)
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Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE
COMPANY, et al.,

Plaintiffs,

v.

THOMAS E. PRICE, M.D., in his official
capacity as Secretary of the Department of Health
and Human Services, et al.,

Defendants.

No. 1:16-cv-00157-RMC

DECLARATION OF DANIEL MERON

I, Daniel Meron, do hereby declare:

1. I am a member of the District of Columbia bar and a partner at the law firm of Latham & Watkins, counsel for Plaintiffs UnitedHealthcare Group family.

2. Attached as Exhibit A is a true and correct copy of the initial Complaint in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed July 13, 2009), ECF No. 1.

3. Attached as Exhibit B is a true and correct copy of the Third Amended Complaint in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Nov. 23, 2011), ECF No. 37.

4. Attached as Exhibit C is a true and correct copy of the United States' Memorandum of Points and Authorities in Support of Motion for Order Consolidating Actions in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Mar. 27, 2017), ECF No. 271-1.

5. Attached as Exhibit D is a true and correct copy of the Declaration of Daniel Meron on Behalf of UnitedHealth Regarding March 14, 2017 Meet-And-Confer in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Mar. 17, 2017), ECF No. 259.

6. Attached as Exhibit E is a true and correct copy the Brief for the United States as Amicus Curiae in Support of Appellant in *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746 (9th Cir. filed Apr. 18, 2016).

7. Attached as Exhibit F is a true and correct copy of the Civil Minutes for Proceedings held July 30, 2013 in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal.), ECF No. 133.

8. Attached as Exhibit G is a true and correct copy of the United States' Notice of Motion and Motion for Leave to Partially Intervene as to United Defendants in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Mar. 6, 2017), ECF No. 243.

9. Attached as Exhibit H is a true and correct copy of the Order Granting United States' Request for Leave to Intervene in Action as to United Defendants in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Mar. 17, 2017), ECF No. 254.

10. Attached as Exhibit I is a true and correct copy of the First Amended Complaint in *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 11-0258 (S.D.N.Y. filed Oct. 3, 2011), attached as Exhibit 3 to Declaration of John E. Lee, *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Mar. 17, 2017), ECF No. 271-2.

11. Attached as Exhibit J is a true and correct copy of the Sealed Order, *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 16-08697 (C.D. Cal. filed Nov. 8, 2016), ECF No. 50.

12. Attached as Exhibit K is a true and correct copy of the Notice of Election of the United States to Intervene in Part and Decline to Intervene in Part and Stipulation Re Unsealing in *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 16-08697 (C.D. Cal. filed Feb. 14, 2017), ECF No. 78.

13. Attached as Exhibit L is a true and correct copy of Order on Corrected Notice of Election of the United States to Partially Intervene in *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 16-08697 (C.D. Cal. filed Mar. 15, 2017), ECF No. 93.

14. Attached as Exhibit M is a true and correct copy of the Amended Scheduling and Case Management Order in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal. filed Apr. 26, 2017), ECF No. 293.

15. Attached as Exhibit N is a true and correct copy of the Joint Report Pursuant to Fed. R. Civ. P. 26, Local Rule 26-1, and the Court's February 21, 2017 Order in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal.), ECF No. 287.

16. Attached as Exhibit O is a true and correct copy of the Joint Supplemental Brief of Defendants-Appellees in *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746 (9th Cir. filed Feb. 10, 2016).

17. Attached as Exhibit P is a true and correct copy of the Statement of Decision Denying the United States of America's Motion to Consolidate in *United States ex rel. Swoben v. Secure Horizons*, No. 09-05013 (C.D. Cal.), ECF No. 295.

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this 28th day of April, 2017 in Washington, DC.

/s/ Daniel Meron
Daniel Meron

Case 1:16-cv-00157-RMC Document 31-2 Filed 04/28/17 Page 1 of 12

EXHIBIT A

FILED

2009 JUL 13 PM 2:11

CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
LOS ANGELES

BY _____

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13 Attorneys for Plaintiff and Qui Tam Relator,
14 James M. Swoben

15 UNITED STATES DISTRICT COURT
16 CENTRAL DISTRICT OF CALIFORNIA

17 UNITED STATES OF AMERICA and
18 STATE OF CALIFORNIA, *ex rel* JAMES
19 M. SWOBEN,

20 Plaintiffs,

21 vs.

22 SCAN HEALTH PLAN, a California
23 corporation, fka SENIOR CARE ACTION
24 NETWORK; SENIOR CARE ACTION
25 NETWORK, a business entity, form
26 unknown,

27 Defendants.

CASE NO. 09-5013JFW
(SEM)

COMPLAINT FOR VIOLATIONS
OF FEDERAL FALSE CLAIMS
ACT AND CALIFORNIA FALSE
CLAIMS ACT; REQUEST FOR
JURY TRIAL

[UNDER SEAL PER 31 U.S.C. §
3730(b)(2)]

28 COMES NOW, Plaintiff and Qui Tam Relator James M. Swoben, individually and on
behalf of the United States of America and the State of California, and alleges as follows:

JURISDICTION AND VENUE

1. Plaintiff and Qui Tam Relator James M. Swoben (Swoben) files this action on
behalf and in the name of the United States Government ("Government") seeking damages and
civil penalties against the defendants for violations of 31 U.S.C. § 3729(a). Swoben also files
this action on behalf and in the name of the State of California ("California") seeking damages

1 and civil penalties against the defendants for violations of California Government Code §
2 12651(a).

3 2. This Court's jurisdiction over the claims for violations of 31 U.S.C. § 3729(a)
4 is based upon 31 U.S.C. § 3732(a). This Court's jurisdiction over the claims for violations of
5 California Government Code § 12651(a) is based upon 31 U.S.C. § 3732(b).

6 3. Venue is vested in this Court under 31 U.S.C. § 3732(a) because at least one of
7 the defendants transacts business in the Central District of California and many acts
8 constituting violations of 31 U.S.C. § 3729(a) occurred in the Central District of California.

9
10 THE PARTIES

11 4. Swoben is a resident and citizen of the United States, the State of California, and
12 of this District. Swoben brings this action of behalf of the Government under 31 U.S.C. §
13 3730(b) and on behalf of California under California Government Code § 12652(c).

14 5. At all times relevant, the Government funded the Medicare program which
15 provides payment of healthcare services for, among others, those 65 years or older. The
16 Government provided a Medicare option known as Medicare+Choice, now known as
17 Medicare Advantage, in which the eligible Medicare beneficiary could enroll with a managed
18 care organization (MCO) contracted with the Government for a capitated rate paid by the
19 Government that would provide at least those services provided to standard Medicare
20 beneficiaries.

21 6. At all time relevant, California administered and partially funded the Medi-Cal
22 program in which eligible Medi-Cal beneficiaries could enroll with a MCO contracted with
23 California for a capitated rate paid by California that would provide at least those services
24 provided to standard Medi-Cal beneficiaries. The Government also partially funded the Medi-
25 Cal program as part of the Government's Medicaid program.

26 7. Defendant SCAN Health Plan is and was a corporation formed under the laws of
27 the State of California, and transacted business in, among other places, the Central District of
28 California. SCAN Health Plan was formerly known and doing business as Senior Care Action

1 Network. Defendant Senior Care Action Network is a business entity, form unknown, that
2 transacted business in, among other places, the Central District of California. Defendants
3 SCAN Health Plan and Senior Care Action Network are collectively referred in this Complaint
4 as "SCAN."

5 8. At all times relevant, SCAN was and is a health maintenance organization
6 (HMO) that provides health care services in Southern California to the elderly covered under
7 Medicare. Between March 2004 and September 2006, Swoben was employed with SCAN.

8
9 COMMON ALLEGATIONS

10 9. During or after about 1984, SCAN was awarded a contract by the Government
11 to operate as a Social HMO Demonstration Project ("Social HMO contract"). The purpose
12 of the Social HMO Demonstration Project was to explore the viability of preventing or
13 delaying older-adult institutionalization in skilled-nursing facilities by providing such eligible
14 individuals with a combination of healthcare and personal care services, including homemaker
15 services, personal-care services, adult day care, respite care, and medical transportation.
16 SCAN served, among other places, the counties of Los Angeles, Riverside and San
17 Bernardino. Under the terms of the Social HMO contract, SCAN agreed to provide such
18 services to Medicare+Choice, now Medicare Advantage, beneficiaries for a monthly capitated
19 payment paid by the Government. Plaintiff is informed and believes that during and after
20 2001, the Government paid SCAN an additional monthly capitated rate of approximately \$800
21 per nursing home certifiable (NHC) beneficiary. Plaintiff is informed and believes that the
22 Social HMO contract ended on or about December 31, 2007.

23 10. During or about 2001, California awarded a contract to SCAN (the "Medi-Cal
24 contract") to provide home and community-based long-term care to Medi-Cal beneficiaries
25 that were 65 years of age or older and eligible for Medicare Parts A and B. The purpose of
26 this contract was to keep senior citizens out of long-term placement in skilled-nursing
27 facilities. The Medi-Cal contract was extended or renewed until about December 31, 2007.
28 Plaintiff is informed and believes that SCAN received a monthly capitated rate of

1 approximately \$3,300 per Medi-Cal beneficiary from Medi-Cal.

2 11. The services SCAN undertook and provided under its Social HMO contract with
3 the Government contract were included in the scope of services SCAN was to provide under
4 its Medi-Cal contract.

5 12. SCAN provided services to numerous patients that were beneficiaries under both
6 the Medicare Social HMO contract and the Medi-Cal contract ("dual eligible beneficiaries").
7 During or about 2007, Swoben discovered that although SCAN undertook and provided such
8 dual eligible beneficiaries the care and services that were covered and paid for by the
9 Government under the Medicare Social HMO contract, SCAN continued to bill for and receive
10 capitated monthly payments of approximately \$3,300 per beneficiary from Medi-Cal without
11 reduction in payment for the care and services SCAN undertook and provided under the
12 Medicare Social HMO contract.

13 13. Under applicable law, Medicare is primary and Medi-Cal secondary in
14 connection with the care and services undertaken and rendered by SCAN to the dual eligible
15 beneficiaries. Plaintiff is informed and believes that by law, or the terms of SCAN's contracts
16 with the Government or California, SCAN was required to not bill, and/or not retain payments
17 from, Medi-Cal for undertaking the services rendered to the dual eligible beneficiaries to the
18 extent such services were covered and paid for under the Medicare Social HMO contract.
19 Plaintiff is informed and believes that Medi-Cal's overpayments for dual eligible NHC
20 beneficiaries amount to at least \$800 per NHC beneficiary between 2001 and 2007 amounting
21 to over \$200 million.

22 14. SCAN's fraudulent billing practices included submitting cost reports and other
23 financial reports to Medi-Cal that failed to disclose SCAN's receipts of monies from the
24 Medicare Social HMO contract. SCAN's utilization of such fraudulent cost reports and other
25 financial reports caused Medi-Cal to overpay SCAN for services it already undertook by virtue
26 of the Medicare Social HMO contract, and concealed such overpayments. At all times
27 relevant, SCAN was aware that such overpayments by Medi-Cal were due and owing to Medi-
28 Cal, but SCAN continued to conceal said overpayments through the use of cost reports and

1 other financial reports that concealed the payments made under the Medicare Social HMO
2 contract.

3 15. SCAN knew that its cost reports, loss ratio reports, and other financial reports
4 submitted to Medi-Cal were fraudulent as evidenced by the fact that its outside actuaries
5 refused to sign and approve such submissions.

6
7 FIRST CLAIM FOR RELIEF

8 (Violation of 31 U.S.C. § 3729(a) against all defendants)

9 16. Plaintiff realleges and incorporates by reference all previous paragraphs of this
10 complaint as though fully set forth at length.

11 17. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
12 3729(a)(1) by knowingly presenting and/or causing to present to agents, contractors or
13 employees of the Government false and fraudulent billings for payment and approval.

14 18. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
15 3729(a)(2) by knowingly making, using, and/or causing to make or use false records and
16 statements to get false and excessive billings paid or approved by Medicare and Medi-Cal.

17 19. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
18 3729(a)(4) by retaining and concealing the excessive capitated payments SCAN received for
19 dual eligible beneficiaries.

20 20. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
21 3729(a)(7) by knowingly making, using and/or causing to make or use false records and
22 statements to conceal, avoid, or decrease its obligation to return to the Medi-Cal program the
23 excessive capitated payments SCAN received for dual eligible beneficiaries.

24 21. Swoben is informed and believes, and upon such information and belief alleges,
25 that as a result of SCAN's concealments and use of false records and statements, Medi-Cal
26 paid in excess of \$200 million more than it would have if SCAN had properly and truthfully
27 billed and reported, and revealed the excessive payments received for, dual eligible
28 beneficiaries.

22. As a result of SCAN's conduct, SCAN is liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent billing, reporting and concealment practices alleged above.

23. As a result of SCAN's conduct, 31 U.S.C. § 3729(a) provides that SCAN is liable to the Government for civil penalties between \$5,000 and \$10,000 for each such false and fraudulent billing, reporting and concealment.

24. Swoben is also entitled to recover his attorneys fees, costs and expenses from the SCAN pursuant to 31 U.S.C. § 3730(d).

SECOND CLAIM FOR RELIEF

(Violation of California Government Code § 12651(a) against defendants)

25. Plaintiff realleges and incorporates by reference all previous paragraphs of this complaint as though fully set forth at length.

26. At all times mentioned, SCAN routinely and repeatedly violated California Government Code § 12651(a)(1) by knowingly presenting and/or causing to present to California employees, agents and/or contractors false and fraudulent billings for payment and approval.

27. At all times mentioned, defendants routinely and repeatedly violated California Government Code § 12651(a)(2) by knowingly making, using, and/or causing to make or use false records and statements to get false and excessive billings paid or approved by Medi-Cal.

28. At all times mentioned, SCAN routinely and repeatedly violated California Government Code § 12651(a)(4) by retaining and concealing the excessive capitated payments SCAN received for dual eligible beneficiaries.

29. At all times mentioned, SCAN routinely and repeatedly violated California Government Code § 12651(a)(7) by knowingly making, using and/or causing to make or use false records and statements to conceal, avoid, or decrease its obligation to return to the Medi-Cal program the excessive capitated payments SCAN received for dual eligible beneficiaries.

30. Swoben is informed and believes, and upon such information and belief alleges,

1 that as a result of SCAN's concealments and use of false records and statements, Medi-Cal
2 paid in excess of \$200 million more than it would have if SCAN had properly and truthfully
3 billed and reported, and revealed the excessive payments received for, dual eligible
4 beneficiaries.

5 31. As a result of SCAN's conduct, SCAN is liable to California for up to three
6 times the amount of damages sustained by California as a result of the false and fraudulent
7 billing, reporting and concealment practices alleged above.

8 32. As a result of SCAN's conduct, California Government Code §12651(a)
9 provides that defendants are liable to California for civil penalties of up to \$10,000 for each
10 such false and fraudulent billing, reporting and concealment.

11 33. Swoben is also entitled to recover his attorneys fees, costs and expenses from
12 SCAN pursuant to California Government Code § 12652(g)(8).

13
14 PRAYER FOR RELIEF

15 WHEREFORE, Plaintiff and Qui Tam Relator James M. Swoben prays for relief as
16 follows:

17 FOR THE FIRST CLAIM FOR RELIEF

- 18 1. Treble the Government's damages according to proof;
19 2. Civil penalties according to proof;
20 3. A relator's award of up to 30% of the amounts recovered by or on behalf of the
21 Government;

22 FOR THE SECOND CLAIM FOR RELIEF

- 23 4. Treble the State of California's damages according to proof;
24 5. Civil penalties according to proof;
25 6. A relator's award of up to 50% of the amounts recovered by or on behalf of the
26 State of California;

27 FOR ALL CLAIMS FOR RELIEF

- 28 7. Attorneys fees, expenses, and costs; and

8. Such other and further relief as the Court deems just and proper.

THE HANAGAMI LAW FIRM
A Professional Corporation

Dated: July 9, 2009

By: 
William K. Hanagami
Attorneys for Plaintiff and Qui Tam Relator,
James M. Swoben

REQUEST FOR JURY TRIAL

Plaintiff and Qui Tam Relator James M. Swoben hereby requests a trial by jury.

THE HANAGAMI LAW FIRM
A Professional Corporation

Dated: July 9, 2009

By: 
William K. Hanagami
Attorneys for Plaintiff and Qui Tam Relator,
James M. Swoben

Complaint.P01.wpd

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

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge John F. Walter and the assigned discovery Magistrate Judge is John E. McDermott.

The case number on all documents filed with the Court should read as follows:

CV09- 5013 JFW (JEMx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

=====

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☒ **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

☐ **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

☐ **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

Case 2:16-cv-08697-MWF-SS Document 254-3 Filed 07/23/18 Page 151 of 513 Page ID #10

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

[Under seal per 31 U.S.C. sec. 3730(b)]

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)

United States of America, *State of California,*
James M. Swoben

DEFENDANTS

SCAU Health Plan, Senior Care Action Network

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)

William K. Hanagami, THE HANAGAMI LAW FIRM, A.P.C.
21700 Oxnard Street, Suite 1150
Woodland Hills, CA 91367-7572 (818) 716-8570

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☒ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated or Principal Place of Business in this State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated and Principal Place of Business in Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

IV. ORIGIN (Place an X in one box only.)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☒ No

☒ MONEY DEMANDED IN COMPLAINT: \$ *600,000.00*

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
False Claims Act (31 U.S.C. sections 3729, et seq.)

VII. NATURE OF SUIT (Place an X in one box only.)

- | OTHER STATUTES | CONTRACT | TORTS
PERSONAL INJURY | TORTS
PROPERTY | PRISONER
PETITIONS | LABOR |
|---|---|--|---|---|---|
| ☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities Exchange
☐ 875 Customer Challenge 12 USC 3410
☒ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes | ☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property | ☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability
☐ 462 Naturalization Application
☐ 463 Habeas Corpus-Alien Detainee
☐ 465 Other Immigration Actions | ☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities - Employment
☐ 446 American with Disabilities - Other
☐ 440 Other Civil Rights | ☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/Other
☐ 550 Civil Rights
☐ 555 Prison Condition
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety/Health
☐ 690 Other | ☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act
☐ 820 Copyrights
☐ 830 Patent
☐ 840 Trademark
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609 |

CV09-5013

FOR OFFICE USE ONLY: Case Number:

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). **IDENTICAL CASES:** Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes
If yes, list case number(s): _____

VIII(b). **RELATED CASES:** Have any cases been previously filed in this court that are related to the present case? ☒ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

- (Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

- (a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☒ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

- (b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

- (c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): W. S. [Signature] Date July 9 2009

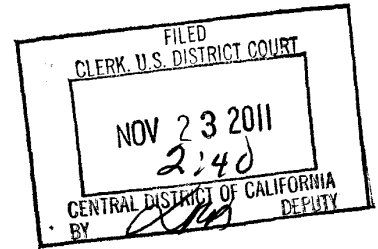
Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

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EXHIBIT B



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12 **AbramZinberg@gmail.com**

13 Attorneys for Plaintiff and Qui Tam Relator

14 UNITED STATES DISTRICT COURT
15 CENTRAL DISTRICT OF CALIFORNIA

16 UNITED STATES OF AMERICA [UNDER
17 SEAL],

18 Plaintiffs,

19 vs.

20 [UNDER SEAL],

21 Defendants.

CASE NO.: CV09-5013 JFW(JEMx)

THIRD AMENDED COMPLAINT
FOR VIOLATIONS OF FEDERAL
FALSE CLAIMS ACT AND
[UNDER SEAL]

[UNDER SEAL PER 31 U.S.C. §
3730(b)(2)]

22 [UNDER SEAL]

1 **William K. Hanagami, SBN 119832**
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13 Attorneys for Plaintiff and Qui Tam Relator,
14 James M. Swoben

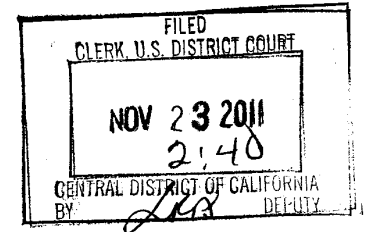
15 UNITED STATES DISTRICT COURT
16
17 CENTRAL DISTRICT OF CALIFORNIA

18 UNITED STATES OF AMERICA and
19 STATE OF CALIFORNIA, *ex rel* JAMES M.
20 SWOBEN,

21 Plaintiffs,

22 vs.

23 SCAN HEALTH PLAN, a California
24 corporation, fka SENIOR CARE ACTION
25 NETWORK; SENIOR CARE ACTION
26 NETWORK, a business entity, form
27 unknown; SCAN GROUP, a California
28 corporation; SECURE HORIZONS, a
business entity, form unknown; UNITED
HEALTHCARE INSURANCE COMPANY,
a Connecticut corporation; UNITED
HEALTHCARE SERVICES, INC.,
Minnesota corporation; UHIC, a business
entity, form unknown; UNITEDHEALTH
GROUP, a business entity, form unknown;
UNITEDHEALTHCARE, a business entity,
form unknown; UNITEDHEALTH, a
business entity, form unknown; PACIFICARE
HEALTH PLAN ADMINISTRATORS,
INC., a corporation; PACIFICARE OF
CALIFORNIA, a corporation; PACIFICARE
LIFE AND HEALTH INSURANCE
COMPANY, a corporation; and
PACIFICARE HEALTH SYSTEMS, a
corporation; WELLPOINT, a business entity,
form unknown; AETNA, a business entity,
form unknown; HEALTH NET, a business



CASE NO.: CV09-5013 JFW(JEMx)

THIRD AMENDED COMPLAINT
FOR VIOLATIONS OF FEDERAL
FALSE CLAIMS ACT AND
CALIFORNIA FALSE CLAIMS
ACT; REQUEST FOR JURY
TRIAL

[UNDER SEAL PER 31 U.S.C. §
3730(b)(2)]

entity, form unknown; HEALTHCARE PARTNERS, a business entity, form unknown; HEALTHCARE PARTNERS MEDICAL GROUP, a business entity, form unknown; and HEALTHCARE PARTNERS INDEPENDENT PHYSICIAN ASSOCIATION, a business entity, form unknown,

Defendants.

COMES NOW, Plaintiff and Qui Tam Relator James M. Swoben, individually and on behalf of the United States of America and the State of California, and alleges as follows:

JURISDICTION AND VENUE

1. Plaintiff and Qui Tam Relator James M. Swoben (Swoben) files this action on behalf and in the name of the United States Government ("Government") seeking damages and civil penalties against the defendants for violations of 31 U.S.C. § 3729(a). Swoben also files this action on behalf and in the name of the State of California ("California") seeking damages and civil penalties against the defendants for violations of California Government Code § 12651(a).

2. This Court's jurisdiction over the claims for violations of 31 U.S.C. § 3729(a) is based upon 31 U.S.C. § 3732(a). This Court's jurisdiction over the claims for violations of California Government Code § 12651(a) is based upon 31 U.S.C. § 3732(b).

3. Venue is vested in this Court under 31 U.S.C. § 3732(a) because at least one of the defendants transacts business in the Central District of California and many acts constituting violations of 31 U.S.C. § 3729(a) occurred in the Central District of California.

THE PARTIES

4. Swoben is a resident and citizen of the United States, the State of California, and of this District. Swoben brings this action of behalf of the Government under 31 U.S.C. § 3730(b) and on behalf of California under California Government Code § 12652(c).

1 5. At all times relevant, the Government funded the Medicare program which
2 provides payment of healthcare services for, among others, those 65 years or older. The
3 Government provided a Medicare option known as Medicare+Choice, now known as
4 Medicare Advantage, in which eligible Medicare beneficiaries could enroll with a managed
5 care organization (MCO) contracted with the Government for a capitated rate paid by the
6 Government that would provide at least those services provided to standard Medicare
7 beneficiaries.

8 6. At all time relevant, California administered and partially funded the Medi-Cal
9 program (the Medicaid program in California) in which eligible Medi-Cal beneficiaries could
10 enroll with a MCO contracted with California for a capitated rate paid by Medi-Cal that would
11 provide at least those services provided to standard Medi-Cal beneficiaries. The Government
12 also partially funded the Medi-Cal program as part of the Government's Medicaid program.

13 7. Defendant SCAN Health Plan and SCAN Group are and were corporations
14 formed under the laws of the State of California, and transacted business in, among other
15 places, the Central District of California. SCAN Health Plan was formerly known and doing
16 business as Senior Care Action Network. Defendant Senior Care Action Network is a business
17 entity, form unknown, that transacted business in, among other places, the Central District of
18 California. All defendants referenced in this paragraph are collectively referred in this
19 Complaint as "SCAN."

20 8. At all times relevant, SCAN was and is a health maintenance organization
21 (HMO) that provides health care services in Southern California to the elderly covered under
22 Medicare. Between March 2004 and September 2006, Swoben was employed with SCAN.

23 9. Defendant United Healthcare Insurance Company is and was a corporation
24 formed under the laws of the State of Connecticut, and transacted business in, among other
25 places, the Central District of California. Defendant United Healthcare Services, Inc. is and
26 was a corporation formed under the laws of the State of Minnesota, and transacted business
27 in, among other places, the Central District of California. Defendants UHIC, UnitedHealth
28 Group, UnitedHealthcare, UnitedHealth, and Secure Horizons are business entities, form

1 unknown, that transacted business in, among other places, the Central District of California.
2 Defendants Pacifcare Health Plan Administrators, Inc., Pacifcare of California, Pacifcare
3 Life and Health Insurance Company, and Pacifcare Health Systems are corporations formed
4 under the laws of one or more states of the United States, and transacted business in, among
5 other places, the Central District of California. All defendants referenced in this paragraph
6 are collectively referred in this Complaint as "Secure Horizons."

7 10. Defendants Wellpoint, Aetna, and Health Net are business entities, form
8 unknown, that transacted business in, among other places, the Central District of California.
9 Defendants SCAN, Secure Horizons, Wellpoint, Aetna, and Health Net are collectively
10 referred in this Complaint as "defendant HMOs."

11 11. Defendants HealthCare Partners, HealthCare Partners Medical Group, and
12 HealthCare Partners Independent Physician Association are business entities, form unknown,
13 that transacted business in, among other places, the Central District of California. Defendants
14 HealthCare Partners, HealthCare Partners Medical Group, and HealthCare Partners
15 Independent Physician Association are collectively referred in this Complaint as "HealthCare
16 Partners."

17
18 COMMON ALLEGATIONS

19 12. During or after about 1984, SCAN was awarded a contract by the Government
20 to operate as a Social HMO Demonstration Project ("Social HMO contract"). The purpose
21 of the Social HMO Demonstration Project was to explore the viability of preventing or
22 delaying older-adult institutionalization in skilled-nursing facilities by providing such eligible
23 individuals with a combination of healthcare and personal care services, including homemaker
24 services, personal-care services, adult day care, respite care, and medical transportation.
25 SCAN served, among other places, the California counties of Los Angeles, Riverside and San
26 Bernardino. Under the terms of the Social HMO contract, SCAN agreed to provide such
27 services to Medicare+Choice, now Medicare Advantage, beneficiaries for a monthly capitated
28 payment paid by the Government. Plaintiff is informed and believes that during and after

1 2001, the Government paid SCAN an additional monthly capitated rate of approximately \$800
2 per nursing home certifiable (NHC) beneficiary. Plaintiff is informed and believes that the
3 Social HMO contract ended on or about December 31, 2007.

4 13. During or about 2001, California awarded a contract to SCAN (the “Medi-Cal
5 contract”) to provide home and community-based long-term care to Medi-Cal beneficiaries
6 that were 65 years of age or older and eligible for Medicare Parts A and B. The purpose of
7 this contract was to keep senior citizens out of long-term placement in skilled-nursing
8 facilities. The Medi-Cal contract was extended or renewed until about December 31, 2007.
9 Plaintiff is informed and believes that SCAN received a monthly capitated rate of
10 approximately \$3,300 per Medi-Cal beneficiary from Medi-Cal.

11 14. The services SCAN was to provide under its Medi-Cal contract were included
12 in the services SCAN undertook and provided under its Social HMO contract with the
13 Government.

14 15. SCAN provided services to numerous patients that were beneficiaries under both
15 the Medicare Social HMO contract and the Medi-Cal contract (“dual eligible beneficiaries”).
16 During or about 2006, Swoben discovered that although SCAN undertook and provided such
17 dual eligible beneficiaries the care and services that were covered and paid for by the
18 Government under the Medicare Social HMO contract, SCAN continued to bill for and receive
19 capitated monthly payments of approximately \$3,300 per beneficiary from Medi-Cal without
20 reduction in payment for the care and services SCAN undertook and provided under the
21 Medicare Social HMO contract.

22 16. Under applicable law, Medicare is primary and Medi-Cal secondary in
23 connection with the care and services undertaken and rendered by SCAN to the dual eligible
24 beneficiaries. Plaintiff is informed and believes that by law, or the terms of SCAN’s contracts
25 with the Government or California, SCAN was required to not bill, and/or not retain payments
26 from, Medi-Cal for undertaking the services rendered to the dual eligible beneficiaries to the
27 extent such services were covered and paid for under the Medicare Social HMO contract.
28 Plaintiff is informed and believes that Medi-Cal’s overpayments for dual eligible NHC

beneficiaries amount to at least \$800 per NHC beneficiary between 2001 and 2007 amounting to more than \$200 million.

17. SCAN was required to periodically provide Medicare and Medi-Cal cost reports and other financial reports and information reflecting SCAN's true cost to furnish the services to be provided under the Medicare Social HMO contract and Medi-Cal contract, respectively. The purpose of such requirement was, among other things, so that Medicare and Medi-Cal could determine if the capitated rate paid to SCAN under the Medicare Social HMO contract or Medi-Cal contract, respectively, was excessive in light of SCAN's costs to furnish services under such contract. If SCAN's costs of furnishing such services under the Medicare Social HMO contract or Medi-Cal contract were significantly lower than the capitated rate paid to SCAN by Medicare or Medi-Cal, respectively, the capitated rate would be lowered accordingly.

18. SCAN's fraudulent billing practices included failing to submit cost reports and other financial reports and information to Medi-Cal that disclosed SCAN's true cost (in light of SCAN's receipt of monies from the Medicare Social HMO contract) of the services to be provided under the Medi-Cal contract, or alternatively, submitting cost reports and other financial reports and information to Medi-Cal that failed to disclose, among other things, SCAN's receipts of monies from the Medicare Social HMO contract. SCAN's utilization of such fraudulent practices and concealments caused Medi-Cal to overpay SCAN for services it already undertook by virtue of, among other things, the Medicare Social HMO contract, and concealed such overpayments. At all times relevant, SCAN was aware that such overpayments by Medi-Cal were due and owing to Medi-Cal, but SCAN continued to conceal said overpayments.

19. SCAN knew that its cost reports, loss ratio reports, and other financial reports submitted to Medi-Cal were fraudulent as evidenced by the fact that its outside actuaries refused to sign and approve such submissions. Further SCAN knew or should have known that it had the ability to provide Medi-Cal the true costs of the services to be provided under the Medi-Cal contract, but failed to do so because SCAN knew that its capitated rates would

1 be reduced if such information was provided to Medi-Cal.

3 FIRST CLAIM FOR RELIEF

4 (Violation of 31 U.S.C. § 3729(a) against SCAN)

5 20. Plaintiff realleges and incorporates by reference paragraphs 1 through 19,
6 inclusive, of this complaint as though fully set forth at length.

7 21. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
8 3729(a)(1) by knowingly presenting and/or causing to present to agents, contractors or
9 employees of the Government false and fraudulent billings for payment and approval.

10 22. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
11 3729(a)(2) by knowingly making, using, and/or causing to make or use false records and
12 statements to get false and excessive billings paid or approved by Medicare and Medi-Cal.

13 23. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
14 3729(a)(4) by improperly retaining and concealing the excessive capitated payments SCAN
15 received.

16 24. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
17 3729(a)(7) by knowingly making, using and/or causing to make or use false records and
18 statements to conceal, avoid, or decrease its obligation to return to the Medi-Cal program the
19 excessive capitated payments SCAN received.

20 25. Swoben is informed and believes, and upon such information and belief alleges,
21 that as a result of SCAN's concealments and use of false records and statements, Medi-Cal
22 paid in excess of \$200 million more than it would have if SCAN had properly and truthfully
23 billed and reported, and revealed the excessive payments received.

24 26. As a result of SCAN's conduct, SCAN is liable to the Government for three
25 times the amount of damages sustained by the Government as a result of the false and
26 fraudulent billing, reporting and concealment practices alleged above.

27 27. As a result of SCAN's conduct, 31 U.S.C. § 3729(a) provides that SCAN is
28 liable to the Government for civil penalties between \$5,000 and \$10,000 for each such false

1 and fraudulent billing, reporting and concealment.

2 28. Swoben is also entitled to recover his attorneys fees, costs and expenses from
3 the SCAN pursuant to 31 U.S.C. § 3730(d).

4
5 SECOND CLAIM FOR RELIEF

6 (Violation of California Government Code § 12651(a) against SCAN)

7 29. Plaintiff realleges and incorporates by reference paragraphs 1 through 28,
8 inclusive, of this complaint as though fully set forth at length.

9 30. At all times mentioned, SCAN routinely and repeatedly violated California
10 Government Code § 12651(a)(1) by knowingly presenting and/or causing to present to
11 California employees, agents and/or contractors false and fraudulent billings for payment and
12 approval.

13 31. At all times mentioned, defendants routinely and repeatedly violated California
14 Government Code § 12651(a)(2) by knowingly making, using, and/or causing to make or use
15 false records and statements to get false and excessive billings paid or approved by Medi-Cal.

16 32. At all times mentioned, SCAN routinely and repeatedly violated California
17 Government Code § 12651(a)(4) by improperly retaining and concealing the excessive
18 capitated payments SCAN received.

19 33. At all times mentioned, SCAN routinely and repeatedly violated California
20 Government Code § 12651(a)(7) by knowingly making, using and/or causing to make or use
21 false records and statements to conceal, avoid, or decrease its obligation to return to the Medi-
22 Cal program the excessive capitated payments SCAN received.

23 34. Swoben is informed and believes, and upon such information and belief alleges,
24 that as a result of SCAN's concealments and use of false records and statements, Medi-Cal
25 paid in excess of \$200 million more than it would have if SCAN had properly and truthfully
26 billed and reported, and revealed the excessive payments received.

27 35. As a result of SCAN's conduct, SCAN is liable to California for up to three
28 times the amount of damages sustained by California as a result of the false and fraudulent

1 billing, reporting and concealment practices alleged above.

2 36. As a result of SCAN's conduct, California Government Code §12651(a)
3 provides that defendants are liable to California for civil penalties of up to \$10,000 for each
4 such false and fraudulent billing, reporting and concealment.

5 37. Swoben is also entitled to recover his attorneys fees, costs and expenses from
6 SCAN pursuant to California Government Code § 12652(g)(8).

7
8 THIRD CLAIM FOR RELIEF

9 (Violation of 31 U.S.C. § 3729(a) against SCAN and Secure Horizons)

10 [Up-Coding]

11 38. Plaintiff realleges and incorporates by reference paragraphs 1 through 19,
12 inclusive, of this complaint as though fully set forth at length.

13 39. At all times relevant, SCAN and Secure Horizons, were and/or operated health
14 maintenance organizations that had HMO contracts with Medicare and Medi-Cal. At all times
15 relevant, SCAN and Secure Horizons, as did other HMOs, submitted diagnoses codes of their
16 respective HMO patients to the Government and California. The diagnosis codes were used
17 to develop risk scores that were used to adjust the capitated payment rates paid by the
18 Government and California. The risk scores compensated an HMO with a population of
19 patients with more severe illnesses than normal through higher capitation rates. Likewise, an
20 HMO with a population of patients with less severe illnesses than normal would see a
21 downward adjustment of its capitation rates because it was servicing a healthier than normal
22 population of patients. SCAN and Secure Horizons were allowed an 18 month period in
23 which to make retrospective corrections to their data submissions of the Government and
24 California.

25 40. Under applicable Medicare and Medi-Cal regulations, defendants can only
26 submit diagnosis codes to the Government and California, respectively, that are supported by
27 properly documented chart notes.

28 41. Beginning in or about 2005 and continuing thereafter, Secure Horizons retained

1 coding companies to perform a retrospective review of the medical charts of tens of thousands
2 of its patients with severe illnesses. Although Secure Horizons provided such coding
3 companies with the lists of patients whose charts were to be reviewed, Secure Horizons
4 concealed from the coding companies what diagnosis codes had been previously submitted to
5 the Government and California.

6 42. Beginning in or about 2005 and continuing thereafter, SCAN retained coding
7 companies to perform a retrospective review of the medical charts of approximately 10,000
8 of its patients with severe illnesses. Although SCAN provided such coding companies with
9 the lists of patients whose charts were to be reviewed, SCAN concealed from the coding
10 companies what diagnosis codes had been previously submitted to the Government and
11 California.

12 43. The coding companies conducted their review of the medical charts of tens of
13 thousands of SCAN and Secure Horizon patients, determined the diagnosis codes that were
14 supported by proper documentation of the reviewed medical charts, and provided their results
15 to SCAN and Secure Horizons, respectively. The coding companies' review resulted in (a)
16 diagnosis codes that were supported by proper documentation of the reviewed medical charts
17 that had been previously submitted to the Government and California, and (b) new diagnosis
18 codes that were supported by proper documentation of the reviewed medical charts that had
19 not been previously submitted to the Government and California. Because SCAN and Secure
20 Horizons concealed from the coding companies what diagnosis codes had been previously
21 submitted to the Government and California, the results of the coding companies' review did
22 not identify the diagnosis codes unsupported by proper documentation of the reviewed medical
23 charts that had been previously submitted to the Government and California.

24 44. SCAN and Secure Horizons made no effort to advise the Government and
25 California of the diagnosis codes for the reviewed medical charts that were not supported, and
26 made no effort to withdraw from the Government and California the previously submitted
27 diagnosis codes that were not supported by proper documentation of the reviewed medical
28 charts.

1 45. Further, the defendants had a duty to have compliance programs in place to
2 monitor and detect attempts to artificially increase risk scores and capitated payments.

3 46. SCAN and Secure Horizons improperly conceived, planned and conducted the
4 coding companies' reviews by not causing the previously submitted diagnosis codes that were
5 unsupported by the coding companies' reviews to be corrected and withdrawn from the
6 Government and California. Rather, the procedures and methods developed and used by
7 SCAN and Secure Horizons were biased in favor of "up coding" the patients' diagnoses
8 because the previously submitted diagnoses that were not unsupported by the coding
9 companies' reviews were not corrected and withdrawn from the Government and California.
10 SCAN and Secure Horizons did so with the knowledge and intent that the coding companies'
11 review would only increase, and not decrease, the number of diagnoses, and thus their
12 respective risk scores in order to increase capitated payments paid by the Government and
13 California.

14 47. During or about 2005 or 2006, SCAN and Secure Horizons submitted to the
15 Government and California the diagnosis codes determined by the coding companies' review,
16 knowing that the effect of such submissions would only increase the number of diagnoses, and
17 thus artificially inflate their respective risk scores.

18 48. As a result of the acts and concealments of SCAN and Secure Horizons, their
19 respective capitated payments paid by the Government and California became inflated due to
20 the artificially high risk scores.

21 49. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
22 violated 31 U.S.C. § 3729(a)(1) by knowingly presenting and/or causing to present to agents,
23 contractors or employees of the Government false and fraudulent billings for payment and
24 approval during and after 2004.

25 50. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
26 violated 31 U.S.C. § 3729(a)(2) by knowingly making, using, and/or causing to make or use
27 false records and statements to get false and excessive billings paid or approved under the
28 Medicare and Medi-Cal contracts during and after 2004.

1 51. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
2 violated 31 U.S.C. § 3729(a)(4) by improperly retaining and concealing the unsupported
3 diagnosis codes and inflated risk scores that inflated the capitated payments they received
4 under the Medicare and Medi-Cal contracts during and after 2004.

5 52. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
6 violated 31 U.S.C. § 3729(a)(7) by knowingly making, using and/or causing to make or use
7 false records and statements to conceal, avoid, or decrease its obligation to return to the
8 Medicare and Medi-Cal programs the inflated capitated payments they received during and
9 after 2004.

10 53. Swoben is informed and believes, and upon such information and belief alleges,
11 that as a result of the concealments and use of false records and statements, Medicare and
12 Medi-Cal paid more than they would have if SCAN and Secure Horizons had properly and
13 truthfully billed and reported, and revealed and withdrawn the diagnosis codes that were not
14 supported by their medical charts.

15 54. As a result of their conduct, defendants are liable to the Government for three
16 times the amount of damages sustained by the Government as a result of the false and
17 fraudulent billing, reporting and concealment practices alleged above.

18 55. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants
19 are liable to the Government for civil penalties between \$5,000 and \$10,000 for each such
20 false and fraudulent billing, reporting and concealment.

21 56. Swoben is also entitled to recover his attorneys fees, costs and expenses from
22 defendants pursuant to 31 U.S.C. § 3730(d).

23
24 FOURTH CLAIM FOR RELIEF

25 (Violation of California Government Code § 12651(a) against SCAN and Secure Horizons)

26 [Up-Coding]

27 57. Plaintiff realleges and incorporates by reference paragraphs 1 through 19,
28 inclusive, and 39 through 56, inclusive, of this complaint as though fully set forth at length.

1 58. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
2 violated California Government Code § 12651(a)(1) by knowingly presenting and/or causing
3 to present to California employees, agents and/or contractors false and fraudulent billings for
4 payment and approval during and after 2004.

5 59. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
6 violated California Government Code § 12651(a)(2) by knowingly making, using, and/or
7 causing to make or use false records and statements to get false and excessive billings paid or
8 approved under the Medi-Cal contract during and after 2004.

9 60. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
10 violated California Government Code § 12651(a)(4) by improperly retaining and concealing
11 the unsupported diagnosis codes and inflated risk scores that inflated the capitated payments
12 they received under the Medi-Cal contract during and after 2004.

13 61. At all times mentioned, SCAN and Secure Horizons routinely and repeatedly
14 violated California Government Code § 12651(a)(7) by knowingly making, using and/or
15 causing to make or use false records and statements to conceal, avoid, or decrease their
16 obligation to return to the Medi-Cal program the inflated the capitated payments they received
17 under the Medicare and Medi-Cal contracts during and after 2004.

18 62. Swoben is informed and believes, and upon such information and belief alleges,
19 that as a result of SCAN's and Secure Horizons' concealments and use of false records and
20 statements, Medi-Cal paid more than it would have if defendants had properly and truthfully
21 billed and reported, and revealed and withdrawn the diagnosis codes that were not supported
22 by their medical charts.

23 63. As a result of their conduct, defendants are liable to California for three times
24 the amount of damages sustained by California as a result of the false and fraudulent billing,
25 reporting and concealment practices alleged above.

26 64. As a result of their conduct, California Government Code § 12651(a) provides
27 that defendants are liable to California for civil penalties of up to \$10,000 for each such false
28 and fraudulent billing, reporting and concealment.

65. Swoben is also entitled to recover his attorneys fees, costs and expenses from defendants pursuant to California Government Code § 12652(g)(8).

FIFTH CLAIM FOR RELIEF

(Violation of 31 U.S.C. § 3729(a) against SCAN)

[PACE]

66. Plaintiff realleges and incorporates by reference paragraphs 1 through 19, inclusive, of this complaint as though fully set forth at length.

67. SCAN's Medi-Cal contract was initially for the period of July 1, 2001 through June 30, 2004, and was extended or renewed a number of times until about December 31, 2007.

68. California Welfare & Institutions Code §14598(c) provides that the SCAN Medi-Cal contract could not be renewed after June 30, 2004. Further, SCAN was ineligible to receive funds after June 30, 2004 under the Medi-Cal contract because SCAN was not a PACE¹ organization as defined under 42 C.F.R. 460.6 because SCAN did not have an agreement with the Government's Centers of Medicare and Medicaid Services (CMS) and California for participation in the PACE program. Accordingly, SCAN's requests for capitation payments from Medi-Cal for the period July 1, 2004 through December 1, 2007 were fraudulent because SCAN was not a PACE organization.

69. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. § 3729(a)(1) by knowingly presenting and/or causing to present to agents, contractors or employees of the Government false and fraudulent billings for payment and approval for the period July 1, 2004 through December 1, 2007.

70. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. § 3729(a)(2) by knowingly making, using, and/or causing to make or use false records and statements to get false and excessive billings paid or approved under the Medi-Cal contract for the period July 1, 2004 through December 1, 2007.

¹PACE means "Programs of All-Inclusive Care for the Elderly." (See, 42 C.F.R. 460.6.)

71. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. § 3729(a)(4) by improperly retaining and concealing the unauthorized capitated payments SCAN received under the Medi-Cal contract for the period July 1, 2004 through December 1, 2007.

72. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. § 3729(a)(7) by knowingly making, using and/or causing to make or use false records and statements to conceal, avoid, or decrease its obligation to return to the Medi-Cal program the unauthorized capitated payments SCAN received under the Medi-Cal contract for the period July 1, 2004 through December 1, 2007.

73. Swoben is informed and believes, and upon such information and belief alleges, that as a result of SCAN's concealments and use of false records and statements, Medi-Cal paid more than it would have if SCAN had properly and truthfully billed and reported, and revealed that it was ineligible to receive payments under the Medi-Cal contract because SCAN was not a PACE organization.

74. As a result of SCAN's conduct, SCAN is liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent billing, reporting and concealment practices alleged above.

75. As a result of SCAN's conduct, 31 U.S.C. § 3729(a) provides that SCAN is liable to the Government for civil penalties between \$5,000 and \$10,000 for each such false and fraudulent billing, reporting and concealment.

76. Swoben is also entitled to recover his attorneys fees, costs and expenses from the SCAN pursuant to 31 U.S.C. § 3730(d).

SIXTH CLAIM FOR RELIEF

(Violation of California Government Code § 12651(a) against SCAN)

[PACE]

77. Plaintiff realleges and incorporates by reference paragraphs 1 through 19, inclusive, of this complaint as though fully set forth at length.

78. SCAN's Medi-Cal contract was initially for the period of July 1, 2001 through

1 June 30, 2004, and was extended or renewed a number of times until about December 31,
2 2007.

3 79. California Welfare & Institutions Code §14598(c) provides that the SCAN
4 Medi-Cal contract could not be renewed after June 30, 2004. Further, SCAN was ineligible
5 to receive funds after June 30, 2004 under the Medi-Cal contract because SCAN was not a
6 PACE² organization as defined under 42 C.F.R. 460.6 because SCAN did not have an
7 agreement with the Government's Centers of Medicare and Medicaid Services (CMS) and
8 California for participation in the PACE program. Accordingly, SCAN's requests for
9 capitation payments from Medi-Cal for the period July 1, 2004 through December 1, 2007
10 were fraudulent because SCAN misrepresented that it had complied with all applicable laws
11 and regulations in connection with such payments, even though SCAN was not a PACE
12 organization.

13 80. At all times mentioned, SCAN routinely and repeatedly violated California
14 Government Code § 12651(a)(1) by knowingly presenting and/or causing to present to
15 California employees, agents and/or contractors false and fraudulent billings for payment and
16 approval for the period July 1, 2004 through December 1, 2007.

17 81. At all times mentioned, SCAN routinely and repeatedly violated California
18 Government Code § 12651(a)(2) by knowingly making, using, and/or causing to make or use
19 false records and statements to get false and excessive billings paid or approved under the
20 Medi-Cal contract for the period July 1, 2004 through December 1, 2007.

21 82. At all times mentioned, SCAN routinely and repeatedly violated California
22 Government Code § 12651(a)(4) by improperly retaining and concealing the unauthorized
23 capitated payments SCAN received under the Medi-Cal contract for the period July 1, 2004
24 through December 1, 2007.

25 83. At all times mentioned, SCAN routinely and repeatedly violated California
26 Government Code § 12651(a)(7) by knowingly making, using and/or causing to make or use
27 false records and statements to conceal, avoid, or decrease its obligation to return to the Medi-
28

²PACE means "Programs of All-Inclusive Care for the Elderly." (See, 42 C.F.R. 460.6.)

1 Cal program the unauthorized capitated payments SCAN received under the Medi-Cal contract
2 for the period July 1, 2004 through December 1, 2007.

3 84. Swoben is informed and believes, and upon such information and belief alleges,
4 that as a result of SCAN's concealments and use of false records and statements, Medi-Cal
5 paid more than it would have if SCAN had properly and truthfully billed and reported, and
6 revealed that it was ineligible to receive payments under the Medi-Cal contract because SCAN
7 was not a PACE organization.

8 85. As a result of SCAN's conduct, SCAN is liable to California for three times the
9 amount of damages sustained by California as a result of the false and fraudulent billing,
10 reporting and concealment practices alleged above.

11 86. As a result of SCAN's conduct, California Government Code § 12651(a)
12 provides that SCAN is liable to California for civil penalties of up to \$10,000 for each such
13 false and fraudulent billing, reporting and concealment.

14 87. Swoben is also entitled to recover his attorneys fees, costs and expenses from
15 the SCAN pursuant to California Government Code § 12652(g)(8).

16
17 SEVENTH CLAIM FOR RELIEF

18 (Violation of 31 U.S.C. § 3729(a) against SCAN)

19 [False Diagnosis Reporting]

20 88. Plaintiff realleges and incorporates by reference paragraphs 1 through 19,
21 inclusive, of this complaint as though fully set forth at length.

22 89. At all times relevant, SCAN was and/or operated a health maintenance
23 organization that had HMO contracts with Medicare and Medi-Cal. At all times relevant,
24 SCAN, as did other HMOs, submitted diagnoses codes of its HMO patients to the Government
25 and California. The diagnosis codes were used to develop risk scores that were used to adjust
26 the capitated payment rates paid by the Government and California. The risk scores
27 compensated an HMO with a population of patients with more severe illnesses than normal
28 through higher capitation rates. Likewise, an HMO with a population of patients with less

1 severe illnesses than normal would see a downward adjustment of its capitation rates because
2 it was servicing a healthier than normal population of patients.

3 90. Under applicable Medicare and Medi-Cal regulations, HMOs can only submit
4 diagnosis codes to the Government and California, respectively, that are supported by properly
5 documented chart notes.

6 91. During or about 2005, Medicare conducted a review of about 200 of SCAN's
7 2003 medical charts of its Medicare patients, and determined that about 40% (more than twice
8 the norm in the industry) of the reviewed chart notes did not support the 2003 diagnosis codes
9 previously supplied to Medicare. As a result, Medicare disallowed the diagnosis codes of the
10 200 reviewed charts that were not supported by properly documented chart notes. During
11 2003, SCAN had more than 90,000 Medicare patients.

12 92. The procedures utilized by SCAN to document chart notes and diagnoses, and
13 submit diagnosis codes to the Government and California remained the same between and
14 including 2003 and 2006. SCAN did not take any corrective action to reduce its error rate (the
15 percentage of submitted diagnosis codes unsupported by properly documented chart notes)
16 during that time.

17 93. Based upon the results of Medicare 2005 review, Plaintiff is informed and
18 believes, and upon such information and belief alleges, that 40% of the 2004 and 2005
19 diagnosis codes SCAN submitted to the Government and California were not supported by
20 properly documented chart notes as SCAN utilized the same procedures to document chart
21 notes and submit diagnosis codes to the Government and California. In spite of the
22 excessively high error rate, SCAN took no action to review the 2004 and 2005 diagnosis codes
23 submitted to the Government and California, and failed to either (a) ensure that the diagnosis
24 codes were supported by properly documented chart notes, or (b) withdraw the 2004 and 2005
25 diagnosis codes that were not supported by properly documented chart notes.

26 94. Plaintiff is informed and believes, and upon such information and belief alleges,
27 that 40% of the diagnosis codes SCAN submitted to the Government and California for 2006
28 and beyond were not supported by properly documented chart notes as SCAN utilized the

1 same procedures to document chart notes and submit diagnosis codes to the Government and
2 California that were in place during 2003.

3 95. As a result of SCAN's submission of diagnosis codes to the Government and
4 California since 2004, 40% of which are invalid because they were not supported by properly
5 documented chart notes, failure to ensure that the diagnosis codes were supported by properly
6 documented chart notes, and failure to withdraw the 2004 and 2005 diagnosis codes that were
7 not supported by properly documented chart notes, the Government and California were
8 induced to and did pay capitation rates to SCAN that were excessively high.

9 96. During each year in question, SCAN's authorized officer or representative
10 submitted to the Government and California an attestation that SCAN had truthfully submitted
11 all required information to the Government and California, respectively, and had complied
12 with all applicable laws and Medicare and Medi-Cal regulations.

13 97. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
14 3729(a)(1) by knowingly presenting and/or causing to present to agents, contractors or
15 employees of the Government false and fraudulent billings for payment and approval by
16 Medicare and Medi-Cal for the period 2004 through and including 2007.

17 98. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
18 3729(a)(2) by knowingly making, using, and/or causing to make or use false records and
19 statements to get false and excessive billings paid or approved by Medicare and Medi-Cal for
20 the period 2004 through and including 2007.

21 99. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
22 3729(a)(4) by improperly retaining and concealing the excessive capitated payments SCAN
23 received from Medicare and Medi-Cal for the period 2004 through and including 2007.

24 100. At all times mentioned, SCAN routinely and repeatedly violated 31 U.S.C. §
25 3729(a)(7) by knowingly making, using and/or causing to make or use false records and
26 statements to conceal, avoid, or decrease its obligation to return to the Medicare and Medi-Cal
27 programs the excessive capitated payments SCAN received from the Government and
28 California for the period 2004 through and including 2007.

101. As a result of SCAN's conduct, SCAN is liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent billing, reporting and concealment practices alleged above.

102. As a result of SCAN's conduct, 31 U.S.C. § 3729(a) provides that SCAN is liable to the Government for civil penalties between \$5,000 and \$10,000 for each such false and fraudulent billing, reporting and concealment.

103. Swoben is also entitled to recover his attorneys fees, costs and expenses from the SCAN pursuant to 31 U.S.C. § 3730(d).

EIGHTH CLAIM FOR RELIEF

(Violation of California Government Code § 12651(a) against SCAN)

[False Diagnosis Reporting]

104. Plaintiff realleges and incorporates by reference paragraphs 1 through 19, inclusive, of this complaint as though fully set forth at length.

105. At all times relevant, SCAN was and/or operated a health maintenance organization that had HMO contracts with Medicare and Medi-Cal. At all times relevant, SCAN, as did other HMOs, submitted diagnoses codes of its HMO patients to the Government and California. The diagnosis codes were used to develop risk scores that were used to adjust the capitated payment rates paid by the Government and California. The risk scores compensated an HMO with a population of patients with more severe illnesses than normal through higher capitation rates. Likewise, an HMO with a population of patients with less severe illnesses than normal would see a downward adjustment of its capitation rates because it was servicing a healthier than normal population of patients.

106. Under applicable Medicare and Medi-Cal regulations, HMOs can only submit diagnosis codes to the Government and California, respectively, that are supported by properly documented chart notes.

107. During or about 2005, Medicare conducted a review of about 200 of SCAN's 2003 medical charts of its Medicare patients, and determined that about 40% (more than twice

1 the norm in the industry) of the reviewed chart notes did not support the 2003 diagnosis codes
2 previously supplied to Medicare. As a result, Medicare disallowed the diagnosis codes of the
3 200 reviewed charts that were not supported by properly documented chart notes. During
4 2003, SCAN had more than 19,000 Medi-Cal patients.

5 108. The procedures utilized by SCAN to document chart notes and diagnoses, and
6 submit diagnosis codes to the Government and California, remained the same between and
7 including 2003 and 2006. SCAN did not take any corrective action to reduce its error rate (the
8 percentage of submitted diagnosis codes unsupported by properly documented chart notes)
9 during that time.

10 109. Based upon the results of Medicare 2005 review, Plaintiff is informed and
11 believes, and upon such information and belief alleges, that 40% of the 2004 and 2005
12 diagnosis codes SCAN submitted to California were not supported by properly documented
13 chart notes as SCAN utilized the same procedures to document chart notes and submit
14 diagnosis codes to the Government and California. In spite of the excessively high error rate,
15 SCAN took no action to review the 2004 and 2005 diagnosis codes submitted to California,
16 and failed to either (a) ensure that the diagnosis codes were supported by properly documented
17 chart notes, or (b) withdraw the 2004 and 2005 diagnosis codes that were not supported by
18 properly documented chart notes.

19 110. Plaintiff is informed and believes, and upon such information and belief alleges,
20 that 40% of the diagnosis codes SCAN submitted to California for 2006 and beyond were not
21 supported by properly documented chart notes as SCAN utilized the same procedures to
22 document chart notes and submit diagnosis codes to the Government and California that were
23 in place during 2003.

24 111. As a result of SCAN's submission of diagnosis codes to the Government and
25 California since 2004, 40% of which are invalid because they were not supported by properly
26 documented chart notes, failure to ensure that the diagnosis codes were supported by properly
27 documented chart notes, and failure to withdraw the 2004 and 2005 diagnosis codes that were
28 not supported by properly documented chart notes, California was induced to and did pay

1 capitation rates to SCAN that were excessively high.

2 112. During each year in question, SCAN's authorized officer or representative
3 submitted to the Government and California an attestation that SCAN had truthfully submitted
4 all required information to the Government and California, respectively, and had complied
5 with all applicable laws and Medicare and Medi-Cal regulations.

6 113. At all times mentioned, SCAN routinely and repeatedly violated California
7 Government Code § 12651(a)(2) by knowingly making, using, and/or causing to make or use
8 false records and statements to get false and excessive billings paid or approved by Medi-Cal
9 for the 2004 through and including 2007.

10 114. At all times mentioned, SCAN routinely and repeatedly violated California
11 Government Code § 12651(a)(4) by improperly retaining and concealing the excessive
12 capitated payments SCAN received from Medi-Cal for the period 2004 through and including
13 2007.

14 115. At all times mentioned, SCAN routinely and repeatedly violated California
15 Government Code § 12651(a)(7) by knowingly making, using and/or causing to make or use
16 false records and statements to conceal, avoid, or decrease its obligation to return to the Medi-
17 Cal program the excessive capitated payments SCAN received from Medi-Cal for the period
18 2004 through and including 2007.

19 116. Swoben is informed and believes, and upon such information and belief alleges,
20 that as a result of SCAN's concealments and use of false records and statements, Medi-Cal
21 paid more than it would have if SCAN had properly and truthfully disclosed the diagnoses
22 supported by properly documented chart notes.

23 117. As a result of SCAN's conduct, SCAN is liable to California for three times the
24 amount of damages sustained by California as a result of the false and fraudulent billing,
25 reporting and concealment practices alleged above.

26 118. As a result of SCAN's conduct, California Government Code § 12651(a)
27 provides that SCAN is liable to California for civil penalties of up to \$10,000 for each such
28 false and fraudulent billing, reporting and concealment.

119. Swoben is also entitled to recover his attorneys fees, costs and expenses from the SCAN pursuant to California Government Code § 12652(g)(8).

NINTH CLAIM FOR RELIEF

(Violation of 31 U.S.C. § 3729(a) against all defendants)

[Up-Coding]

120. Plaintiff realleges and incorporates by reference paragraphs 1 through 19, inclusive, of this complaint as though fully set forth at length.

121. At all times relevant, defendant HMOs, as did other HMOs, submitted diagnoses codes of their respective HMO patients to the Government and California. The diagnosis codes were used to develop risk scores that were used to adjust the capitated payment rates paid by the Government and California. The risk scores compensated an HMO with a population of patients with more severe illnesses than normal through higher capitation rates. Likewise, an HMO with a population of patients with less severe illnesses than normal would see a downward adjustment of its capitation rates because it was servicing a healthier than normal population of patients. Defendants were allowed an 18 month period in which to make retrospective corrections to their data submissions of the Government and California.

122. Under applicable Medicare and Medi-Cal regulations, defendants can only submit diagnosis codes to the Government and California, respectively, that are supported by properly documented chart notes.

123. HealthCare Partners is a medical group that provided medical services to the HMO patients of, and under various contracts with, defendant HMOs. Defendant HMOs utilized the diagnosis codes of its various contracted healthcare providers, such as and including HealthCare Partners, to develop risk scores that were used to adjust the capitated payment rates paid by the Government and California to defendant HMOs.

124. During or after June 2008, HealthCare Partners utilized software, HCC Manager, to evaluate claims data and reviewed the medical charts of more than 125,000 of HealthCare Partners' patients with severe illnesses. Healthcare partners used the data for prospective care,

as well as retrospective review of its Medicare and Medi-Cal patients' medical charts for previous years' submissions.

125. HealthCare Partners conducted its review of the medical charts of thousands of its patients, determined the diagnosis codes that were supported by proper documentation of the reviewed medical charts, and provided their results to the defendant HMOs. HealthCare Partners' review resulted in (a) diagnosis codes that were supported by proper documentation of the reviewed medical charts that had been previously submitted to the Government and California, and (b) new diagnosis codes that were supported by proper documentation of the reviewed medical charts that had not been previously submitted to the Government and California. The results of HealthCare Partners' review did not identify the diagnosis codes unsupported by proper documentation of the reviewed medical charts that had been previously submitted to the Government and California.

126. HealthCare Partners and defendant HMOs made no effort to advise the Government and California of the diagnosis codes for the reviewed medical charts that were unsupported by proper documentation, and made no effort to withdraw from the Government and California the previously submitted diagnosis codes that were unsupported by proper documentation of the reviewed medical charts.

127. HealthCare Partners and defendant HMOs improperly conceived, planned and conducted the coding company's reviews by not causing the previously submitted diagnosis codes that were unsupported by HealthCare Partners' reviews to be corrected and withdrawn from the Government and California. Rather, the procedures and methods developed and used were biased in favor of "up coding" the patients' diagnoses because the previously submitted diagnoses that were not unsupported by HealthCare Partners' reviews were not corrected and withdrawn from the Government and California. HealthCare Partners and defendant HMOs did so with the knowledge and intent that HealthCare Partners' reviews would only increase, and not decrease, the number of diagnoses, and thus their respective risk scores in order to increase capitated payments paid by the Government and California.

128. During or about 2008-2011, HealthCare Partners and defendant HMOs

submitted to the Government and California the diagnosis codes determined by HealthCare Partners' reviews, knowing that the effect of such submissions would only increase the number of diagnoses, and thus artificially inflate their respective risk scores and capitated payments.

129. As a result of the acts and concealments of HealthCare Partners and defendant HMOs, their respective capitated payments paid by the Government and California became inflated due to the artificially high risk scores.

130. Further, the defendant HMOs had a duty to have compliance programs in place to monitor and detect attempts to artificially increase risk scores and capitated payments.

131. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated 31 U.S.C. § 3729(a)(2) by knowingly making, using, and/or causing to make or use false records and statements to get false and excessive billings paid or approved under the Medicare and Medi-Cal contracts during and after 2008.

132. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated 31 U.S.C. § 3729(a)(4) by improperly retaining and concealing the unsupported diagnosis codes and inflated risk scores that inflated the capitated payments they received under the Medicare and Medi-Cal contracts during and after 2008.

133. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated 31 U.S.C. § 3729(a)(7) by knowingly making, using and/or causing to make or use false records and statements to conceal, avoid, or decrease its obligation to return to the Medicare and Medi-Cal programs the inflated capitated payments they received during and after 2008.

134. Swoben is informed and believes, and upon such information and belief alleges, that as a result of the concealments and use of false records and statements, Medicare and Medi-Cal paid more than they would have if HealthCare Partners and defendant HMOs had properly and truthfully billed and reported, and revealed and withdrawn the diagnosis codes that were not supported by their medical charts.

135. As a result of their conduct, defendants are liable to the Government for three times the amount of damages sustained by the Government as a result of the false and

fraudulent billing, reporting and concealment practices alleged above.

136. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants are liable to the Government for civil penalties between \$5,000 and \$10,000 for each such false and fraudulent billing, reporting and concealment.

137. Swoben is also entitled to recover his attorneys fees, costs and expenses from defendants pursuant to 31 U.S.C. § 3730(d).

TENTH CLAIM FOR RELIEF

(Violation of California Government Code § 12651(a) against all defendants)

[Up-Coding]

138. Plaintiff realleges and incorporates by reference paragraphs 1 through 19, inclusive, and 121 through 137, inclusive, of this complaint as though fully set forth at length.

139. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated California Government Code § 12651(a)(1) by knowingly presenting and/or causing to present to California employees, agents and/or contractors false and fraudulent billings for payment and approval during and after 2008.

140. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated California Government Code § 12651(a)(2) by knowingly making, using, and/or causing to make or use false records and statements to get false and excessive billings paid or approved under the Medi-Cal contract during and after 2008.

141. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated California Government Code § 12651(a)(4) by improperly retaining and concealing the unsupported diagnosis codes and inflated risk scores that inflated the capitated payments they received under the Medi-Cal contract during and after 2008.

142. At all times mentioned, HealthCare Partners and defendant HMOs routinely and repeatedly violated California Government Code § 12651(a)(7) by knowingly making, using and/or causing to make or use false records and statements to conceal, avoid, or decrease their obligation to return to the Medi-Cal program the inflated the capitated payments they received

1 under the Medicare and Medi-Cal contracts during and after 2008.

2 143. Swoben is informed and believes, and upon such information and belief alleges,
3 that as a result of HealthCare Partners' and defendant HMOs' concealments and use of false
4 records and statements, Medi-Cal paid more than it would have if defendants had properly and
5 truthfully billed and reported, and revealed and withdrawn the diagnosis codes that were not
6 supported by their medical charts.

7 144. As a result of their conduct, defendants are liable to California for three times
8 the amount of damages sustained by California as a result of the false and fraudulent billing,
9 reporting and concealment practices alleged above.

10 145. As a result of their conduct, California Government Code § 12651(a) provides
11 that defendants are liable to California for civil penalties of up to \$10,000 for each such false
12 and fraudulent billing, reporting and concealment.

13 146. Swoben is also entitled to recover his attorneys fees, costs and expenses from
14 defendants pursuant to California Government Code § 12652(g)(8).

15
16 PRAYER FOR RELIEF

17 WHEREFORE, Plaintiff and Qui Tam Relator James M. Swoben prays for relief as
18 follows:

19 FOR THE FIRST CLAIM FOR RELIEF

20 1. Treble the Government's damages according to proof;
21 2. Civil penalties according to proof;
22 3. A relator's award of up to 30% of the amounts recovered by or on behalf of the
23 Government;

24 FOR THE SECOND CLAIM FOR RELIEF

25 4. Treble the State of California's damages according to proof;
26 5. Civil penalties according to proof;
27 6. A relator's award of up to 50% of the amounts recovered by or on behalf of the
28 State of California;

FOR THE THIRD CLAIM FOR RELIEF

7. Treble the Government's damages according to proof;
8. Civil penalties according to proof;
9. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR THE FOURTH CLAIM FOR RELIEF

10. Treble the State of California's damages according to proof;
11. Civil penalties according to proof;
12. A relator's award of up to 50% of the amounts recovered by or on behalf of the State of California;

FOR THE FIFTH CLAIM FOR RELIEF

13. Treble the Government's damages according to proof;
14. Civil penalties according to proof;
15. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR THE SIXTH CLAIM FOR RELIEF

16. Treble the State of California's damages according to proof;
17. Civil penalties according to proof;
18. A relator's award of up to 50% of the amounts recovered by or on behalf of the State of California;

FOR THE SEVENTH CLAIM FOR RELIEF

19. Treble the Government's damages according to proof;
20. Civil penalties according to proof;
21. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR THE EIGHTH CLAIM FOR RELIEF

22. Treble the State of California's damages according to proof;

23. Civil penalties according to proof;

24. A relator's award of up to 50% of the amounts recovered by or on behalf of the State of California;

FOR THE NINTH CLAIM FOR RELIEF

25. Treble the Government's damages according to proof;

26. Civil penalties according to proof;

27. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR THE TENTH CLAIM FOR RELIEF

28. Treble the State of California's damages according to proof;

29. Civil penalties according to proof;

30. A relator's award of up to 50% of the amounts recovered by or on behalf of the State of California;

FOR ALL CLAIMS FOR RELIEF

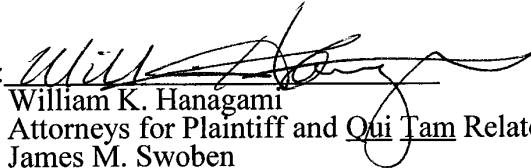
31. Attorneys fees, expenses, and costs; and

32. Such other and further relief as the Court deems just and proper.

ABRAM J. ZINBERG, ESQ.

THE HANAGAMI LAW FIRM
A Professional Corporation

Dated: November 23, 2011

By: 
William K. Hanagami
Attorneys for Plaintiff and Qui Tam Relator,
James M. Swoben

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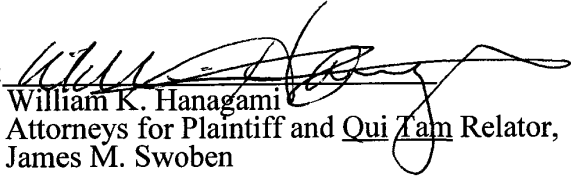
REQUEST FOR JURY TRIAL

Plaintiff and Qui Tam Relator James M. Swoben hereby requests a trial by jury.

ABRAM J. ZINBERG, ESQ.

THE HANAGAMI LAW FIRM
A Professional Corporation

Dated: November 23, 2011

By: 
William K. Hanagami
Attorneys for Plaintiff and Qui Tam Relator,
James M. Swoben

Complaint.P05.wpd

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EXHIBIT C

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17 Attorneys for the United States of America

18 UNITED STATES DISTRICT COURT
19 FOR THE CENTRAL DISTRICT OF CALIFORNIA
20 WESTERN DIVISION

21 UNITED STATES OF AMERICA *ex*
rel. JAMES M. SWOBEN,

22 Plaintiffs,

23 v.

24 SECURE HORIZONS, a business entity,
25 form unknown, *et al.*,

26 Defendants.

No. CV 09-5013 JFW (JEMx)

UNITED STATES' MEMORANDUM OF
POINTS AND AUTHORITIES IN
SUPPORT OF MOTION FOR ORDER
CONSOLIDATING ACTIONS

[FILED/LODGED CONCURRENTLY:
NOTICE OF MOTION; DECLARATION;
[PROPOSED] ORDER]

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MEMORANDUM OF POINTS AND AUTHORITIES

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I.

INTRODUCTION

The United States of America hereby moves this Court for an order consolidating this *qui tam* action under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, filed by Relator James Swoben (the “Swoben action”) with another *qui tam* action filed under the FCA by Relator Benjamin Poehling, *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, CV 16-8697-MWF (SSx) (the “Poehling action”). Both actions are pending in this District, but the Poehling action is before Judge Fitzgerald. The requested consolidation includes Swoben’s claims against UnitedHealth Group, Inc.; United Healthcare Insurance Co.; UnitedHealthcare Services, Inc.; UnitedHealthCare, Inc.; Pacificare Life and Health Insurance Co.; Pacificare Health Plan Administrators, Inc.; Pacificare Health Systems; and UHC of California (formerly known as Pacificare of California). It also includes Poehling’s claims against UnitedHealth Group, Inc. and its subsidiary, WellMed Medical Management, Inc.¹ (Collectively, these requested consolidated defendants are referred to as “United” or “the United defendants” herein). The United States seeks to consolidate Swoben and Poehling’s claims against the United defendants for all purposes (*i.e.*, pre-trial activities as well as trial).

In addition, the United States seeks to include Swoben’s claims against HealthCare Partners LLC; Healthcare Partners Medical Group, Inc.; and Healthcare Partners Independent Physician Association (collectively “HCP”) in the consolidated action against United at least for purpose of pre-trial activities, including discovery and motion practice.² Swoben’s claims against the United defendants and HCP are based on

¹ WellMed Medical Management (“WellMed”) is a provider of health care services to beneficiaries in United’s Medicare Advantage plans in Texas and Florida. United acquired WellMed in 2011 and, since that time, United has owned and operated WellMed.

² HCP is a provider of health care services to beneficiaries in United’s Medicare Advantage plans in several states, including California. HCP is one of the largest providers of services to Medicare Advantage beneficiaries in this District. For over the last decade, United has contracted with HCP to provide services to beneficiaries in United’s Medicare Advantage plan in California, which is United’s largest Medicare

1 the same facts concerning reviews conducted by coding vendors of HCP's medical
2 records (also known as "charts") documenting HCP's medical encounters with Medicare
3 beneficiaries in the United defendants' Medicare Advantage plan in California.

4 Pursuant to [Federal Rule of Civil Procedure 42\(a\)\(2\)](#), consolidation is warranted
5 with respect to United and HCP for the following reasons:

6 First, both *qui tam* actions involve common questions of law and fact concerning
7 the biased one-sided medical record reviews (also known as "chart reviews") by which
8 United and HCP distorted the information provided to the Medicare Program about the
9 health status of Medicare beneficiaries in United's Medicare Advantage plans in order to
10 obtain inflated payments from the Medicare Program.³ Although the material facts
11 underlying each of the Relators' claims differ as described below, they involve common
12 factual questions. This includes United's knowledge of its compliance and legal
13 obligations with respect to the integrity of the data it submitted to the Medicare Program
14 for payments based on beneficiaries' medical conditions, and United's understanding of
15 its legal responsibility for the integrity of diagnoses reported to it by its providers,
16 including HCP, that it then submitted to the Medicare Program for payment. The two
17 actions also involve many of the same legal questions, including but not limited to
18 United's compliance obligations with CMS' regulations and the FCA.

19 Second, consolidation will avoid duplicate filings of the same or similar papers
20 and procedural and substantive motions (*e.g.*, consolidation provides the Court with the

21
22 Advantage plan in the country. United pays HCP a percentage of the monies that the
23 Medicare Program pays United for these beneficiaries. United is legally responsible for
the validity of the diagnoses that HCP reports to it and that it then submits to Medicare
to obtain these monies.

24 ³ The Ninth Circuit's decision in *Swoben* describes the Medicare Advantage
25 Program, including the risk adjustment system used to adjust the fixed payments to
26 Medicare Advantage plans based on the health status of beneficiaries in their plans. *See*
27 [United States ex rel. Swoben v. United Healthcare Ins. Co.](#) 848 F.3d 1161, 1167-70 (9th
28 Cir. 2016). The court explained that providers report diagnoses to Medicare Advantage
Organizations (MAOs), such as United, which in turn submit them to the Medicare
Program. *Id.* at 1167. The court also explained the obligations of MAOs to ensure the
accuracy of provider-reported diagnoses and to look both ways at chart reviews to
correct both over-coding and under-coding (*i.e.*, inaccurate coding) by their providers.
Id. at 1168-70.

1 ability to order that one set of substantive motion papers for both cases be filed or that
2 one motion to compel discovery relevant to both case be submitted) and will avoid the
3 same or similar discovery in two separate actions before two separate judges. For
4 example, the parties will likely file substantive motions in both the *Swoben* and *Poehling*
5 actions concerning the applicability of the Ninth Circuit's opinion in *Swoben*.
6 Additionally, the parties will likely file discovery motions in both actions relating to the
7 United defendants' withholding of thousands of relevant documents based on claims of
8 privilege. As a third example, in both actions, United will likely seek the same
9 documents from the government and to depose the same government witnesses.

10 Third, the United States' motion to consolidate is timely, as both actions are at an
11 early and similar stage of litigation. The Ninth Circuit recently remanded this action,
12 Swoben recently filed his Fourth Amended Complaint on March 13, 2017, a Joint Rule
13 26(f) Meeting Report is due on April 17, 2017, a Scheduling Conference has been set for
14 and the United States' complaint-in-intervention is due on May 1, 2017, and discovery
15 has not yet commenced. Similarly, the United States recently intervened in the *Poehling*
16 action on February 14, 2017, received leave to file its complaint-in-intervention by May
17 16, 2017 in that action, with Poehling also receiving leave to file a Second Amended
18 Complaint on that date, and discovery has not yet commenced. For the same reasons,
19 there is also no prejudice to United or HCP and no inefficiencies presented by
20 consolidating the two *qui tam* actions at this time, especially for the purpose of pre-trial
21 activities, including discovery and motion practice.

22 Contemporaneously with the filing of this motion, the United States is providing a
23 courtesy copy of this motion to Judge Fitzgerald in order to provide notice to the
24 *Poehling* court of the United States' request to consolidate the two actions. The United
25 States defers to the Court's discretion on the issue of which action should be transferred
26 in order to accomplish consolidation (*i.e.*, whether the smaller *Swoben* action should be
27 transferred or the larger *Poehling* action, which involves claims against United that are
28 unrelated to chart reviews, should be transferred).

1 This motion is made following the conference of counsel under Local Rule 7-3 on
2 March 14, 2017. Relators Swoben and Poehling do not oppose the motion. United
3 opposes this motion. HCP does not oppose consolidation with respect to the United
4 defendants, but opposes being included in the consolidated action for any purpose.
5 United's and HCP's oppositions are without merit for the reasons stated below.

6 This motion is based on the facts and arguments set forth below, the declaration
7 and exhibits filed concurrently herewith, and such other and further argument the Court
8 may allow at the time of the hearing.

9 **II.**

10 **STATEMENT OF FACTS**

11 **A. The *Swoben* Action**

12 In 2010, Swoben filed his Second Amended Complaint, adding the United
13 defendants to his action. (Docket No. 23). In 2011, Swoben filed a Third Amended
14 Complaint alleging that the United defendants were responsible for one-sided chart
15 reviews conducted by or for HCP and possibly other providers in California. (Docket
16 No. 37, ¶¶ 41, 43-48, & 120-137). In early 2013, the United States settled as to some
17 defendants and declined to intervene as to United and others. (Docket No. 56).

18 After the United States declined to intervene, the defendants moved to dismiss
19 Swoben's Third Amended Complaint pursuant to [Federal Rules of Civil Procedure 8](#),
20 9(b), and 12(b)(6). Swoben did not defend his Third Amended Complaint; rather, he
21 sought leave to file a Fourth Amended Complaint. (Docket No. 115). Swoben's
22 proposed allegations remained focused on chart reviews by or on behalf of HCP in
23 California and the United defendants' involvement with those reviews. The proposed
24 allegations were also limited to Secure Horizons' involvement in provider-conducted
25 chart reviews in California.⁴ This Court denied Swoben's request for leave to amend his
26 complaint and dismissed his action. (Docket Nos. 133 & 134). Swoben appealed.

27 ⁴ UHC of California is United's Medicare Advantage plan in California. When
28 United acquired it in 2005, it was known as PacifiCare of California and its managed
care insurance products were branded as Secured Horizons in California.

1 Although the United States declined to intervene as to United and other defendants
2 in the *Swoben* action upon review of his Third Amended Complaint, the United States
3 continued to monitor the *Swoben* action, including its progress on appeal. Furthermore,
4 to protect the public's interest in combating healthcare fraud, the United States filed an
5 *amicus* brief in the Ninth Circuit supporting Swoben's legal arguments relating to the
6 FCA. *See* Ninth Circuit PACER Docket Sheet, Declaration of John E. Lee, Ex. 1
7 (Docket No. 68).

8 On August 10, 2016, the Ninth Circuit vacated and remanded the *Swoben* action,
9 holding that the proposed Fourth Amended Complaint alleged "a cognizable legal
10 theory" under the FCA. *United States ex. rel. Swoben v. United Healthcare Ins. Co.*, 832
11 F.3d 1084, 1097 (9th Cir. 2016). On December 16, 2016, the Ninth Circuit issued an
12 amended opinion, reaffirming that Swoben's proposed Fourth Amended Complaint
13 stated a cognizable legal theory under the FCA and satisfied Rule 9(b) as to the United
14 defendants and HCP. *United States ex. rel. Swoben v. United Healthcare Ins. Co.*, 848
15 F.3d at 1182. On February 7, 2017, the Ninth Circuit issued its mandate and remanded
16 the *Swoben* action to this Court. (Docket. No. 225).

17 On March 13, 2017, Swoben filed his Fourth Amended Complaint against United
18 and HCP. (Docket No. 251). Swoben's Fourth Amended Complaint does not name any
19 other defendants. Swoben's allegations, if proved, would hold United responsible for the
20 one-sided chart reviews conducted by HCP and possibly other unidentified California
21 providers for beneficiaries in United's California Medicare Advantage plan.⁵

22 In his Fourth Amended Complaint, Swoben alleges that, beginning in or about
23 2005, the United defendants and HCP retained coding companies to conduct chart
24

25 ⁵ Under the FCA, United can be held liable for causing providers to violate the
26 statute. *See, e.g.,* 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Furthermore, pursuant to its
27 regulatory and contractual obligations to the Medicare Program, United has
28 responsibility for ensuring that the diagnosis data reported by its providers is accurate.
Accordingly, United is responsible for allowing and/or causing its providers to conduct
chart reviews that address only under-coding and not also over-coding, especially when
United has information that there is an over-coding problem.

1 reviews of tens of thousands of beneficiaries. (Docket No. 251, Lee Decl., Ex. 2, ¶ 17).
2 He also alleges that the chart reviewers did not identify previously-submitted diagnosis
3 codes unsupported by the charts because the United defendants and HCP failed to
4 provide them with lists of these previously-submitted codes. (*Id.*, ¶ 18). Swoben refers
5 to software used by defendants to conduct these one-sided chart reviews (*id.*, ¶ 19 & 21);
6 to the United defendants' involvement in the creation of a template by a California
7 industry group, the Industry Collaborative Effort for Healthcare (ICE), and the use of
8 this template by HCP and possibly other providers in California to report the results of
9 chart reviews from 2006 to 2012 to the United defendants (*id.*, ¶ 27-32). Swoben alleges
10 that United and HCP employees were involved in the development of this template. (*Id.*,
11 ¶ 30). Lastly, Swoben alleges that, based on audits conducted by the government, the
12 United defendants and HCP knew that they had submitted or caused the submission of
13 many invalid diagnosis codes to the Medicare Program. (*Id.*, ¶ 33).

14 On March 17, 2017, the Court filed an Order allowing the United States to
15 intervene in Swoben's Fourth Amended Complaint as to the United defendants. (Docket
16 No. 254). The Court's Order also required the United States to file its Complaint-in-
17 Intervention by May 1, 2017. (*Id.*).

18 **B. The Poehling Action**

19 In early 2011, a related *qui tam* action was filed by Benjamin Poehling in the
20 United States District Court for the Western District of New York. Poehling was the
21 Director of Finance for UnitedHealthcare Medicare & Retirement (UHMR), a part of
22 defendant UnitedHealthcare, until late 2012. UHMR managed United's Medicare
23 Advantage plans. From 2007 to 2012, Poehling was intimately involved in United's
24 development and operation of its national Chart Review Program⁶ and other programs
25

26 ⁶ United started its national Chart Review Program in or about 2006. Since that
27 time, it has grown from a review of approximately 600,000 medical records annually to
28 over 1.5 million medical records annually. Some large capitated provider groups like
HCP are not included in this national program. These groups often conduct their own
chart reviews with or without United's assistance or other involvement. United has the
obligation to ensure that these self-conducted reviews are conducted lawfully.

1 and activities relating to the submission of diagnosis data to the Medicare Program for
2 risk adjustment payments based on the health status of beneficiaries in United's
3 Medicare Advantage plans. *See Poehling* First Amended Complaint ("FAC"), Lee
4 Decl., Ex. 3, *e.g.*, ¶¶ 16-17, 114-66.

5 Poehling's FAC focuses on United's large national Chart Review Program that it
6 developed after acquiring PacifiCare in 2006. Poehling's allegations about this national
7 Chart Review Program are disbursed throughout his FAC. Paragraph 115 first mentions
8 the Chart Review Program and explains that its objective was to increase risk scores.
9 Paragraphs 121 to 140 then provide more information about this program. Paragraph
10 127 alleges that United's chart reviews failed to look both ways, that is, United failed to
11 look at the result of the reviews to delete previously-submitted diagnoses that were not
12 validated by the chart reviews. Paragraph 128 explains that a United subsidiary, Ingenix
13 (now known as OptumInsight) conducted the reviews using internal coders and external
14 coding vendors. Significantly, paragraph 129 explains that the chart reviews were blind
15 (*i.e.*, the coders who review the charts did not know the diagnosis codes reported by the
16 providers to United) and that the coders were instructed to code every medical condition
17 supported by the charts. In paragraphs 131-132, Poehling further explains how United
18 defrauded the government by relying on the blind chart review results to submit
19 additional codes but not to delete unsupported codes that were previously reported by
20 providers to United and submitted by United to Medicare for payments. He further
21 alleges, in paragraph 134, how United could have deleted or corrected the unsupported
22 codes previously submitted to Medicare. In paragraphs 167 to 170, he alleges that
23 United deliberately designed its national Chart Review Program to avoid making these
24 deletes that it could have and should have made.

25 In paragraphs 137 to 140, Poehling also provides facts about the scope of United's
26 national Chart Review Program and its return on investment (ROI) from the program.
27 Paragraph 137 alleges that, for payment year 2007 (the year payments were based on
28 diagnoses from 2006 date of service medical encounters), United's ROI was 15 to 1.

1 Paragraph 139 states that United reviewed approximately 1.8 to 2 million charts in 2006,
2 2007, and 2008 combined. These allegations are supported by Poehling's Exhibit 4,
3 attached to his FAC. Exhibit 4 also shows that these one-way chart reviews were being
4 conducted nationally (the exhibit mentions chart reviews in NY, NC, CA, CO, TX, NV,
5 OK, AZ, NJ, and CT, as well as chart reviews in the NW and East Coast generally).
6 Poehling provides additional information about the scope of the national Chart Review
7 Program in paragraph 171 of his FAC. Poehling alleges that, for date-of-service year
8 2009 (payment year 2010), United reviewed approximately 1.4 million charts to find and
9 submit additional diagnoses to the government.

10 Also of great significance, Poehling's FAC alleges that United's senior executives
11 knew that the chart reviews looked only one way, even though United was obligated to
12 look both ways. (FAC ¶ 140 & 191-197). Poehling also identifies the senior executives
13 with knowledge. (*Id.*, ¶ 191-193). He attaches Exhibit 7 to his FAC as evidence of this
14 knowledge. He explains that, based on their knowledge that United should look both
15 ways, these senior executives developed a pilot program in 2010. (*Id.*, ¶¶ 181-183). He
16 further alleges that United even tried to sell the idea of "looking both ways" to its
17 commercial clients. (*Id.*, ¶¶ 260-263). Finally, in his FAC, Poehling alleges that United
18 falsely certified that the risk adjustment data (*i.e.*, diagnosis data) it provided to the
19 Medicare Program was accurate and truthful. (*Id.*, ¶¶ 79 & 326). Poehling attaches a
20 copy of one such false certification to his complaint. (*Id.*, Exhibit 1).

21 In addition, Poehling's FAC includes claims and allegations unrelated to United's
22 Chart Review Program. In particular, Poehling's FAC focuses on United's Risk
23 Adjustment Coding Compliance Review (RACCR) Program (also referred to as a "chart
24 validation" program) pursuant to which United reviewed the medical records of large
25 provider groups like HCP and WellMed to determine if the diagnoses they reported were
26 accurate. (*Id.*, ¶¶ 172-179, 181-183). He alleges that United purposefully designed
27 RACCR to make it appear as if it were addressing inaccurate coding (also known as
28 "over-coding") by these large provider groups. In reality, however, United was doing

1 very little to address this problem, which was due in large part to the financial incentives
2 it gave providers to increase the reporting of diagnoses. Poehling's FAC includes
3 allegations about these financial incentives that United gave to providers, such as
4 WellMed, to increase beneficiaries' risk scores by reporting additional diagnoses and by
5 up-coding or over-coding. (*Id.*, ¶¶ 94, 111, 118, 200-214). These incentives are
6 characterized as kickbacks. (*Id.*, ¶ 200).

7 The United States District Court for the Western District of New York transferred
8 the *Poehling* action to this District because of the related *Swoben* action and the
9 convenience of parties and witnesses. Contrary to what United contends, *see*
10 Declaration of Daniel Meron on Behalf of UnitedHealth Regarding March 14, 2017
11 Meet-And-Confer, ¶ 8 (Docket No. 259), neither that Court nor the government had an
12 obligation to provide United with the opportunity to oppose the transfer. If United had
13 been so entitled, that Court would have provided it with the opportunity.

14 *Poehling* was transferred to enable it to be related or consolidated with *Swoben*
15 due to the existence of common questions of fact and law.⁷ Transfer was in the interest
16 of justice because relating or consolidating the two *qui tam* actions will, among other
17 things, conserve judicial resources, avoid duplicative discovery and other activities, and
18 avoid inconsistent judicial decisions.⁸

19 Moreover, this matter has a significant nexus to this District.⁹ For example,
20 United's largest Medicare Advantage plan is located in California, many Medicare

22 ⁷ The government did not engage in "forum-shopping." *See* Declaration of Daniel
23 Meron on Behalf of UnitedHealth Regarding March 14, 2017 Meet-And-Confer at ¶ 7
(Docket No. 259) (incorrectly alleging that the government did so).

24 ⁸ There is no question that venue is proper in this District. An FCA action "may
25 be filed in any judicial district in which the defendant or, in the case of multiple
26 defendants, any one defendant can be found, resides, transacts business, or in which any
[fraudulent] act ... occurred." 31 U.S.C. § 3732. United and most, if not all, of the other
defendants named by Poehling in his FAC can be found or transact business in this
District and a substantial amount of the unlawful activity occurred in this District.

27 ⁹ United's representations to this Court that the claims asserted in *Poehling* have
28 "little or no nexus to the Central District of California, and there is no legitimate reason
for litigating those claims here" are baseless. *See* Declaration of Daniel Meron on

1 beneficiaries in this District are enrolled in that plan, and United's national Chart Review
2 Program and RACCR Program included numerous providers in this District. As another
3 example, United's offices in this District (Santa Ana, California) conducted United's
4 national Chart Review Program, RACCR Program, Claims Verification Program, and
5 various other activities at issue in the *Poehling* action, and United employees and other
6 agents (e.g., United's "expert" coding vendor) who work or worked in this District were
7 very involved in and/or have relevant knowledge concerning the unlawful conduct
8 alleged by Poehling. Many relevant documents are also located at United's Santa Ana
9 office and at other locations in this District.

10 On February 14, 2017, pursuant to 31 U.S.C. § 3730(b)(4), the United States
11 intervened in the *Poehling* action as to United and WellMed with respect to the claims
12 and allegations in Poehling's FAC relating to United's Chart Review Program, Claims
13 Verification Program, and Chart Validation/RACCR Program. See Lee Decl., Ex. 4.
14 Pursuant to Judge Fitzgerald's Orders dated February 15 and March 14, 2017, the United
15 States will file its Complaint-in-Intervention in the *Poehling* action by May 16, 2017.
16 *Id.*, Exs. 5 & 7. The same Orders also grant Poehling until May 16, 2017, to file an
17 amended complaint. Accordingly, at this time, the United States does not know whether
18 Poehling will continue to pursue his FCA claims against defendants other than United
19 and WellMed. Those other defendants include Health Net, Inc., Aetna, Inc., Humana,
20 Inc., Arcadian Management Services, Tufts Associated Health Plans, BCBS of Florida,
21 BCBS of Michigan, Bravo Health, Inc. (now known as Cigna), Emblemhealth,
22 Healthfirst New York, Medica Holding Company, Wellcare Health Plans, and
23 MedAssurant.¹⁰

24
25 _____
26 Behalf of UnitedHealth Regarding March 14, 2017 Meet-And-Confer at ¶ 6. Thus,
27 United's proposed motion to transfer *Poehling* to Minneapolis is without merit.

28 ¹⁰ The United States did not intervene against those other defendants, but has on-
going investigations of four of them, including Humana, Aetna, Bravo and Health Net.
On March 14, 2017, the United States filed a Corrected Notice of Intervention in
Poehling, explaining that, until it completes those investigations, it cannot reach a
decision as to those companies' potential FCA liability with respect to their submission
of claims to the Medicare Program for risk adjustment payments. See Lee Decl., Ex. 6.

III.

ARGUMENT

A. Consolidation is Warranted Because the Two Actions Involve Common Questions of Law and Fact and Consolidation Will Serve Judicial Economy and Avoid Inconsistent Judicial Decisions

Federal Rule of Civil Procedure 42(a) provides as follows:

If actions before the court involve a common question of law or fact, the court may:

- (1) join for hearing or trial any or all matters at issue in the actions;
- (2) consolidate the actions; or
- (3) issue any other orders to avoid unnecessary cost or delay.

“The district court has broad discretion under this rule to consolidate cases pending in the same district.” *Investors Research Co. v. United States District Court for the Central District of California*, 877 F.2d 777, 777 (9th Cir. 1989) (citations omitted). “Consolidation is proper when it serves the purposes of judicial economy and convenience.” *Waldrup v. Countrywide Fin. Corp.*, 2016 WL 6744442, at *2 (C.D. Cal. Nov. 14, 2016) (ordering consolidation of cases involving the same defendants). “[T]ypically, consolidation is favored.” *Ho Keung Tse v. Apple, Inc.*, 2013 WL 451639, at *3 (N.D. Cal. Feb. 5, 2013) (citing *In re Oreck Corp. Halo Vacuum and Air Purifiers Marketing and Sales*, 282 F.R.D. 486, 490 (C.D. Cal. 2012)). “The purpose of consolidation is to enhance court efficiency and to avoid substantial danger of inconsistent adjudications.” *Dusky v. Bellasaire Invs.*, 2007 WL 4403985, at *1 (C.D. Cal. No. 26, 2007) (citing *E.E.O.C. v. HBE Corp.*, 135 F.3d 543, 551 (8th Cir. 1998)). “The Court need find only one common question of fact or law in common in order to permit consolidation.” *Id.* at *2.

“The district court, in exercising its broad discretion to order consolidation of actions presenting a common issue of law or fact under Rule 42(a), weighs the saving of time and effort consolidation would produce against any inconvenience, delay, or

1 expense that it would cause.” *Huene v. United States*, 743 F.2d 703, 704 (9th Cir. 1984);
2 see also *Ferguson v. Corinthian Colleges Inc.*, 2011 WL 1519352, at *2 (C.D. Cal. Apr.
3 15, 2011) (ordering consolidation where the “involved parties [we]re nearly identical”
4 and “the two cases share[d] numerous common issues that the parties seek to resolve”)
5 (internal quotation marks omitted). Courts in the Ninth Circuit have consolidated actions
6 involving many of the same witnesses, *Sarafian v. Wright Med. Tech., Inc.*, 2017 U.S.
7 Dist. LEXIS 4237 (C.D. Cal. Jan. 9, 2017) (Lee Decl., Ex. 8); when the cases were at
8 similar stages of litigation, *GCIU-Emplr. Ret. Fund v. Quad/Graphic, Inc.*, 2016 WL
9 4411480, at *3 (C.D. Cal. Aug. 16, 2016); and when unconsolidated actions “may lead
10 to unwarranted differences in outcome[.]” *Dusky*, 2007 WL 403985, at *3.

11 Consolidation, however, does not affect the substantive rights of the parties. *J.G.*
12 *Link & Co. v. Cont’l Cas. Co.*, 470 F.2d 1133, 1138 (9th Cir. 1972). Consolidation
13 “does not merge the suits into a single cause, or change the rights of the parties, or make
14 those who are parties in one suit parties in another.” *Johnson v. Manhattan Ry. Co.*, 289
15 U.S. 479, 496-97 (1933).

16 1. Common Questions of Law and Fact

17 Both the *Swoben* and *Poehling* actions involve some common questions of law
18 and fact. For example, both actions concern the biased one-sided “chart reviews” by
19 which United distorted the information provided to the Medicare Program about the
20 health status of Medicare beneficiaries in its Medicare Advantage Plans in order to
21 obtain inflated payments to which it was not entitled. In particular, the resolution of both
22 actions will require the interpretation and application of the Ninth Circuit’s opinion in
23 *Swoben*. If the cases are not consolidated, both Judge Fitzgerald and this Court will be
24 called upon to decide the merits of United’s extraordinarily narrow (and incorrect)
25 interpretation of the opinion. This presents the potential for inconsistent judicial
26 decisions on the same legal issue.

27 As a second example, both actions raise the same factual question as to whether
28 United acted “knowingly,” as that term is defined by the FCA; that is, with actual

1 knowledge of the false diagnosis data that it submitted to the Medicare Program for
2 payments, or in reckless disregard or deliberate ignorance of the false data. *See 31*
3 *U.S.C. § 3729(b)(1)(A)*. This issue depends in part on what United knew about the
4 problem with invalid diagnoses being reported by providers, including, but not limited
5 to, its large provider groups like HCP and WellMed. So, for instance, facts about
6 United's knowledge from its involvement in the Industry Collaborative Effort ("ICE")
7 group in California and what it knew from internal and government audits is relevant to
8 both the *Swoben* and *Poehling* actions.

9 As a third example, both actions raise the question of whether United and its
10 providers could have, with reasonable diligence, conducted chart reviews in a manner
11 that looked both ways to correct unsupported diagnoses codes submitted to the Medicare
12 Program and submit additional codes based on blind chart reviews. The government
13 believes the answer is yes – but the government also believes United will argue that it
14 and its providers would have been unduly burdened by conducting chart reviews that
15 looked both ways.

16 The two actions also involve common defenses, which, although the government
17 believes them to be without merit, United will nonetheless likely raise. For example, in
18 both actions, United will likely continue asserting its "coding error rate" defense. United
19 contends that it is legally entitled to submit a certain percentage of invalid diagnoses or
20 false claims to the Medicare Program each year and retain the payments based on those
21 invalid diagnoses and false claims because of the term "actuarial equivalence" in the
22 Medicare Advantage statute. *See 42 U.S.C. § 1395w-23(a)(1)(C)(i)*. The United States
23 strongly disputes this claimed entitlement.

24 As another example, in both actions, United likely will contend that government
25 employees told it that it could deliberately ignore the negative results of its chart reviews
26 (*i.e.*, the results showing that many diagnosis codes reported by providers were invalid)
27 and keep the Medicare monies to which it was not entitled. Again, the United States
28 disputes this purported defense. If *Swoben* and *Poehling* are not consolidated, two

1 separate courts will decide these common legal and factual issues.

2 Finally, both the *Swoben* and *Poehling* actions involve common questions relating
3 to the first-to file (FTF) issue under the FCA. The FTF rule states that “[w]hen a person
4 brings a[] [*qui tam*] action under this subsection, no person other than the government
5 may . . . bring a related action based on the *facts underlying the pending action*.” 31
6 U.S.C. § 3730(b)(5) (emphasis added). In the Ninth Circuit, the dispositive question is
7 whether the “material facts” set forth in the earlier-filed action are the same as the
8 “material facts” set forth in the later-filed action. See *United States ex rel. Hartpence v.*
9 *Kinetic Concepts Inc.*, 792 F.3d 1121, 1131-32 (9th Cir. 2015). In order to compare the
10 complaints in the two actions, the court must look at the complaint in the earlier-filed
11 action at the time the later-filed action was filed. See *United States ex rel. Grynberg v.*
12 *Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004). The relation back
13 doctrine does not apply. *Id.*

14 Although United contends that consolidation is premature because United intends
15 to file a motion to dismiss the *Poehling* action, its argument is meritless. United’s
16 motion will likely assert that the complaint in the *Swoben* action includes material facts
17 about United’s national Chart Review Program and Swoben asserted those material facts
18 before Poehling filed his FAC in 2011. However, at the time that Poehling filed his
19 FAC, Swoben’s Second Amended Complaint was pending and that complaint did not
20 include any facts about United’s national Chart Review Program. Furthermore, if the
21 allegations in Swoben’s Second Amended Complaint (which are limited to chart reviews
22 conducted by coding companies hired by Secure Horizon in California in 2005) did not
23 satisfy Rule 9(b), it would not bar subsequent complaints. See, e.g., *Walburn v.*
24 *Lockheed Martin Corp.*, 431 F.3d 966, 972-73 (6th Cir. 2005) (earlier-filed complaint
25 must satisfy Rule 9(b) in order to be given preemptive effect).

26 Furthermore, United’s FTF concern weighs *in favor*, rather than against,
27 consolidation. If United proceeds to argue to Judge Fitzgerald that the Court should
28 compare Poehling’s FAC to Swoben’s recently filed Fourth Amended Complaint and

1 that all of the material facts set forth in Poehling's 2011 FAC about United's national
2 Chart Review Program are included in Swoben's 2017 Fourth Amended Complaint, then
3 Judge Fitzgerald will be called upon to decide the scope of the *Swoben* action now
4 before this Court. Should that occur, there is the potential that Judge Fitzgerald might
5 reach a different decision than this Court.

6 **2. Conservation of Resources and Avoidance of Inconsistent**
7 **Decisions**

8 Considerations of judicial economy and convenience, as well as the avoidance of
9 inconsistent judicial decisions on common questions of law and fact, weigh heavily in
10 favor of consolidation. Consolidation will provide economies of scale, both procedurally
11 and substantively, and thereby conserve judicial resources. Consolidation will also avoid
12 unnecessary costs to and burdens on the parties and third-parties from whom discovery
13 will be sought.

14 For example, unless and until the two *qui tam* actions are consolidated, the parties
15 – United, HCP, WellMed, and the United States – would be required to propound and
16 respond to very similar discovery requests (including interrogatories, document requests,
17 and depositions) in both actions and litigate very similar discovery issues, including
18 privilege issues, in both actions. The parties will also be burdening two different judges
19 and their staff with the same or very similar filings, including procedural, discovery, and
20 substantive motions. Two judges will also be called upon to determine related factual
21 issues and some of the same legal issues with the potential for inconsistencies in their
22 decisions. Given these considerations, consolidation is warranted here because it would
23 conserve judicial and party resources. See *Russell v. Werner Enterprises, Inc.*, 2016 WL
24 3912910, *5 (D. Az. July 20, 2016) (even where cases having a common defendant were
25 filed nearly two years apart and were at different stages, consolidation would conserve
26 resources and made cases “precisely the type of cases Rule 42(a) serves to consolidate”),
27 *report and recommendation adopted in full*, 2016 WL 4367150 (D. Az. Aug. 16, 2016).

1 **3. Lack of Prejudice to Defendants**

2 The very concrete procedural and substantive benefits of consolidation are in no
3 way offset by any purported concerns about delay, confusion, or prejudice, which are not
4 implicated here. Both cases are at a very early stage of litigation, with no discovery
5 having commenced in either case. Accordingly, neither action will be set back by
6 consolidation. And, consolidation will in no way impair the ability of United, HCP, or
7 WellMed to present their legal arguments and defenses.

8 **a. HCP will not be prejudiced by inclusion in the consolidated case**

9 In its Local Rule 7-3 Conference Declaration, HCP makes two arguments why it
10 should not be included in the consolidated action against United. First, it argues the
11 United States is not seeking to intervene against it in *Swoben* and the government's
12 Complaint-in-Intervention will not name it as a defendant. *See* Declaration of Michael
13 C. Theis Regarding March 14, 2017 Local Rule 7-3 Conference at ¶ 7 (Docket No. 255).
14 However, as HCP knows, it is already a defendant in Swoben's Fourth Amended
15 Complaint. Moreover, as HCP also well knows, the United States has not yet sought
16 leave to intervene against it in the *Swoben* action because HCP and the government are
17 currently engaged in on-going discussions of a possible resolution of the matter. The
18 United States thus reserves its right to seek leave to intervene against HCP, and there is
19 still the possibility that the United States will amend its Complaint-in-Intervention to
20 include HCP.

21 Second, HCP argues that it should not be included in the consolidated action
22 because it does not want to be part of the much larger *Poehling* action against United.
23 *See id.*¹¹ However, HCP should be part of the consolidated action at least for the pre-
24 trial stage of the litigation because there are common questions of law and fact presented
25 by Swoben's claims against United and Swoben's claims against HCP. The allegations
26

27 ¹¹ HCP agrees with the United States that Swoben's Fourth Amended Complaint is
28 narrowly focused on chart reviews conducted in California and that Poehling's much
larger FAC is focused on a nationwide scheme. *See id.*, ¶¶ 7-8.

1 against both United and HCP are intertwined (*i.e.*, Swoben alleges that United caused
2 HCP to perform one-sided chart reviews and that HCP did so). Furthermore, discovery
3 in both cases will include some of the same witness depositions and productions of
4 documents, and motion practice will most likely include some of the same legal and
5 factual issues. Discovery, motion practice, and other pre-trial activities relating to these
6 allegations should not be duplicated as part of two separate actions – one against United
7 and a separate action against HCP. The Court may later consider arguments for and
8 against severing HCP and United for trial should the need arise. In any event, HCP has
9 failed to cite the type of prejudice that would counsel against consolidation. *See, e.g.*,
10 *Avetisyan v. Equifax Information Services LLC*, 2015 WL 12669875, *2 (C.D. Cal. May
11 13, 2015) (noting that prejudice would result from a “stark contrast in presentation and
12 capabilities in the representations” of parties where one plaintiff was *pro per*); *see also*
13 *Lewis v. City of Fresno*, 2009 WL 1948918, *1 (E.D. Cal. July 6, 2009) (noting that
14 “risks of prejudice and confusion [from consolidation] may be reduced by the use of
15 cautionary instructions to the jury”) (citation omitted).

16 **b. United will not be prejudiced by consolidation**

17 United’s opposition to consolidation is in reality not that consolidation is
18 “premature” or that venue is improper. United desires to remove Poehling from this
19 controversy because he is extremely knowledgeable about United’s fraudulent conduct.
20 Should that fail, United desires to move the *Poehling* action to Minneapolis (United’s
21 home turf), which United considers a much friendlier forum given the Ninth Circuit’s
22 decision in *Swoben*. United is concerned that consolidation will lessen its already weak
23 prospects of prevailing on those motions. Notably, however, United cannot argue that
24 consolidation would deny it of any substantive rights to make those motions.¹²

25 First, in its attempt to unnecessarily forestall consolidation, United tries to confuse
26 the test for determining the appropriateness of consolidation (*i.e.*, whether there are one
27

28 ¹² “[T]he law is clear that an act of consolidation does not affect any of the
substantive rights of the parties.” *J.G. Link & Co. v. Cont’l Cas. Co.*, 470 F.2d at 1138.

1 or more common questions of law or fact) with the test for determining whether an
2 earlier-filed case bars a later-filed case based on the FTF rule (*i.e.*, whether the “material
3 facts” underlying the claims in the earlier-filed action are the same as the “material
4 facts” underlying the claims in the later-filed action). *See* Declaration of Daniel Meron
5 on Behalf of UnitedHealth Regarding March 14, 2017 Meet-And-Confer, ¶ 4 (Docket
6 No. 259). However, these are two distinct tests and there can be two separate *qui tam*
7 actions with different “material facts” that pose one or more common questions of law or
8 fact. Indeed, that is the situation here.

9 Second, United contends that the government purportedly “did not articulate any
10 rational explanation for its haste” in filing this motion now. *Id.* at 13. The government,
11 however, is filing this motion now for good reasons. The Court is moving the *Swoben*
12 action quickly. Pursuant to its February 21, 2017 Order, the parties are required to file
13 their Joint Report on April 17, 2017, and attend a Rule 26(f) Scheduling Conference on
14 May 1, 2017. (Docket No. 231). Pursuant to its March 17, 2017 Order, the United
15 States is required to file its Complaint-in-Intervention on May 1, 2017. (Docket No.
16 254). The government anticipates that the *Swoben* action will continue to move quickly.
17 Consolidating the *Poehling* action with the *Swoben* action will enable the Court to keep
18 moving *Swoben* at this pace. Otherwise, the parties may need to move to stay *Swoben*
19 until Judge Fitzgerald denies United’s FTF and transfer motions, and then the cases are
20 consolidated. If *Swoben* is not stayed, then certain pre-trial activities such as scheduling
21 conferences and Rule 26 disclosures may need to be re-done. Thus, efficiencies of
22 consolidation are best achieved when consolidation occurs early.

23 Third, United contends that this motion is premature because: (1) the government
24 has not yet filed its Complaints-in-Intervention in *Swoben* and *Poehling*; (2) *Poehling*
25 has until May 16, 2017 to file an amended complaint and, thus, it is uncertain whether he
26 will pursue his claims against any of the other non-United defendants; (3) United has not
27 yet had the opportunity to move to dismiss the *Poehling* action on FTF grounds; and, (4)
28 if it is unsuccessful in dismissing *Poehling* (which it likely will be), United has not yet

1 had the opportunity to move to transfer the action to Minneapolis. *See* Declaration of
2 Daniel Meron on Behalf of UnitedHealth Regarding March 14, 2017 Meet-And-Confer,
3 ¶¶ 3, 9, 10, & 11 (Docket No. 259). Each of these reasons is meritless because they fail
4 to show prejudice to United. *See Avetisyan v. Equifax Information Services LLC*, 2015
5 WL 12669875 at *2. Indeed, far from prejudicing United, these factors, taken together,
6 weigh in favor of consolidation because having such issues unfold and resolved in the
7 context of a consolidated proceeding would be much more efficient and lead to
8 consistent judicial results than having them determined independently in one proceeding
9 with uncertain consequences in another related proceeding.

10 In particular, as to (1), although the government has not yet filed its Complaints-
11 in-Intervention in the *qui tam* actions, the government has filed its Notices of
12 Intervention specifying the claims and allegations as to which it is intervening in both
13 actions. Months before filing its Notices of Intervention, the government provided
14 United with detailed information and evidence regarding the claims and issues and the
15 government's position relating to United's Chart Review, RACCR, and the Claims
16 Verification Programs. Accordingly, United is well aware of the claims against it and
17 that the claims in *Swoben* and *Poehling* present common questions of law and fact
18 concerning United's national Chart Review Program and involvement in, knowledge of,
19 and responsibility for the chart reviews conducted by providers, including HCP, in
20 California. Thus, there is no need to delay consideration of the consolidation issue
21 merely because the government has not yet filed its Complaints-in-Intervention.

22 As to (2), consolidation of the two actions against United will not prejudice
23 defendants remaining in the *Poehling* action after Poehling files his amended complaint
24 on May 16, 2017. The Court can coordinate the actions against United and any
25 remaining defendants as necessary for purposes of coordinating the same or similar
26 discovery (*e.g.*, the government's production of documents) and other overlapping pre-
27 trial activities (as well as postpone a decision about joining other defendants with United
28

1 for hearings or trial). This should benefit, not prejudice, the other defendants, as it will
2 avoid unnecessary costs and delays.

3 As to (3), as explained above, one of the reasons the actions should be
4 consolidated now is so that one judge may decide the FTF issues. That is, one judge
5 should decide whether any claims asserted in Poehling's 2011 First Amended Complaint
6 are barred by Swoben's 2010 Second Amended Complaint *and* whether any claims
7 asserted in Swoben's 2017 Fourth Amended Complaint are barred by Poehling's 2011
8 First Amended Complaint.¹³ If two judges makes these rulings, there is the possibility of
9 inconsistent judicial decisions. Furthermore, even in the unlikely event that United's
10 motion to dismiss *Poehling* is successful, the claims against United in *Poehling* could be
11 reasserted by the government either directly in the *Swoben* action *or* the United States
12 could file a separate action against United and seek to consolidate its own separate action
13 with *Swoben*.¹⁴ Postponing consolidation now is postponing the inevitable.

14 As to (4), assuming for the sake of argument that United succeeds in moving the
15 *Poehling* action to Minneapolis, the result would be multi-district litigation (MDL) so
16 that discovery, motion practices, and other activities could be coordinated and not
17 duplicated in the two *qui tam* actions. Accordingly, some form of *de facto* consolidation
18 would inevitably result. However, because venue is proper and convenient in this
19 District, the better course would be for the cases against United to be consolidated in this
20 District rather than consuming further judicial resources required for an MDL.

21 **B. The Consolidated *Swoben* and *Poehling* Actions Should Not Be Merged**

22 The United States is not seeking to join any of the claims in *Swoben* and *Poehling*
23 or to join the Relators in one action. Rather, the Court can consolidate the two actions
24 without merging them into one. *See, e.g., Roy v. County of Los Angeles*, 2015 WL
25 [12743601](#), at n. 6 (C.D. Cal. July 28, 2015) ("it is well-established that consolidation

26
27 ¹³ In the government's view, Swoben's Fourth Amended Complaint alleges no
28 facts relating to United's national Chart Review Program. But, even if it did, it would
likely be barred by Poehling's earlier-filed FAC based on the FTF rule.

¹⁴ The FTF rule does not bar the United States from filing a separate action.

1 does not necessarily ‘merge the suits into a single action, or cause the parties to one
2 action to be parties to another’”) (quoting 9A [Fed. Prac. & Proc. Civ. § 2382](#) (3d ed.))
3 (other citations omitted). This Court should consolidate, but there is no need to merge,
4 the *Swoben* and *Poehling* actions. Accordingly, the United States intends to file separate
5 Complaints-in-Intervention in *Swoben* and *Poehling*. The United States, however,
6 reserves its right to amend its Complaint-in Intervention in *Swoben*, or to file its own
7 separate action, in the unlikely event that Poehling’s claims related to United’s national
8 Chart Review Program are dismissed based on the FTF bar.

9 **IV.**

10 **CONCLUSION**

11 For the foregoing reasons, the United States respectfully requests that the Court
12 grant its motion for consolidation.

1 Dated: March 27, 2017

Respectfully submitted,

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EXHIBIT D

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 Company, PacifiCare Health Systems
 (collectively, "UnitedHealth")

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA and
 STATE OF CALIFORNIA, *ex rel* JAMES
 M. SWOBEN,

Plaintiffs,

v.

SCAN HEALTH PLAN, a California
 corporation, fka SENIOR CARE ACTION
 NETWORK; SENIOR CARE ACTION
 NETWORK, a business entity, form
 unknown; SCAN GROUP, a California
 corporation; SECURE HORIZONS, a
 business entity, form unknown; UNITED
 HEALTHCARE INSURANCE
 COMPANY, a Connecticut corporation;
 UNITED HEALTHCARE SERVICES,
 INC., a Minnesota corporation; UHIC, a
 business entity, form unknown;
 UNITEDHEALTH GROUP, a business
 entity, form unknown;

CASE NO. CV09-5013 JFW
 (JEMX)

DECLARATION OF DANIEL
 MERON ON BEHALF OF
 UNITEDHEALTH REGARDING
 MARCH 14, 2017 MEET-AND-
 CONFER

1 UNITEDHEALTHCARE, a business
2 entity, form unknown; UNITEDHEALTH,
3 a business entity, form unknown;
4 PACIFICARE HEALTH PLAN
5 ADMINISTRATORS, INC., a corporation;
6 PACIFICARE OF CALIFORNIA, a
7 corporation; PACIFICARE LIFE AND
8 HEALTH INSURANCE COMPANY, a
9 corporation; and PACIFICARE HEALTH
10 SYSTEMS, a corporation; WELLPOINT, a
11 business entity, form unknown; AETNA, a
12 business entity, form unknown; HEALTH
13 NET, a business entity, form unknown;
14 HEALTHCARE PARTNERS, a business
15 entity, form unknown; HEALTHCARE
16 PARTNERS MEDICAL GROUP, a
17 business entity, form unknown; and
18 HEALTHCARE PARTNERS
19 INDEPENDENT PHYSICIAN
20 ASSOCIATION, a business entity, form
21 unknown,

22 Defendants.

Declaration of Daniel Meron

I, Daniel Meron, declare and state as follows:

1. I am a partner at Latham & Watkins LLP. I represent UnitedHealth¹ in the above-captioned manner. Pursuant to this Court's March 7, 2017 Order (ECF No. 246), UnitedHealth submits this declaration setting forth the results of the parties' meeting on March 14, 2017, in which the parties conferred both about the government's proposed motion to partially intervene and its proposed motion to consolidate this matter with *United States ex rel. Poehling v. United Health Group*, No. 2:16-cv-08697-MWF-SS (C.D. Cal.).

2. **Motion to Partially Intervene:** UnitedHealth indicated at the meeting that it does not oppose the government's proposed motion to partially intervene, and would be willing to stipulate to partial intervention if the Court determines a stipulation (rather than an unopposed motion) is appropriate. No other participants at the meeting indicated that they would oppose the government's proposed motion.

3. **Motion to Consolidate with Poehling:** UnitedHealth indicated that a motion to consolidate is premature at this time as the parties and the Court need additional information before determining whether consolidation is appropriate. UnitedHealth respectfully submits that the proper time to determine whether consolidation is appropriate is after the government's proposed complaints in intervention in both cases have been filed, along with whatever amended complaint is filed by the relator in *Poehling*. At that point, the parties and the Court(s) will have all the operative complaints, the operative parties, and the operative claims before them, which will allow all parties and the Court(s) to determine the most

¹ This Declaration utilizes the name "UnitedHealth" to refer to the following Defendants: UnitedHealthcare Insurance Company, UnitedHealthCare Services Inc., UHIC, UnitedHealth Group, UnitedHealthCare, UnitedHealth, Pacificare Health Plan Administrators, UHC of California (f.k.a. PacifiCare of California), PacifiCare Life and Health Insurance Company, and PacifiCare Health Systems. Secure Horizons is a brand name used by UnitedHealth, not a legal entity.

1 efficient way to proceed, including whether consolidation furthers the interests of
2 efficiency and justice. Moreover, until the Court(s) have the operative complaints
3 and parties before them, it is not possible to determine whether either or both cases
4 (*Swoben* and *Poehling*) should be heard in the Central District of California.
5 UnitedHealth has repeatedly informed the government, both before and at the
6 March 14 meet-and-confer, that it might be willing to stipulate at the appropriate
7 time that consolidation is appropriate, but that no party, including the Court, can
8 make an informed decision now given the absence of the information noted above.
9 UnitedHealth has repeatedly suggested, to no avail, that the government's haste in
10 filing a motion to consolidate is unnecessary and serves only to burden the Court
11 with a motion that may, in fact, be unnecessary and that cannot be decided unless
12 and until the Court is presented with all of the operative complaints and putative
13 defendants, including those named by the government and those named by the
14 Relator in *Poehling* in as-yet-unfiled complaints.

15 4. The ill-timed nature of the proposed motion to consolidate was further
16 evidenced during the meeting when the government took the position that the
17 complaints filed by the respective relators in the two cases—*Swoben* and
18 *Poehling*—are “very different,” with *Swoben*'s second amended complaint
19 properly applying only to claims from the 2005-2006 time period related to
20 conduct in California specifically, and *Poehling*'s complaint applying to
21 nationwide claims during a later period. In that regard, the motion to consolidate
22 would appear to be ill-conceived, in the same way that the government's earlier
23 attempt to have the cases deemed “related” was deemed ill-conceived by this Court
24 when this Court rejected the government's attempt to designate *Poehling* a related
25 case to *Swoben*. See Order Re Transfer Pursuant to General Order 16-05, ECF No.
26 59, *United States ex rel. Poehling v. United Health Group*, No. 2:16-cv-08697-
27 MWF-SS (C.D. Cal. Dec. 15, 2016); see also C.D. Cal. General Order 16-05
28 II.I.1.b (providing that related case status is generally appropriate where cases

1 “arise from the same or a closely related transaction happening, or event,” “call for
2 determination of the same or substantially related or similar questions of law and
3 fact,” or would “entail substantial duplication of labor if heard by different
4 judges”). It is hard to see why “very different,” unrelated cases could warrant
5 consolidation under Federal Rule of Civil Procedure 42(a).

6 5. The government has taken the view that consolidation is appropriate
7 now because it is intending to file identical, or substantially identical, complaints
8 in each case. Of course, consolidation based on common issues in the
9 government’s complaints would be appropriate, if at all, only *after* the government
10 files its complaints. UnitedHealth cannot, and this Court should not, simply accept
11 the government’s assurance that allegations in future complaints—which are not
12 scheduled to be filed until May—will automatically convert these “very different”
13 cases into closely related ones that should be consolidated. But even setting aside
14 that threshold problem, the government’s intended motion to consolidate is
15 premature and unnecessary at this time for three additional reasons.

16 6. *First*, a motion to consolidate presupposes that there will be two
17 separate cases, both properly venued in the Central District of California, for the
18 Court to consolidate. It remains unclear, however, whether the Central District of
19 California is even the proper venue for litigating the allegations in the *Poehling*
20 case. As noted, the government agrees with UnitedHealth that Poehling’s existing
21 complaint raises allegations concerning UnitedHealth’s nationwide chart review
22 and other programs, going far beyond the claims the government believes to be
23 properly implicated by *Swoben*’s California-limited complaint. The broader claims
24 contemplated by the government based on Poehling’s allegations have little or no
25 nexus to the Central District of California, and there is no legitimate reason for
26 litigating those claims here.

27 7. That the claims would be considered in this District at all is purely a
28 result of the government’s strategic gamesmanship. In the government’s view,

1 apparently, these nationwide claims were properly raised only in Poehling's
2 complaint, which was filed in the Western District of New York in 2011. The
3 government pursued those claims through an investigation there until November
4 2016. Despite being aware since 2012 of the pendency of both the *Swoben* case in
5 California and the *Poehling* case in New York, and despite being actively involved
6 as an amicus in *Swoben* at the Ninth Circuit since February 2016, the government
7 strategically waited until November 2016—*after* the Ninth Circuit issued its
8 decision on the pleading-stage dismissal of the *Swoben* case, *see United States ex*
9 *rel. Swoben v. United Healthcare Ins. Co.*, 832 F.3d 1084, 1094 -95 (9th Cir.
10 2016)—to move to transfer the *Poehling* case into the Ninth Circuit's jurisdiction,
11 thereby creating the “problem” it is now trying to “solve” by consolidation. The
12 government's blatant attempt to forum-shop the *Poehling* case is not a legitimate
13 reason to consolidate the *Poehling* and *Swoben* cases.

14 8. Making matters worse, the government made a strategic decision to
15 file its motion to transfer the *Poehling* case from the Western District of New York
16 on an *ex parte* basis before the *Poehling* case had been unsealed or the government
17 had even intervened. Nothing would have prevented the government from moving,
18 before intervention, to partially unseal the *Poehling* case and provide UnitedHealth
19 with an opportunity to oppose the motion. (Indeed, despite a request by
20 UnitedHealth over a month ago, the government still has yet to provide
21 UnitedHealth with a copy of the still-sealed transfer motion it filed in the Western
22 District of New York.) But instead, as a result of the government's strategic ploy
23 to prevent UnitedHealth from being heard, UnitedHealth had no opportunity to
24 object to the transfer on the grounds that *Poehling* lacks any meaningful
25 connection to the Central District of California and would be more conveniently
26 and appropriately litigated—for *all* parties—elsewhere.

27 9. Based on *Poehling*'s nationwide focus, UnitedHealth anticipates filing
28 a motion to transfer the *Poehling* case. That motion would be filed before Judge

1 Fitzgerald, to whom the *Poehling* case has been assigned. The appropriate time for
2 filing such a motion, of course, will be after the government files its complaint in
3 intervention in May, at which time it will be possible to discern, among other
4 things, which witnesses and evidence will be necessary in any proceeding on the
5 government's new, nationwide claims. As UnitedHealth explained during the
6 meet-and-confer conference, if the *Poehling* case is transferred elsewhere, the
7 question of consolidation in the Central District would be rendered moot.

8 10. *Second*, a motion for consolidation is premature because it is unclear
9 whether the *Poehling* case should be permitted to proceed at all given the False
10 Claims Act's so-called "first-to-file bar," which precludes any "person other than
11 the Government" from bringing a "related action based on the facts underlying" an
12 existing *qui tam* suit. 31 U.S.C. § 3730(b)(5). The first-to-file bar is jurisdictional.
13 Judge Fitzgerald has ordered Poehling to file any amended complaint by May 16th,
14 and the time to file a motion to dismiss Poehling's complaint on first-to-file bar
15 grounds would be after an amended complaint is filed. If Judge Fitzgerald
16 concludes that Poehling's complaint is barred by Swoben's earlier-filed complaint,
17 then there would not even be two cases to consolidate—the government would just
18 bring all of its claims in the *Swoben* case. In that eventuality, as UnitedHealth also
19 explained during the meet-and-confer, the government's motion to consolidate
20 would be moot.

21 11. *Third*, and relatedly, the continued uncertainty about the content of the
22 amended complaint Poehling may file in May makes it difficult for the parties and
23 the Court to evaluate consolidation at this time. At this point in the case, Swoben
24 and the United States have both limited the defendants against whom they are
25 pursuing claims to the UnitedHealth family of companies (in the case of both
26 Swoben and the United States) and the HealthCare Partners entities (in the case of
27 Swoben). During the meeting, however, counsel for Poehling was unwilling to
28 divulge whether Poehling intends to similarly limit his claims to those the

1 government intends to press, or instead plans to pursue claims against the
2 numerous other defendants named in his current complaint (as well as the many
3 additional theories his current complaint asserts against UnitedHealth that are
4 unrelated to the retrospective review theories the government has indicated it
5 intends to pursue). If Poehling's complaint *does* continue to press claims against
6 defendants who are not named in Swoben's complaint, or to press theories and
7 claims against UnitedHealth that are unrelated to the government's claims, that
8 could substantially complicate potential consolidation. The Court and the parties
9 should have answers to those questions before any decision is made on
10 consolidation. (Moreover, if Poehling does intend to continue to press claims
11 against additional defendants, those defendants should have been included in the
12 meet-and-confer about consolidation of the cases. Poehling and the government,
13 however, have apparently taken no steps to involve those parties in the decision at
14 this time.)

15 12. UnitedHealth has made clear to the government that, depending on the
16 content of as yet unfiled complaints and the resolution of threshold motions,
17 consolidation might in the future become appropriate. UnitedHealth likewise
18 agrees with the government on the importance of avoiding duplicative discovery,
19 and has committed to working cooperatively and constructively with the
20 government to avoid duplication of efforts. Despite these representations, the
21 government is insisting on going forward and burdening the Court now with a
22 premature and potentially unnecessary motion, and burdening defendants with the
23 need to brief a motion that might well become moot.

24 13. Notably, during the meet and confer, the government did not articulate
25 any rational explanation for its haste. UnitedHealth believes that the appropriate
26 course is for the cases to remain separate until after the filing of the government's
27 and Poehling's complaints in May and the filing of threshold motions, at which
28 time additional information will be available, and the Court and the parties can

1 evaluate the most efficient path forward based on a fuller understanding of the
2 cases. Until that time, UnitedHealth remains willing to work with the government
3 and the relators to avoid unnecessary duplication of labor for the parties *or* the
4 Court, and regrets that UnitedHealth and the government were unable to reach
5 agreement on this issue.

6 I declare under penalty of perjury that the foregoing is true and correct.

7 Executed on March 17, 2017, in Washington, D.C.

8
9 By/s/ Daniel Meron

10 Daniel Meron
11 Attorney for Defendants
12 UNITED HEALTHCARE
13 INSURANCE COMPANY, UNITED
14 HEALTHCARE SERVICES, INC.,
15 UHIC, UNITEDHEALTH GROUP,
16 UNITEDHEALTHCARE,
17 UNITEDHEALTH, PACIFICARE
18 HEALTH PLAN
19 ADMINISTRATORS, INC.,
20 PACIFICARE OF CALIFORNIA,
21 PACIFICARE LIFE AND HEALTH
22 INSURANCE COMPANY,
23 PACIFICARE HEALTH SYSTEMS
24
25
26
27
28

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EXHIBIT E

No. 13-56746

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

UNITED STATES OF AMERICA,

Plaintiff,

and

JAMES M. SWOBEN, Qui Tam Relator,

Plaintiff-Appellant,

v.

UNITED HEALTHCARE INSURANCE COMPANY,
a Connecticut corporation, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Central District of California

**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE
IN SUPPORT OF APPELLANT**

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INTRODUCTION AND SUMMARY

A central, distinguishing feature of Medicare Advantage (MA) is the provision of Medicare benefits by private health-insurance organizations in exchange for capitated payments from the government (*i.e.*, fixed monthly payments for each enrollee). The Centers for Medicare & Medicaid Services (CMS) adjusts these payments for various “risk” factors that affect expected healthcare expenditures, to ensure that MA organizations are paid more for those enrollees expected to incur higher healthcare costs and less for healthier enrollees expected to incur lower costs. To make these adjustments, CMS collects “risk adjustment” data, including medical diagnosis codes, from MA organizations.

This payment model creates powerful incentives for MA organizations to exaggerate the expected healthcare costs for their enrollees by “over-reporting” diagnosis codes. To combat these incentives and ensure that the government is not overpaying MA plans, CMS requires that submitted diagnoses be supported by patient medical records. And given the critical importance of accurate data, a fundamental prerequisite to payment under the program is that plans

expressly certify “based on best knowledge, information, and belief” that the information they have provided is “accurate, complete, and truthful,” 42 C.F.R. § 422.504(l)(2).

In this declined *qui tam* suit under the False Claims Act, relator alleges that defendants conducted retrospective reviews of patient records designed solely to find information that would lead to increased government payments (*i.e.*, to find additional diagnosis codes not previously submitted to CMS but purportedly supported by medical records), and systematically ignored information that would lead to decreased payments (*i.e.*, submitted diagnosis codes not supported by medical records). Relator alleges that defendants thereby submitted “false or fraudulent” claims for payment under 31 U.S.C.

§ 3729(a)(1)(A), and also knowingly and improperly avoided or decreased an obligation to pay the government under 31 U.S.C.

§ 3729(a)(1)(G). This Court directed the parties to file supplemental briefs addressing whether the conduct alleged by relator “would cause [an MA organization’s] certification to be false for purposes of [42 C.F.R.] § 422.504(l) and the False Claims Act.”

Because the False Claims Act is the government’s primary tool to combat fraud and recover losses due to fraud, proper resolution of this question is important to the United States. Nearly a third of all Medicare beneficiaries are enrolled in Medicare Advantage, and the United States has a strong interest in ensuring that MA organizations provide CMS with “accurate, complete, and truthful” information—and in ensuring that those organizations are held liable under the False Claims Act where they knowingly fail to do so.

To the extent defendants designed chart reviews solely to find and report information that would lead to increased governmental payments (*i.e.*, additional diagnosis codes) and ignored available information that would lead to decreased payments (*i.e.*, unsupported diagnosis codes), defendants’ certifications regarding the accuracy, completeness, and truthfulness of the data submitted to CMS were false in at least two ways.

First, CMS has made clear that MA organizations must exercise “due diligence” to ensure the accuracy of submitted data. The certification required under 42 C.F.R. § 422.504(*l*) is thus best understood to carry with it a representation that a plan has acted with

reasonable diligence and implemented measures to find errors. If a plan has not exercised such diligence—especially where it has implemented record-review procedures specifically designed *not* to reveal unsupported diagnosis codes—the plan’s certification under § 422.504(*l*) is “false or fraudulent” under 31 U.S.C. § 3729(a)(1)(A) & (B).

Second, even apart from the regulatory duty to exercise “due diligence,” if an MA organization knows that it has submitted unsupported diagnoses, *see* 31 U.S.C. § 3729(b)(1), its certification that the information it has submitted is “accurate, complete, and truthful” is false or fraudulent under the False Claims Act. A plan cannot escape False Claims Act liability by deliberately ignoring available information suggesting that some of the diagnosis codes it has submitted to CMS may not be supported by medical records.

Finally, regardless of whether an MA organization’s certification under § 422.504(*l*) is false, where a plan deliberately designs its chart reviews in a way that prevents the discovery of unsupported diagnosis codes or ignores information suggesting that it may have submitted unsupported diagnoses, it has “knowingly and improperly avoid[ed]” an “obligation” to pay money to the government and is independently liable

under 31 U.S.C. § 3729(a)(1)(G), the “reverse false claims” provision of the False Claims Act. Just as MA organizations cannot shirk their obligation to exercise reasonable diligence to ensure that the information they have submitted is “accurate, complete, and truthful,” they cannot purposely avoid taking steps to determine whether they have received payments to which they are not entitled. That is precisely the sort of “ostrich-like” behavior that the False Claims Act was intended to reach. *See United States v. Bourseau*, 531 F.3d 1159, 1168 (9th Cir. 2008).

ARGUMENT

I. The Conduct Alleged Is Sufficient to State a Claim That Defendants Falsely Certified the Accuracy of Data Submitted to Obtain Payments from the Government

A. Defendants’ Certifications Are False Because Defendants Failed to Exercise Due Diligence in Ensuring the Accuracy of Submitted Data

1. Unlike the traditional Medicare program, which uses a fee-for-service payment model, Medicare Advantage uses a capitated payment system under which participating plans receive a fixed monthly payment for each enrollee. CMS adjusts these capitated payments to account for various “risk” factors that affect expected healthcare

expenditures, including the relative health of a plan's enrollees compared with that of the average Medicare beneficiary. *See* 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. § 422.308(c)(1). To make this adjustment, CMS collects data from MA organizations, in particular, diagnosis codes the plans receive from healthcare providers after medical encounters with enrollees. Using past diagnosis codes, CMS calculates a risk score that is used prospectively to calculate monthly payments. *See* 42 C.F.R. § 422.310(g). In general, the more severe the diagnosis, the higher the risk score and thus the greater the risk-adjusted payment made to an MA plan.

Because risk-adjustment data provide the foundation for payment under Medicare Advantage, participating plans must expressly certify that the data they submit, including diagnosis codes, are “accurate, complete, and truthful.” 42 C.F.R. § 422.504(l)(2). Although CMS has not prescribed precise steps MA organizations must take to verify data, the agency has long made clear that this certification requirement imposes “an obligation to undertake ‘due diligence’ to ensure the accuracy, completeness, and truthfulness of encounter data submitted.” 65 Fed. Reg. 40,170, 40,268 (June 29, 2000). CMS has explained that

the certification is not merely a representation that MA organizations “have not altered the data, and that they have transmitted it to [CMS] as they received it from the provider.” *Id.* Rather, MA organizations must make affirmative “good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.” *Id.*¹

In addition, MA organizations are required to “[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’[s] program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse.” 42 C.F.R. § 422.503(b)(4)(vi).

¹ CMS again recognized this affirmative duty to ensure the accuracy of submitted data in 2014, when it promulgated a regulation to implement the Affordable Care Act’s overpayment provision, 42 U.S.C. § 1320a-7k(d). The agency explained that it has “always expected” MA organizations to implement “appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment.” 79 Fed. Reg. 29,844, 29,923 (May 23, 2014). CMS rejected the suggestion that MA organizations “are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists.” *Id.* “[A]t a minimum,” the agency explained, the “reasonable diligence” referred to in the overpayment regulation includes “proactive compliance activities . . . to monitor for the receipt of overpayments.” *Id.* The agency made clear that this “reasonable diligence” standard imposed no new requirement but instead stemmed from the longstanding requirement to certify risk-adjustment data submitted to CMS. *Id.*

Compliance with this threshold requirement for participation in Medicare Advantage is both a condition of participation and a condition of payment for purposes of liability under the False Claims Act. *See United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1176 (9th Cir. 2006) (explaining that threshold conditions of participation can also be conditions of payment).

In light of the comprehensive duties MA organizations have to exercise reasonable diligence and implement effective measures to ensure the accuracy of risk-adjustment data submitted to CMS, the certification required by 42 C.F.R. § 422.504(*l*) is best understood to include representations not only that the data are accurate, but also that a plan has made reasonable efforts to uncover and weed out unsupported diagnosis codes. Those representations are false where, as alleged here, defendants not only failed to take affirmative steps to find unsupported diagnosis codes, but deliberately designed their retrospective chart reviews to *prevent* the discovery of unsupported codes and thereby avoid any negative payment adjustments.

The Supreme Court's recent decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. 1318

(2015), supports the conclusion that a plan's failure to exercise due diligence to ensure the accuracy of submitted data renders its express certification that the data are "accurate, complete, and truthful" false. In *Omnicare* the Court held that investors could proceed on a securities-fraud claim based on the omission of material facts concerning a statement of opinion. Invoking common-law principles governing the tort of misrepresentation, the Court concluded that it was well-established that even "the expression of an opinion may carry with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." *Id.* at 1330 (quoting *Prosser and Keeton on the Law of Torts* § 109, at 760 (5th ed. 1984)).

Here, the underlying regulatory scheme expressly requires that an MA organization make reasonable efforts to ensure the accuracy of submitted data. Accordingly, a plan's certification that its data are "accurate, complete, and truthful" necessarily carries with it a representation that the plan has exercised the required due diligence, which must include reasonable efforts to uncover unsupported

diagnoses. If a plan fails to exercise such diligence, its express certification is false for purposes of the False Claims Act.

2. To support their contention that their express certifications under § 422.504(*l*) are not “false or fraudulent” under the False Claims Act, defendants argue (Supp’l Br. 4-8) that they have no obligation to take *any* affirmative steps to ensure the accuracy of the data received from providers in order to make the required certification. Because the certification is based on “best knowledge, information, and belief,” defendants contend, MA organizations are certifying only that they are “faithfully submitting” diagnosis codes received from providers, Defs.’ Supp’l Br. 1, and that they “did not *know* of any unsupported diagnosis codes,” *id.* at 4.

As discussed above, this argument is flatly inconsistent with the “due diligence” requirement CMS adopted when it promulgated the certification requirement in 2000. *See* 65 Fed. Reg. at 40,268 (explaining that MA organizations “have an obligation to undertake ‘due diligence’ to ensure the accuracy, completeness, and truthfulness of encounter data”). Moreover, this argument is inconsistent with defendants’ own practices, which rely on retrospective chart reviews to

supplement their risk-adjustment data with diagnoses that were not reported by providers.

CMS's decision in 2014 not to finalize a proposed requirement that any chart reviews conducted by an MA organization be designed to find not just additional diagnoses to submit to CMS but also unsupported diagnoses that had previously been submitted to CMS—a “look both ways” requirement—does not relieve defendants of the broad obligation to exercise due diligence in ensuring the accuracy of submitted diagnoses. Contrary to defendants' suggestion (Supp'l Br. 11), no negative inference can be drawn from the agency's decision not to specifically mandate a particular type of inquiry to ensure the accuracy of risk-adjustment data. Indeed, as explained above, *supra* note 1, in that same rulemaking, CMS made clear that the certification under § 422.504(*l*) requires plans to exercise reasonable diligence to ensure the accuracy of submitted data. *See* 79 Fed. Reg. at 29,923.

Moreover, the mere inclusion of “best knowledge and belief” language in a certification does not relieve the speaker of all responsibility for the accuracy of the certified statement. If it did, express certifications of this sort would have no meaning or value to the

government as a verification of compliance with essential program requirements.

Defendant's argument that a "best knowledge" certification "does not warrant that plans have undertaken affirmative steps to find unsupported codes," Defs.' Supp'l Br. 6, finds no support in *United States v. Ekelman & Associates*, 532 F.2d 545 (6th Cir. 1976). In that case, the Sixth Circuit held that a representation is not "reckless" unless it is an "unqualified assertion of fact based on the personal knowledge of the party making the assertion when that party has no basis in fact for making it." *Id.* at 549. Stressing that the "certification of truth 'to the best of my knowledge and belief' is a qualified assertion of facts represented," *id.*, the court held that the defendant lending institution lacked "actual knowledge" that the information submitted to secure loan guarantees from the government was false, and therefore was not liable under the common law or the False Claims Act, *id.* at 548-50.

Ekelman was decided before Congress expanded the definition of "knowledge" under the False Claims Act (in 1986) to reach those who "failed to make simple inquiries which would alert [them] that false

claims are being submitted.” S. Rep. No. 99-345, at 21 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5286. And CMS has explained that the “best knowledge, information, and belief” standard it adopted in § 422.504(l) was meant to be “consistent with” the constructive-knowledge standard of the False Claims Act. 65 Fed. Reg. at 40,268.

Moreover, *Ekelman* involved a regulatory scheme in which the defendant was not expected to make independent efforts to verify the accuracy of information submitted. In contrast, MA plans must implement effective compliance programs and exercise reasonable diligence to ensure the accuracy of data submitted. Thus, whatever force *Ekelman* might have in other contexts, the “best knowledge” certification under § 422.504(l) is best understood to convey a meaningful representation that submitted data are accurate.² That statement is false if a plan has failed to exercise reasonable diligence to

² In any event, even if this Court were to adopt *Ekelman*’s narrow view of a “best knowledge” certification, as we discuss in subsection B, defendants’ certifications would still be false because defendants deliberately ignored information suggesting that at least some diagnosis codes were not supported by medical records. *See Ekelman*, 532 F.2d at 550 (limiting analysis to circumstances in which defendant “had no knowledge” of misrepresentations).

ensure the accuracy of submitted data, especially if it has implemented procedures designed *not* to reveal unsupported diagnoses.

Defendants' reliance on relator's apparent concession that plans that do not conduct chart reviews "have no duty to verify the accuracy of provider diagnosis codes," Defs.' Supp'l Br. 5, is similarly unavailing. Whatever relator may have conceded, CMS has long made clear that it is not enough for plans simply to pass along data received from providers. Instead, plans must exercise "due diligence" to ensure the accuracy of submitted data and must implement effective compliance programs to prevent, detect, and correct errors. At a minimum, plans cannot implement procedures specifically designed *not* to reveal unsupported diagnoses. Otherwise, the express certifications regarding the accuracy, completeness, and truthfulness of submitted data would be worthless.

B. Defendants' Certifications Are Also False Because Defendants Ignored Available Information Suggesting That At Least Some Diagnoses Were Unsupported

Even apart from defendants' false representations concerning their diligence in ensuring the accuracy of submitted data, defendants' certifications that the risk-adjustment data submitted to CMS are

“accurate, complete, and truthful” are false on the independent ground that defendants willfully ignored available information suggesting that at least some of the diagnosis codes submitted were *not* properly supported by patients’ medical records. That is just the sort of “ostrich-like” behavior that Congress sought to reach in adding the “deliberate ignorance” and “reckless disregard” prongs to the knowledge standard of the False Claims Act in 1986. *See* 31 U.S.C. § 3729(b)(1); S. Rep. No. 99-345, at 7, 20-21; *see also Bourseau*, 531 F.3d at 1168.

Relator alleges that defendants used coding consultants to retrospectively review patient medical records and compile a list of all supported diagnosis codes, with the goal of finding additional diagnoses to submit to CMS. Defendants, however, did not check whether diagnosis codes previously submitted to CMS were included on the list of diagnoses found by the reviewers to be supported by the medical records.

To the extent an MA organization “knows” that a submitted diagnosis code is not, or may not be, supported by patient medical records, its certification under § 422.504(*l*) as to the accuracy, completeness, and truthfulness of submitted data is “false” under the

False Claims Act. If a code that had previously been submitted to CMS did not appear on the reviewers' list, then defendants had sufficient information to determine whether the previously submitted code was unsupported—or at least were on notice that further investigation was necessary. That is true even though the reviewers themselves were not provided a list of previously submitted diagnosis codes and even though defendants failed to “look both ways”—that is, to compare the two lists, not only to check whether diagnoses found by the reviewers had been submitted to CMS, but also to check whether submitted diagnoses appeared on the reviewers' list of diagnoses supported by the medical records. That defendants chose not to connect the dots—using information readily available to them—simply confirms that they acted in a deliberately ignorant or reckless manner in falsely certifying the accuracy, completeness, and truthfulness of submitted data. *See* 31 U.S.C. § 3729(b)(1).

In arguing that MA organizations have no legal obligation to conduct chart reviews that “look both ways,” defendants contend (Supp'l Br. 10) that a submitted diagnosis may be supported by medical records even if it is not found in a particular chart review, because it may be

supported by other medical records not included in that review.³ This observation, however, does not advance defendants’ argument. At a minimum, the failure of a reviewer to include a previously submitted diagnosis code on its list of supported diagnoses should put the plan on notice that further investigation into the submitted diagnosis is necessary. Even if it turns out that the diagnosis is supported by other medical records, the failure of plan to investigate to make that determination—after it has been put on notice that the diagnosis may not be supported—makes its broad certification regarding the accuracy, completeness, and truthfulness of submitted data false.

³ Defendants argue that plans could ensure the accuracy of reported data in “myriad ways,” but then note only two: (1) plans could attempt to determine whether specific providers “have aberrational patterns of coding,” and (2) plans could “separately audit all diagnosis codes submitted during a given year for a sample of their beneficiaries.” Defs.’ Supp’l Br. 9. Notably, defendants do not assert that they have actually undertaken any of these alternatives, and this Court need not decide whether such measures would constitute reasonable diligence.

II. The Conduct Alleged Is Also Sufficient to State a Claim That Defendants Knowingly and Improperly Avoided an Obligation to Repay Money to the Government

In addition to potentially violating the False Claims Act's prohibitions on false claims, 31 U.S.C. § 3729 (a)(1)(A) & (B), the conduct relator alleges may also give rise to liability under the Act's "reverse false claims" provision, 31 U.S.C. § 3729(a)(1)(G). When an MA organization designs its retrospective chart reviews solely to find information that would lead to increased payments from CMS (*i.e.*, additional diagnosis codes) and ignores available information that would lead to negative payment adjustments, its conduct falls squarely within the reverse-false-claims provision, which "is designed to cover [g]overnment money or property that is knowingly retained by a person even though they have no right to it." S. Rep. No. 111-10, at 13-14 (2009), *reprinted in* 2009 U.S.C.C.A.N. 430, 441.

Before 2009, a person was liable for a "reverse" false claim if he "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7) (2008). The 2009 amendments to the False Claims Act eliminated the

need for a false statement and imposed liability on anyone who “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G). As amended the Act also defines an “obligation” to include “the retention of any overpayment.” *Id.* § 3729(b)(3).

The pattern of conduct alleged in this case, which extends from 2005 to 2012, falls comfortably within both the former and current versions of the reverse-false-claims provision. To the extent an MA organization has submitted unsupported diagnoses, the higher risk-adjusted payment associated with those diagnoses exceeds the amount the plan is entitled to. When a plan deliberately ignores information suggesting that it may have submitted unsupported diagnoses, it has “knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Government,” 31 U.S.C. § 3729(a)(1)(G).⁴

⁴ For conduct occurring before the 2009 amendments, defendants’ false certifications would provide the “false record or statement” needed to establish liability under § 3729(a)(7).

The overpayment provision that the Affordable Care Act added to the Social Security Act in 2010, 42 U.S.C. § 1320a-7k(d), confirms that such conduct gives rise to reverse-false-claims liability. Defining an “overpayment” as “any funds that a person receives or retains under [the Medicare and Medicaid statutes] to which the person, after applicable reconciliation, is not entitled,” *id.* § 1320a-7k(d)(4), this provision requires that an overpayment be returned within 60 days after it is “identified,” *id.* § 1320a-7k(d)(2). It further provides that the continued retention of an overpayment beyond this 60-day deadline is an “obligation” for purposes of the False Claims Act. *Id.* § 1320a-7k(d)(3). CMS’s 2014 regulation implementing this provision states that an MA organization “has identified an overpayment when [the entity] has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an overpayment.” 42 C.F.R. § 422.326(c).⁵

⁵ The implementing regulation also defines “applicable reconciliation” to be the final deadline for submitting risk-adjustment data. *See* 42 C.F.R. § 422.326(a). A risk-adjustment payment to which an MA organization is not entitled thus does not become an “overpayment” until the final deadline for submitting diagnosis codes.

An MA organization violates the Affordable Care Act's mandate to return overpayments, and thus the False Claims Act, when it fails to exercise reasonable diligence to uncover unsupported diagnoses or ignores information suggesting that it may have submitted unsupported diagnoses.⁶

In similar circumstances, courts have held that healthcare providers may not avoid reverse-false-claims liability simply by ignoring audits or terminating investigations that would have revealed overpayments received from the government. In *Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015), for example, the court denied a motion to dismiss claims brought under § 3729(a)(1)(G) where the defendants were on notice that certain claims submitted to the government might contain erroneous billing codes. Likewise, in *United States ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.*, No. 11-cv-00892, 2013 WL 1307013 (E.D. Wis. Mar. 28, 2013), the court held that the relator stated a claim under § 3729(a)(1)(G) where

⁶ Although some of the conduct alleged here predates the enactment of the Affordable Care Act and all of the conduct predates the promulgation of CMS's implementing regulation, these statutory and regulatory overpayment provisions are instructive as to what Congress intended in enacting the reverse-false-claims provision.

the defendant had found high rates of improper “upcoding” by physicians in audits but failed to follow up on non-audited claims.

The reasoning of those cases applies with equal force here. Defendants cannot escape False Claims Act liability by conducting the sort of “one-way reviews” alleged by relator and deliberately ignoring information suggesting that they submitted unsupported diagnoses and therefore received payments to which they were not entitled.

CONCLUSION

For the foregoing reasons, this Court should hold that the conduct alleged by relator is sufficient to state claims that defendants falsely certified the accuracy of data submitted to the government to obtain payment and knowingly and improperly avoided an obligation to repay money to the government.

Respectfully submitted,

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APRIL 2016

**CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)**

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font.

I further certify that this brief complies with the 4,200-word limit in this Court's order dated February 16, 2016, because it contains 4,114 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ Karen Schoen

Karen Schoen

CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2016, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Karen Schoen
Karen Schoen

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EXHIBIT F

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

JS-6

CIVIL MINUTES -- GENERAL

Case No. **CV 09-5013-JFW (JEMx)**

Date: July 30, 2013

Title: United States of America, et al. -v- Scan Health Plan, et al.

PRESENT:

HONORABLE JOHN F. WALTER, UNITED STATES DISTRICT JUDGE

**Shannon Reilly
Courtroom Deputy**

**None Present
Court Reporter**

ATTORNEYS PRESENT FOR PLAINTIFFS:

None

ATTORNEYS PRESENT FOR DEFENDANTS:

None

PROCEEDINGS (IN CHAMBERS):

**ORDER GRANTING MOTION OF DEFENDANTS
HEALTHCARE PARTNERS, LLC, HEALTHCARE
PARTNERS MEDICAL GROUP, INC., AND
HEALTHCARE PARTNERS INDEPENDENT PHYSICIAN
ASSOCIATION TO DISMISS THIRD AMENDED
COMPLAINT [filed 6/26/13; Docket No. 111];**

**ORDER GRANTING AETNA'S MOTION TO DISMISS
PLAINTIFF'S THIRD AMENDED COMPLAINT [filed
6/26/13; Docket No. 112];**

**ORDER GRANTING DEFENDANT WELLPOINT, INC.'S
MOTION TO DISMISS PLAINTIFF'S THIRD AMENDED
COMPLAINT [filed 6/26/13; Docket No. 113]; and**

**ORDER GRANTING DEFENDANTS UNITEDHEALTH
AND HEALTH NET'S MOTION TO DISMISS
RELATOR'S THIRD AMENDED COMPLAINT [filed
6/26/13; Docket No. 114]**

On June 26, 2013, Defendants Healthcare Partners, LLC; Healthcare Partners Medical Group, Inc.; and Healthcare Partners Independent Physician Association (collectively, "Healthcare Partners") filed a Motion to Dismiss Third Amended Complaint ("Motion to Dismiss"). On June 26, 2013, Defendant Aetna filed a Motion to Dismiss Plaintiff's Third Amended Complaint ("Motion to Dismiss"). On June 26, 2013, Defendant WellPoint, Inc. ("WellPoint") filed a Motion to Dismiss Plaintiff's Third Amended Complaint ("Motion to Dismiss"). On June 26, 2013, Defendants United Healthcare Insurance Company, UnitedHealthCare Services Inc., UHIC, UnitedHealth Group,

UnitedHealthCare, United Health, PacifiCare Health Plan Administrators, UHC of California (f/k/a PacifiCare of California), PacifiCare Life and Health Insurance Company, PacifiCare Health Systems (collectively, the “UnitedHealth Defendants”)¹, and Health Net filed a Motion to Dismiss Relator’s Third Amended Complaint (“Motion to Dismiss”). On July 8, 2013, Plaintiff and *Qui Tam* Relator James M. Swoben (“Swoben”) filed his Opposition.² On July 15, 2013, Healthcare Partners filed a Reply. On July 15, 2013, Aetna filed a Reply. On July 15, 2013, WellPoint filed a Reply. On July 15, 2013, the UnitedHealth Defendants and Health Net filed a Reply. Pursuant to Rule 78 of the Federal Rules of Civil Procedure and Local Rule 7-15, the Court found the matter appropriate for submission on the papers without oral argument. The matter was, therefore, removed from the Court’s July 29, 2013 hearing calendar and the parties were given advance notice. After considering the moving, opposing, and reply papers³, and the arguments therein, the Court rules as follows:

I. Factual and Procedural Background

On July 13, 2009, Swoben filed his initial Complaint under seal, naming Defendants Scan Health Plan and Senior Care Action Network. On September 30, 2009, Swoben filed his First Amended Complaint, which added SCAN Group (SCAN Group, Scan Health Plan, and Senior Care Action Network are collectively referred to as the “SCAN Defendants”) and the UnitedHealth Defendants. On October 19, 2010, Swoben filed his Second Amended Complaint. On November 23, 2011, Swoben filed his Third Amended Complaint, which added WellPoint, Aetna, Health Net, and the Healthcare Partners.

On August 17, 2012, the SCAN Defendants, the United States, the State of California, and Swoben reached a settlement, and this case was dismissed as to the SCAN Defendants. On or about January 8, 2013, the United States and the State of California declined to intervene in the action against the remaining defendants. On January 8, 2013, the Court issued an order unsealing this action and directing Swoben to serve the Third Amended Complaint on the remaining defendants.

In the Third Amended Complaint, Swoben alleges the following claims for relief against the remaining defendants: (1) the third claim for relief for violation of 31 U.S.C. § 3729(a) against the UnitedHealth Defendants; (2) the fourth claim for relief for violation of California Government Code § 12651(a) against the UnitedHealth Defendants; (3) the ninth claim for relief for violation of 31 U.S.C. § 3729(a) against the UnitedHealth Defendants, Health Net, Aetna, WellPoint, and HealthCare Partners; and (4) the tenth claim for relief for violation of California Government Code § 12651(a) against the UnitedHealth Defendants, Health Net, Aetna, WellPoint, and HealthCare

¹ The UnitedHealth Defendants includes Defendant Secured Horizons, which Swoben specifically identifies in the third and fourth claims for relief. However, Secured Horizons is a brand name and not a legal entity.

² Swoben filed a single Opposition in response to all four Motions to Dismiss.

³ Although Swoben filed an improper Sur-Reply on July 16, 2013 [Docket No. 129] which was not considered by the Court, Swoben has not filed a motion for leave to amend the Third Amended Complaint.

Partners. Based on the Notice of Dismissal of Fourth and Tenth Claims for Relief from Third Amended Complaint filed by Swoben on July 15, 2013, the Court entered an Order dismissing the fourth and tenth claims for relief on July 19, 2013. Accordingly, only the third and ninth claims for relief remain at issue in this action, and those are the claims for relief the UnitedHealth Defendants, Health Net, Aetna, WellPoint, and HealthCare Partners seek to dismiss in their Motions to Dismiss.

In the third and ninth claims for relief, Swoben, a former employee of Defendant SCAN Health Plan, alleges that the health maintenance organizations defendants, the SCAN Defendants, the UnitedHealth Defendants, Health Net, Aetna, and WellPoint (collectively, the “HMO Defendants”), and their contracted medical group, HealthCare Partners, defrauded the Medicare Advantage program by committing a type of auditing fraud, which involved improperly designed and performed retrospective reviews, that resulted in overpayments by Medicare.

A. Medicare System and CMS

Medicare is a health insurance program administered by the Centers for Medicare & Medicaid Services (“CMS”), designed to provide access to health insurance for Americans aged 65 and older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant). Eligible Medicare beneficiaries are provided a choice of either signing up for traditional fee-for-service (“FFS”) coverage under Medicare Part A (Hospital Insurance) and Part B (Medical Insurance), or selecting a private plan option under Part C, which is also known as “Medicare Advantage.” 42 U.S.C. § 1395w-21(a).

Under the traditional FFS model, physicians and hospitals (known as “providers”) who care for beneficiaries are reimbursed directly by the federal government. Under Medicare Advantage, a private insurer (“MA Plan”) is responsible for providing the benefits that traditional Medicare offers and, in return, receives capitated, per-member-per-month (“PMPM”) payments from the federal government. See 42 U.S.C. § 1395w-23(a)(1). Because MA Plans receive the same monthly payment regardless of the volume of services a beneficiary actually uses, the MA Plan assumes the risk a beneficiary’s expenses may exceed the capitated payment for that month.

Between 2000 and 2007, the federal government developed a system for adjusting monthly payments to MA Plans to reflect, in part, the health status of their beneficiaries. See 42 U.S.C. § 1395w-23(a)(3). Through “risk adjustment,” the federal government sought to ensure that MA Plans are “paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees).” *Medicare Program: Establishment of the Medicare Advantage Program*, 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005). To help accomplish this goal, risk adjusted capitated payments are partially based on beneficiary demographics and health status. See 42 U.S.C. § 1395w-23(a)(1)(C)(i); 42 C.F.R. § 422.308(c).

Risk adjusted capitated payments to MA Plans take into account the relative severity of patient conditions as compared to the average Medicare FFS beneficiary. 42 U.S.C. § 1395w-23(a)(1)(C)(i); 42 C.F.R. § 422.308(c)(i). Payments are adjusted by a “multiplier” (or “risk score”) that enhances or lowers reimbursement to the MA Plan on a member-by-member basis depending on the member’s relative expected health care expenditures under FFS Medicare as

compared to the average FFS beneficiary under Medicare.⁴ 42 C.F.R. § 422.308(c). Because MA Plans are compensated on a relative system, the contracts fundamentally presume that both the MA Plans and Medicare will filter and treat diagnostic information the same way.

MA Plans do not themselves diagnose beneficiaries. Rather, MA Plans primarily receive diagnosis codes from providers (e.g., physicians and medical groups). MA Plans also separately retain coding companies to perform retrospective reviews of medical records relating to certain “encounters” (e.g., patient visits to a doctor or hospital) to determine if the providers had properly reflected all the diagnosis codes for that encounter. Where appropriate, additional diagnosis codes identified in these reviews are transmitted to Medicare.⁵

Medicare groups certain diagnosis codes associated with each beneficiary and groups them into hierarchical condition categories (“HCCs”), which are disease groupings that predict average health care spending. 42 C.F.R. § 422.2. HCCs are used to “risk adjust” MA payments. *Id.* Because these HCCs are disease groupings, a number of different diagnosis codes can be properly linked to the same HCC (e.g., the codes for liver transplants, heart transplants, and lung transplants, among others, all link to the HCC: “Major Organ Transplant Status”).

B. CMS Audits

CMS performs periodic risk adjustment data validation audits (“RADV”) in which it assesses whether diagnosis codes that have been submitted were appropriately documented. When CMS conducts RADV audits, it seeks to determine, separate and apart from whether the patient in fact has the underlying condition, whether the particular medical chart under review sufficiently documents that the patient was seen by a provider with an appropriate physician specialty, who took the appropriate actions to diagnose that particular condition during that particular encounter. CMS’s regulations provide that so long as a particular diagnosis is adequately documented by a single medical record, the diagnosis will be deemed valid, even if other medical charts fail to properly document that diagnosis. See, e.g., 42 C.F.R. § 422.31 l(c)(2)(i)(C) (requires the submission of only one medical record for purposes of appealing the results of an RADV audit). Thus, if multiple providers submit the same diagnosis code for a patient, there would be no impact

⁴ Therefore, the more severe the diagnoses, the higher the risk scores, and, thus, the greater the capitated payments.

⁵ A typical retrospective review will result in three categories of diagnosis codes: (1) diagnosis codes supported by properly documented medical charts that were already reported to Medicare shortly after healthcare services were performed on the patients; (2) new diagnosis codes supported by properly documented medical charts that were not previously reported to Medicare; and (3) diagnosis codes that were previously submitted to Medicare that are not supported by properly documented medical charts. Although a new diagnosis code for a patient encounter discovered during a retrospective review may be submitted to the federal government, any diagnosis codes discovered that were not supported by properly documented medical charts must be withdrawn. New diagnosis codes discovered during a retrospective review tend to increase the patients’ risk scores, and, thus, increase capitated payments to the HMO. Diagnosis codes that are not supported by properly documented medical charts tend to decrease the patients’ risk scores, and, thus, lower capitated payments to the HMO.

on the capitated payment due the MA Plan even if one of the diagnosis codes derived from a particular provider's records was later determined to lack adequate documentation.

In the Third Amended Complaint, Swoben alleges that between 2008 and 2011, the HMO Defendants and HealthCare Partners retrospectively reviewed the medical charts of tens of thousands of their Medicare Advantage patients and, after those reviews, HealthCare Partners failed to report the diagnosis codes that had previously been submitted to Medicare but were not supported by properly documented medical charts. Swoben alleges that, instead, HealthCare Partners only submitted new diagnosis codes to Medicare that were admittedly supported by properly documented medical charts but that had not been previously reported to Medicare, which resulted in artificially high risk scores for the patients and inflated capitated payments to the HMO Defendants. Swoben also alleges in conclusory fashion that the HMO Defendants were aware that HealthCare Partners' retrospective reviews were faulty because they were not designed or performed in a way that would discover previously submitted diagnosis codes that were not supported by properly documented medical charts.

As to the UnitedHealth Defendants, Swoben separately alleges that, beginning in 2005 and continuing to or about 2011, the UnitedHealth Defendants retained independent coding companies to perform retrospective reviews of its patients with severe illnesses. According to Swoben, although the UnitedHealth Defendants provided the coding companies with lists of patients whose charts were selected for review, the UnitedHealth Defendants concealed from the coding companies diagnosis codes for those patients that had been previously submitted to Medicare. As a result, Swoben alleges that the coding companies properly reported the new diagnosis codes supported by properly documented medical charts that had not been previously submitted, but were unable to report the unsupported diagnosis codes. Therefore, Swoben alleges in conclusory fashion that the concealment of the previously reported unsupported diagnosis codes ensured that the retrospective reviews would only result in higher capitated payments paid to the UnitedHealth Defendants by the federal government.

II. Legal Standard

A motion to dismiss brought pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the claims asserted in the complaint. "A Rule 12(b)(6) dismissal is proper only where there is either a 'lack of a cognizable legal theory' or 'the absence of sufficient facts alleged under a cognizable legal theory.'" *Summit Technology, Inc. v. High-Line Medical Instruments Co., Inc.*, 922 F. Supp. 299, 304 (C.D. Cal. 1996) (quoting *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988)). However, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1964-65 (2007). "[F]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 1965.

In deciding a motion to dismiss, a court must accept as true the allegations of the complaint and must construe those allegations in the light most favorable to the nonmoving party. *See, e.g., Wyler Summit Partnership v. Turner Broadcasting System, Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). "However, a court need not accept as true unreasonable inferences, unwarranted deductions of

fact, or conclusory legal allegations cast in the form of factual allegations.” *Summit Technology*, 922 F. Supp. at 304 (citing *Western Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981) *cert. denied*, 454 U.S. 1031 (1981)).

“Generally, a district court may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion.” *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n. 19 (9th Cir. 1990) (citations omitted). However, a court may consider material which is properly submitted as part of the complaint and matters which may be judicially noticed pursuant to Federal Rule of Evidence 201 without converting the motion to dismiss into a motion for summary judgment. See, e.g., *id.*; *Branch v. Tunnel*, 14 F.3d 449, 454 (9th Cir. 1994).

Where a motion to dismiss is granted, a district court must decide whether to grant leave to amend. Generally, the Ninth Circuit has a liberal policy favoring amendments and, thus, leave to amend should be freely granted. See, e.g., *DeSoto v. Yellow Freight System, Inc.*, 957 F.2d 655, 658 (9th Cir. 1992). However, a Court does not need to grant leave to amend in cases where the Court determines that permitting a plaintiff to amend would be an exercise in futility. See, e.g., *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987) (“Denial of leave to amend is not an abuse of discretion where the pleadings before the court demonstrate that further amendment would be futile.”).

III. Discussion

A. Swoben’s Claims for Violation of the False Claims Act Must Be Dismissed.

To allege a claim for violation of the False Claims Act, the plaintiff must allege specific facts to demonstrate that: (1) the defendant made a false statement or engaged in a fraudulent course of conduct; (2) the defendant did so with the required scienter; (3) the statement or course of conduct was material; and (4) the statement or course of conduct caused the government to pay out money of forfeit moneys due. *United States v. Corinthian Colleges*, 655 F.3d 984, 992 (9th Cir. 2011).

In this case, it is undisputed that Swoben’s third and ninth claims for relief alleged in the Third Amended Complaint fail to adequately allege claims for violation of the False Claims Act. In his Opposition, Swoben does not meaningfully oppose the arguments made by the UnitedHealth Defendants, Aetna, WellPoint, HealthCare Partners, and Health Net in their respective Motions to Dismiss as to why his third and ninth claims for relief are inadequate and, instead, Swoben simply asks the Court for leave to file a Fourth Amended Complaint. Accordingly, HealthCare Partners’ Motion to Dismiss, Aetna’s Motion to Dismiss, WellPoint’s Motion to Dismiss, and the UnitedHealth Defendants and Health Net’s Motion to Dismiss are granted and Swoben’s third and ninth claims for relief are dismissed.

B. Leave to Amend Swoben’s Claims for Violation of the False Claims Act Should Be Denied.

The remaining issue to be decided is whether the dismissal of the third and ninth claims for relief should be with or without leave to amend. Leave to amend a pleading is generally freely granted, and is within the discretion of the Court. Fed. R. Civ. P. 15(a); *Foman v. Davis*, 371 U.S.

178, 182 (1962); *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir.1987) (citation omitted). In addition, leave to amend should be granted unless the district court “determines that the pleading could not possibly be cured by the allegation of other facts.” *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir.2000)). However, the liberality in granting leave to amend is subject to the qualification that amendment will not prejudice the opposing party, will not create undue delay, is not sought in bad faith, and does not constitute an-exercise in futility. *DCD Programs*, 833 F.2d at 186 (citations omitted); see also *Johnson v. Buckley*, 356 F.3d 1067 (9th Cir. 2004); *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1482 (9th Cir.1997). After considering each of the relevant factors, the Court concludes that Swoben’s claims should be dismissed without leave to amend.⁶

1. Leave to Amend Would Be Futile.

Claims brought pursuant to the False Claims Act are subject to the heightened pleading requirements of Rule 9(b). “In alleging fraud or mistake, Rule 9(b) requires a party to ‘state with particularity the circumstances constituting fraud or mistake’ including ‘the who, what, when, where, and how of the misconduct charged.’” *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)). “In addition, ‘[t]he plaintiff must set forth what is false or misleading about a statement, and why it is false.’” *Id.* (quoting *Decker v. GlenFed, Inc. (In re GlenFed, Inc. Sec. Litig.)*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc)). Although a plaintiff is not required to provide “representative examples of a false claim to support every allegation,” he must at least allege “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.*; see also *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051-52 (9th Cir. 2001) (explaining that Rule 9(b) requires that a complaint be “specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong”).

Although Swoben has been able to generally allege his view of an alleged fraudulent scheme, Swoben at this late date and after three attempts to amend his Complaint is still unable to allege the actual false representations, the makers of the false statements, and facts, as opposed to Swoben’s speculation, that plausibly demonstrate the federal government was actually overcharged. See, e.g., *United States ex rel. Cafasso v. General Dynamics C4 Systems, Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (“It is not enough to describe a fraudulent scheme in detail but then to allege simply and without any stated reason . . . that claims requesting illegal payments must have been submitted”). The Court may not make any assumptions about the defendants’

⁶ On July 9, 2013, the Court issued an Order to Show Cause Re Sanctions, which required Swoben, among other things, to file a declaration which described “in detail the proposed Fourth Amended Complaint and why such an amendment would not be futile or denied due to evidence of a lack of diligence or undue delay.” On July 12, 2013, Swoben filed the Declaration of William K. Hanagami in Response to July 9, 2013 Order to Show Cause Re Proposed First [*sic*] Amended Complaint (“Hanagami Declaration”) and the Declaration of Abram J. Zinberg (“Zinberg Declaration”). In determining that leave to amend should be denied, the Court has considered not only the arguments made and facts presented in Swoben’s Opposition, but also the facts presented in the Hanagami and Zinberg Declarations.

submission of actual claims to the federal government without stripping all meaning from Rule 9(b)'s mandate of specificity or ignoring "the true essence of the fraud," which involves an actual claim for payment from the federal government and not merely a preparatory scheme. *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006). In this case, even with the "new" facts Swoben states he would allege in a Fourth Amended Complaint, his claims would still be defective because he: (1) fails to describe the HealthCare Partners' retrospective review process with particularity, including the types of charts reviewed or whose charts were reviewed; (2) fails to allege that the reviewed charts belonged to members of the HMO Defendants' Medicare Advantage plans; (3) fails to allege with any particularity the HMO Defendants' involvement, if any, in the HealthCare Partners retrospective review process or the nature and extent of the HMO Defendants' knowledge of the reviews; (4) fails to allege any specific diagnosis codes that were submitted to the federal government that were actually false; and (5) fails to allege that he has reviewed any of the medical records associated with HealthCare Partners' patients to determine whether particular diagnosis codes were unsupported by those medical records.

Therefore, the Court concludes that granting Swoben leave to amend his third and ninth claims for relief for violation of the False Claims Act would be futile because after three prior attempts to amend his Complaint, he has failed to demonstrate that he can allege additional facts to satisfy the level of particularity required under Rule 9(b).⁷ At best, Swoben's proffered new facts simply expand his view of the fraudulent scheme, but, as the Ninth Circuit held in *Cafasso*, even a detailed description of a fraudulent scheme without factual allegations that demonstrate that claims requesting illegal payments were submitted to the federal government is insufficient.⁸

In addition, leave to amend Swoben's third and ninth claims for relief for violation of the False Claims Act would be futile because his claims are based on publicly available information. The False Claims Act requires the dismissal of claims that are based on information that has been "publicly disclosed," unless the plaintiff is the "original source" of that information. 31 U.S.C. § 3730(e)(4)(A). The public-disclosure bar in Section 3730(e)(4)(A) establishes a two-tiered inquiry: (1) it must be determined "whether there has been a prior 'public disclosure' of the 'allegations or transactions' underlying the qui tam suit"; and (2) "[i]f and only if there has been such a public disclosure," it must next be determined "whether the relator is an 'original source' within the meaning of § 3730(e)(4)(B)." *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1243 (9th Cir. 2000). An "original source" is an individual who either: (i) has prior to a public disclosure

⁷ This conclusion is supported by the fact that the federal government has declined to intervene in this action. See, e.g., *United States ex rel. Black v. Health & Hospital Corp. Of Marion County*, 2011 WL 1161737 (D. Md. Mar. 28, 2011) (holding that dismissal of complaint with prejudice was appropriate where "Relator, now on the fourth iteration of his complaint, in the second U.S. District Court, and after the government has twice declined to intervene, fails to provide sufficiently particular allegations of Defendants' fraudulent activities").

⁸ In addition, any argument that Swoben will be able to amend his complaint to comply with the requirements of Rule 9(b) after he has had the opportunity to conduct discovery is unpersuasive. The purpose of Rule 9(b) is to require a plaintiff to demonstrate that there is some substance to his "claim of fraud before a defendant will be subjected to the rigors of the discovery process." *U.S. ex rel. Riley v. Alpha Therapeutic Corp.*, 1997 WL 818593, *4 (N.D. Cal. Nov. 10, 1997).

under subsection (e)(4)(a), has voluntarily disclosed to the federal government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the federal government before filing an action under this section. 31 U.S.C. § 3730(e)(4)(B). To qualify as an original source, “a plaintiff must have direct and independent knowledge of the information on which the allegations are based.” *Battle v. Board of Regents for Georgia*, 468 F.3d 755, 762 (11th Cir. 2006). Where the plaintiff fails to provide the district court with “specific facts showing that [he] had direct and independent knowledge of the [information] on which [he] bases [his] FCA claims,” dismissal for lack of subject-matter jurisdiction is appropriate. *Id.*

In this case, the majority of “new” facts Swoben seeks to add to his Fourth Amended Complaint, including the error rates for RADV audits, are publicly available in CMS reports and other documents, such as *Payment Accuracy*, *Medicare Advantage (Part C)* and *Pillsbury Client Alert*. In addition, Swoben fails to allege, nor does it appear that he could, that he is the original source of this information. Therefore, even if Swoben’s “new” factual allegations were specific enough to support his claims for violation of the False Claims Act, they would still fail to support his claims because they are based on publicly available information. Accordingly, amendment of Swoben’s third and ninth claims for relief would be futile.

2. Swoben Unduly Delayed in Amending his Claims for Violation of the False Claims Act.

In addition, leave to amend is denied based on undue delay. In most situations, undue delay by itself is insufficient to justify denying a request to amend. *Bowles v. Reade*, 198 F.3d 752, 758 (9th Cir. 1999). However, in some egregious cases, delays may be sufficient on their own to deny amendment. See *AmerisourceBergen Corp. v. Dialysist West, Inc.*, 465 F.3d 946, 953 (9th Cir. 2006). Under the undue delay analysis, a relevant inquiry is also whether the plaintiff “knew or should have known the facts and theories raised by amendment in the original pleading.” *Jackson v. Bank of Hawaii*, 902 F.2d 1385, 1388 (9th Cir. 1990).

In this case, it is clear that Swoben was aware of the purportedly “new” allegations he proposes to add to the Fourth Amended Complaint since at least 2005. Zinberg Declaration, 2:28-3:2. For example, Swoben became aware that the HMO Defendants and HealthCare Partners used an Excel spreadsheet to submit retrospective review information to Medicare that did not allow for the submission of unsupported diagnosis codes “while employed with SCAN” (Hanagami Declaration, 7:28-8:9), which was “[b]etween March 2004 and September 2006” (Third Amended Complaint, ¶ 8), and well before he filed his original Complaint on July 9, 2009. Because the facts and theories in Swoben’s proposed Fourth Amended Complaint were admittedly known to him “since the inception of the cause of action” (*Royal Insurance Co. Of America v. Southwest Marine*, 194 F.3d 1009, 1017 (9th Cir. 1999)), and because Swoben has not offered any credible explanation for “his failure to develop his contentions originally” (*Allen v. City of Beverly Hills*, 911 F.2d 367, 364 (9th Cir. 1990)), leave to amend is denied.

Accordingly, the third and ninth claims for relief in Swoben’s Third Amended Complaint are dismissed without leave to amend.

IV. Conclusion

For all the foregoing reasons, HealthCare Partners' Motion to Dismiss, Aetna's Motion to Dismiss, WellPoint's Motion to Dismiss, and the UnitedHealth Defendants and Health Net's Motion to Dismiss are **GRANTED**, and Swoben's third and ninth claims for relief for violation of the False Claims Act are **DISMISSED without leave to amend** as to HealthCare Partners, Aetna, WellPoint, the UnitedHealth Defendants, and Health Net. Accordingly, Swoben's Third Amended Complaint is **DISMISSED with prejudice** as to HealthCare Partners, Aetna, WellPoint, the UnitedHealth Defendants, and Health Net.

IT IS SO ORDERED.

Case 1:16-cv-00157-RMC Document 31-8 Filed 04/28/17 Page 1 of 4

EXHIBIT G

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17 UNITED STATES DISTRICT COURT
18 FOR THE CENTRAL DISTRICT OF CALIFORNIA
19 WESTERN DIVISION

20 UNITED STATES OF AMERICA and
21 STATE OF CALIFORNIA *ex rel.*
JAMES M. SWOBEN,

22 Plaintiffs,

23 v.

24 SCAN HEALTH PLAN, a California
25 corporation, *et al.*,

26 Defendants.

No. CV 09-5013 JFW (JEMx)

UNITED STATES' NOTICE OF
MOTION AND MOTION FOR LEAVE
TO PARTIALLY INTERVENE AS TO
UNITED DEFENDANTS

[FILED/LODGED CONCURRENTLY:
MEMORANDUM OF POINTS AND
AUTHORITIES; DECLARATION;
[PROPOSED] ORDER]

DATE: April 3, 2017
TIME: 1:30 p.m.
COURT: Hon. John F. Walter

1 PLEASE TAKE NOTICE that, on April 3, 2017, at 1:30 p.m., or as soon
2 thereafter as the matter may be heard, in the courtroom of the Honorable John F. Walter,
3 United States District Judge, Courtroom 7A, United States Courthouse, 350 W. 1st
4 Street, Los Angeles, California 90012, the United States of America will and hereby
5 does move for leave to intervene in this action as to defendants UnitedHealth Group,
6 Inc.; United Healthcare Insurance Co.; UnitedHealthcare Services, Inc.;
7 UnitedHealthCare, Inc.; Pacificare Life and Health Insurance Co.; and UHC of
8 California (collectively, "United defendants").

9 This motion is and will be made on the grounds that, pursuant to 31 U.S.C. §
10 3730(c)(3), good cause exists to permit the United States to intervene in this action as to
11 the United defendants. Further, this motion is and will be made on the grounds that the
12 United States should be granted leave to intervene pursuant to Rule 24 of the Federal
13 Rules of Civil Procedure.

14 This motion is based upon the accompanying memorandum of points and
15 authorities, declaration, the pleadings and other papers on file herein, and such argument
16 and evidence as may be presented in connection with the hearing of this motion.

17 This motion is made following the conference of counsel pursuant to L.R. 7-3
18 which took place on February 22, 2017. At the time of filing of this motion, the
19 following parties have stated that they do not oppose the United States' motion: relator
20 James Swoben; defendants HealthCare Partners, LLC and HealthCare Partners Medical
21 Group, Inc.; defendant Aetna; and defendant Wellpoint. The United defendants have
22 stated that they would not oppose the motion if the Court finds that there is good cause
23 to intervene.

Dated: March 6, 2017

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General, Civil Division
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United States Attorney
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Assistant United States Attorney
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United States Department of Justice

/s/ John E. Lee

JOHN E. LEE
Assistant United States Attorney

Attorneys for the United States of America

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EXHIBIT H

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17 UNITED STATES DISTRICT COURT
18 FOR THE CENTRAL DISTRICT OF CALIFORNIA
19 WESTERN DIVISION

20 UNITED STATES OF AMERICA and
21 STATE OF CALIFORNIA *ex rel.*
JAMES M. SWOBEN,

22 Plaintiffs,

23 v.

24 SECURE HORIZONS, a business entity,
25 form unknown, *et al.*,

26 Defendants.
27
28

NOTE: CHANGES MADE BY THE COURT

No. CV 09-5013 JFW (JEMx)

ORDER GRANTING UNITED STATES'
REQUEST FOR LEAVE TO
INTERVENE IN ACTION AS TO
UNITED DEFENDANTS

[FILED CONCURRENTLY: JOINT
STIPULATION OF PARTIES
REGARDING UNITED STATES'
REQUEST FOR LEAVE TO
INTERVENE IN ACTION AS TO
UNITED DEFENDANTS]

1 The United States of America (the "United States"), having requested leave to
2 intervene in this action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, as
3 to defendants UnitedHealth Group, Inc.; United Healthcare Insurance Co.;
4 UnitedHealthcare Services, Inc.; UnitedHealthCare, Inc.; Pacificare Life and Health
5 Insurance Co.; and UHC of California (collectively, "United Defendants"), all other
6 parties to the action having consented and stipulated thereto, and good cause appearing,

7 IT IS HEREBY ORDERED as follows:

8 1. Pursuant to 31 U.S.C. § 3730(c)(3), there is good cause to allow the United
9 States to intervene in this action as to the United Defendants. Intervention of the United
10 States as to the United Defendants is further warranted under Rule 24(a)(2) and (b)(1)(B)
11 of the Federal Rules of Civil Procedure.

12 2. The United States is granted leave to intervene in this action as to the
13 United Defendants.

14 3. The United States shall file and serve its notice of election regarding
15 intervention within seven days of the filing of this Order.

16 4. The United States shall file and serve its complaint-in-intervention in this
17 action by **May 1, 2017**.

18
19 IT IS SO ORDERED.

20 Dated: March 17, 2017


UNITED STATES DISTRICT JUDGE

Case 1:16-cv-00157-RMC Document 31-10 Filed 04/28/17 Page 1 of 106

EXHIBIT I

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17 UNITED STATES DISTRICT COURT
18 FOR THE CENTRAL DISTRICT OF CALIFORNIA
19 WESTERN DIVISION
20

21 UNITED STATES OF AMERICA *ex*
rel. JAMES M. SWOBEN,

22 Plaintiffs,

23 v.

24 SECURE HORIZONS, a business entity,
25 form unknown, *et al.*,

26 Defendants.

No. CV 09-5013 JFW (JEMx)

DECLARATION OF JOHN E. LEE IN
SUPPORT OF MOTION FOR ORDER
CONSOLIDATING ACTIONS;
EXHIBITS

[FILED/LODGED CONCURRENTLY:
NOTICE OF MOTION AND MOTION;
MEMORANDUM OF POINTS AND
AUTHORITIES; [PROPOSED] ORDER]

27 DATE: May 1, 2017
TIME: 1:30 p.m.
28 COURT: Hon. John F. Walter

DECLARATION OF JOHN E. LEE

I, John E. Lee, declare:

1. I am an Assistant United States Attorney in the United States Attorney's Office for the Central District of California. Along with other attorneys in the United States Department of Justice, I have been assigned to represent the United States of America in *United States ex rel. Swoben v. Secure Horizons*, CV 09-5013-JFW (JEMx) (the "Swoben action"), and *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, CV 16-8697-MWF (SSx) (the "Poehling action").

2. Attached hereto as Exhibit 1 is a true and correct copy of the Ninth Circuit's PACER Docket Sheet in *United States ex. rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746.

3. Attached hereto as Exhibit 2 is a true and correct copy of Relator James Swoben's Fourth Amended Complaint filed on March 13, 2017 in the *Swoben* action (Docket No. 251).

4. Attached hereto as Exhibit 3 is a true and correct copy of the First Amended Complaint filed in the *Poehling* action (Docket No. 8).

5. Attached hereto as Exhibit 4 is a true and correct copy of the Notice of Election of the United States to Intervene in Part and Decline to Intervene in Part and Stipulation re Unsealing, filed on February 14, 2017 in the *Poehling* action (Docket No. 78).

6. Attached hereto as Exhibit 5 is a true and correct copy of the Order on Notice of Election of the United States to Intervene, filed on February 15, 2017 in the *Poehling* action (Docket No. 79).

7. Attached hereto as Exhibit 6 is a true and correct copy of the Corrected Notice of Election of the United States to Partially Intervene, filed on March 14, 2017 in the *Poehling* action (Docket No. 92).

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, EX
REL. [UNDER SEAL]

Plaintiff,

v.

[UNDER SEAL]

Defendants.

Civil Action No: 11-cv-0258-A

FIRST AMENDED COMPLAINT

FILED IN CAMERA AND UNDER SEAL

DO NOT ENTER IN PACER

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, EX
REL. BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC.,
WELLMED MEDICAL MANAGEMENT,
INC., HEALTH NET, INC., ARCADIAN
MANAGEMENT SERVICES, INC.,
TUFTS ASSOCIATED HEALTH PLANS,
INC., AETNA INC., BLUE CROSS AND
BLUE SHIELD OF FLORIDA, INC.,
BLUE CROSS BLUE SHIELD OF
MICHIGAN, BRAVO HEALTH, INC.,
EMBLEMHEALTH, INC., MANAGED
HEALTH, INC., d/b/a HEALTHFIRST
NEW YORK, HUMANA, INC., MEDICA
HOLDING COMPANY, WELLCARE
HEALTH PLANS, INC., and
MEDASSURANT, INC.,

Defendants.

Civil Action No: 11-cv-0258-A

**FIRST AMENDED COMPLAINT
FOR VIOLATION OF FALSE
CLAIMS ACT, 31 U.S.C. § 3729 ET
SEQ.**

**FILED IN CAMERA AND UNDER
SEAL PURSUANT TO 31 U.S.C.
§ 3730(b)(2)**

DO NOT ENTER IN PACER

For its complaint, the United States of America *ex rel.* Benjamin Poehling
("United States") alleges as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States under the Federal False Claims Act, 31 U.S.C. §§ 3729–33 (the "FCA"), against UnitedHealth Group, Inc., WellMed Medical Management, Inc., Health Net, Inc., Arcadian Management Services, Inc., Tufts Associated Health Plans, Inc., Aetna Inc., Blue Cross and Blue Shield of Florida, Inc., Blue Cross Blue Shield of Michigan, Bravo

Health, Inc., EmblemHealth, Inc., Managed Health, Inc., d/b/a Healthfirst New York, Humana, Inc., Medica Holding Company, WellCare Health Plans, Inc. (collectively the “Health Plan Defendants”) and MedAssurant, Inc. (“MedAssurant”) (collectively hereafter collectively “Defendants”).

2. Defendants are now and have been, in some cases since at least 2006, engaged in a widespread scheme to knowingly submit, or cause to be submitted, false claims for payment to the United States by submitting false “risk adjustment” information to the Centers for Medicare & Medicaid Services (“CMS”) in order to improperly increase the amounts CMS pays them or their clients. Likewise, Defendants have knowingly retained overpayments received from CMS as a result of their false risk adjustment submissions.

3. The Medicare Advantage (“MA”) program is designed to apply to Medicare a form of the “managed care” model commonly used by private health insurance companies. Under the managed care model, an employer or other organization seeking health care for its members—here the United States through the Medicare Program—pays a managed care organization a fixed fee to provide health services to its members. The payment is typically a per-member-per-month (“PMPM”) rate, also known as a capitation rate. The managed care organization receiving capitation payments (often a hospital, physician group, or other health insurance company) is responsible for paying hospitals, physicians and all other medical providers for health care services provided to the members of the plan. This differs from traditional fee-for-service (“FFS”) models, where the organization pays individual physicians, hospitals and other providers for each service they provide to the organization’s members.

4. Through the MA program, Medicare allows private health insurers to set up managed care plans to cover Medicare beneficiaries. Medicare pays a monthly capitation rate for each beneficiary enrolled as a member of a MA plan. MA plans must then use that money to pay hospitals, physicians and other health care providers for the services the plan members receive and cover the plans' administrative expenses. Certain MA plans are also given money to pay for the plan members' prescription drugs. Under both types of plans, CMS adjusts the capitation rate for each beneficiary to reflect that beneficiary's individual demographics (*e.g.*, age and gender), geographic location, and health status.

5. The adjustment for each member's health status is one of the most significant components of the capitation rate. Individuals with multiple and/or serious health conditions account for more healthcare costs than healthy members. Accordingly, CMS pays a substantially higher capitation rate for members who have been recently treated for one or more serious, expensive diseases or conditions. These increased payments are known as "risk adjustment" payments. On average, CMS pays a MA plan close to \$3,000 per year for each condition that a member has that requires a risk adjustment payment.

6. To receive these risk adjustment payments, MA plans submit claims to CMS each year for each member for each qualifying disease or condition. When the plan submits these claims, it must assert that the member received treatment in the twelve-month period before the payment year for the diagnosed condition from a qualified healthcare provider. MA organizations may only submit a diagnosis for risk adjustment

that: (1) stems from a face-to-face visit; (2) with a qualified healthcare provider; (3) during the appropriate service period; and (4) is documented in a medical record.

7. The Health Plan Defendants are engaged in systematic fraud in which they routinely:

(a) “Upcode” risk adjustment claims by submitting claims for diagnoses that the member does not have or for which the member was not treated in the relevant year, or by claiming that a member was treated for a more serious condition than the member actually has; and

(b) refuse to correct (and refuse to reimburse Medicare for) previously submitted risk adjustment claims when defendants discover, or in the exercise of reasonable care should discover, that those previously submitted claims were false.

8. MedAssurant and United (through its subsidiary Ingenix) are engaged in systematic fraud by assisting and causing MA organizations, including many of the Health Plan Defendants, to submit fraudulent risk adjustment claims, and failing to correct (and reimburse Medicare) for previously submitted false claims.

9. Through this fraudulent scheme, defendants have defrauded the United States of hundreds of millions—and likely billions—of dollars.

10. Defendants’ conduct alleged herein violates the federal False Claims Act. The federal False Claims Act (the “FCA”) was originally enacted during the Civil War. Congress substantially amended the Act in 1986—and, again, in 2009 and 2010—to enhance the ability of the United States Government to recover losses sustained as a result of fraud against it. The Act was amended after Congress found that fraud in

federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

11. The FCA prohibits, *inter alia*: (a) knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; (b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; (c) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government; and (d) conspiring to violate any of these three sections of the FCA. 31 U.S.C. §§3729(a)(1)(A)-(C), and (G). Any person who violates the FCA is liable for a civil penalty of up to \$11,000 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. §3729(a)(1).

12. For purposes of the FCA, a person “knows” a claim is false if that person: “(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. §3729(b)(1). The FCA does not require proof that the defendants specifically intended to commit fraud. *Id.* Unless otherwise

indicated, whenever the words “know,” “learn,” “discover” or similar words indicating knowledge are used in this Complaint, they mean knowledge as defined in the FCA.

13. Each claim for risk adjustment payments that defendants have submitted or caused to be submitted to CMS, where the patient was not treated, by a qualified provider, for that condition in the year in question, and/or the treatment and condition are not properly documented in the medical record is a false and/or fraudulent claim within the meaning of the FCA, so long as defendant knew that the claim was false when it was submitted, or the defendant later discovered its falsity and refused to correct the claim.

14. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

15. Based on the foregoing laws, *qui tam* plaintiff Benjamin Poehling seeks, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that the Defendants made or caused to be made in connection with false and/or fraudulent claims for Medicare Advantage and Medicare Part D risk adjustment payments.

II. PARTIES

A. Plaintiffs

16. Relator Benjamin Poehling is Director of Finance for UnitedHealthcare Medicare & Retirement (“UHMR”), a subsidiary of UnitedHealth Group (“UHG”). (This Complaint refers to UHG and its subsidiaries and affiliates collectively as “UHG” or “United.”) Prior to the fall of 2010, UHMR was known as Ovations, Inc. (unless

otherwise specified, this Complaint refers to Ovations, Inc. as UHMR when it is discussed as distinct from United).

17. Relator joined United in 2002 from Arthur Andersen, where he had participated in consulting engagements for UHG. In mid-2002, Relator joined United subsidiary Ingenix, Inc. (“Ingenix”) in New Jersey. Relator transferred to UHMR in 2004, relocating to Minnesota. At UHMR, Relator has held a variety of positions within the Finance Department. When United’s risk adjustment services were moved to Ingenix in mid-2007, Relator was assigned to be UHMR’s day-to-day liaison with the risk adjustment segment at Ingenix. In this new position, Relator is responsible for coordinating with Ingenix to provide UHMR with risk adjustment services, described in depth below. The scope and workload of the assignment grew from a part-time responsibility (shared with his other duties) until Relator was working full-time with Ingenix on risk adjustment. During this period, risk adjustment was becoming increasingly important to UHG’s revenue, and attracted increasing attention from UHG’s and UHMR’s senior management.

18. The United States, on whose behalf Relator brings this suit, is the real party in interest. The United States has ongoing contracts with defendants through CMS, in accordance with defendants’ participation in the Medicare and Medicaid programs.

B. Defendants

19. Defendant UnitedHealth Group Inc. (“UHG”) is a Minnesota corporation headquartered in Minnetonka, Minnesota. For purposes of this Complaint, defendant UHG includes all subsidiaries and affiliates that do business with the United States, including without limitation UHMR (formerly Ovations), UnitedHealthcare Community & State (“UHCS” and formerly AmeriChoice), Ingenix (rebranded as OptimumInsight in

20. UHG is the parent corporation for a large number of businesses within two basic market areas—health benefits and health services. United’s health benefits business, UnitedHealthcare, covers health insurance benefits in both public and private markets. United’s managed care company for the private sector is UnitedHealthcare Employer & Individual (“UHEI”). United’s managed care companies for the public sector—Medicare and Medicaid—are UHMR and UHCS. Together, UHMR and UHCS form United’s Public & Senior Markets Group (“PSMG”). The health services business, meanwhile, offers various services to consumers and the health care industry, including United’s health benefits companies. The principal companies within health services, now known as Optum, are Ingenix, recently renamed OptumInsight (discussed below), which provides data services and consulting, OptumHealth, which provides a variety of specialty and ancillary services (such as dental and chiropractic benefits as well as acquiring provider groups), and Prescription Solutions, now named OptumRx, a pharmacy benefits manager. UHG reports revenue in four segments: (a) UnitedHealthcare (UHEI, UHMR, and UHCS); (b) OptumHealth; (c) OptumInsight (formerly Ingenix); and (d) OptumRx (formerly Prescription Solutions).

21. United—through its UHMR and UHCS subsidiaries—is the largest provider of health insurance coverage for Medicare beneficiaries pursuant to MA contracts with CMS. United operates MA plans in all fifty states and the District of Columbia. These MA plans covered approximately 2.2 million enrolled MA

beneficiaries. United is also the largest provider of Medicare Part D plans with an enrollment of over 4.7 million Medicare beneficiaries as of June 30, 2011. United additionally offers Medicare supplemental and hospital indemnity insurance plans, as well as various care services. United's revenue from UHMR (including the bulk of its Medicare Advantage business) was \$32.1 billion in 2009 and \$35.9 billion in 2010. This business segment accounted for 37% of UHG's total revenue in 2009 and 2010.

22. United's Ingenix subsidiary offers data and consulting services to United companies as well as other insurance companies, hospitals, physicians, and others. Ingenix's revenues were \$1.8 billion in 2009 and \$2.3 billion in 2010. (Ingenix was renamed as OptumInsight in 2011, but is referred to herein as Ingenix unless otherwise noted.) Historically, risk adjustment services were provided to UHMR through a team located within the UHMR business unit. In 2007, United moved its risk adjustment services group, or Clinical Assessment Solutions ("CAS"), to Ingenix. (CAS has changed titles several times. It has also operated as Advanced Clinical Solutions ("ACS"), Clinical Performance Solutions ("CPS"), and, currently, Clinical Performance & Compliance ("CPC").)

23. Between August 2006 and June 2011, Medicare Part C beneficiaries enrolled in UHG plans resided in the Western District of New York for approximately 308,078 "person-months." Each person-month equates to one month of a Part C beneficiary's enrollment in a United health plan.

24. Defendant WellMed Medical Management, Inc. ("WellMed") is a Texas corporation headquartered in San Antonio, Texas. WellMed provides healthcare benefits for United's Medicare members in certain regions pursuant to a capitation agreement

25. Defendant Health Net, Inc. (“Health Net”) is a Delaware corporation headquartered in Woodland Hills, California. Health Net operates MA plans pursuant to contracts with CMS. Currently, Health Net has approximately 203,000 members enrolled in its MA plans. United holds a contract with Health Net whereby United submits Health Net’s risk adjustment data to CMS and performs additional risk adjustment services, including chart reviews, as described below. Between August 2006 and June 2011, Health Net plan members resided in the Western District of New York for approximately 24,960 Part C “person-months.” For purposes of this Complaint, defendant Health Net includes all subsidiaries and affiliates that do business with the United States.

26. Defendant Arcadian Management Services, Inc. (“Arcadian”) is a Delaware corporation headquartered in Oakland, California. Arcadian operates MA plans pursuant to contracts with CMS, covering approximately 64,000 MA beneficiaries. Until approximately August 2011, United held a contract with Arcadian whereby United submitted Arcadian’s risk adjustment data to CMS and performed additional risk adjustment services, including chart reviews, as described below. In August 2011, Arcadian was acquired by defendant Humana, Inc., and terminated its contract with United for risk adjustment services around that time. Between August 2006 and June 2011, Arcadian plan members resided in the Western District of New York for

approximately 3,690 Part C “person-months.” For purposes of this Complaint, defendant Arcadian includes all subsidiaries and affiliates that do business with the United States.

27. Defendant Tufts Associated Health Plans, Inc. (“Tufts”) is a Delaware corporation headquartered in Waltham, Massachusetts. Tufts operates MA plans pursuant to contracts with CMS, covering approximately 88,000 MA beneficiaries. United holds a contract with Tufts whereby United submits Tufts’ risk adjustment data to CMS and performs additional risk adjustment services, including chart reviews, as described below. Between August 2006 and June 2011, Tufts plan members resided in the Western District of New York for approximately 423 Part C “person-months.” For purposes of this Complaint, defendant Tufts includes all subsidiaries and affiliates that do business with the United States.

28. Defendant Aetna Inc. (“Aetna”) is a Pennsylvania corporation headquartered in Hartford, Connecticut. Aetna offers a broad range of health insurance products including MA and Medicaid managed care plans. Aetna’s MA plans cover over 400,000 individuals. Between August 2006 and June 2011, Medicare Part C beneficiaries enrolled in Aetna plans resided in the Western District of New York for approximately 28,380 “person-months.” For purposes of this Complaint, defendant Aetna includes all subsidiaries and affiliates that do business with the United States.

29. Defendant Blue Cross and Blue Shield of Florida, Inc. (“BCBS Florida”) is a health insurance provider headquartered in Jacksonville, Florida. BCBS Florida’s plans have a total enrollment of over 3 million members, including over 55,000 members enrolled in MA plans. Between August 2006 and June 2011, BCBS Florida plan members resided in the Western District of New York for approximately 1,229 Part C

“person-months.” For purposes of this Complaint, defendant BCBS Florida includes all subsidiaries and affiliates that do business with the United States.

30. Defendant Blue Cross Blue Shield of Michigan (“BCBS Michigan”) is a Michigan non-profit health care corporation headquartered in Detroit, Michigan. BCBS Michigan’s plans cover approximately 4.3 million members, including over 260,000 MA beneficiaries. Between August 2006 and June 2011, BCBS Michigan’s MA plan beneficiaries resided in the Western District of New York for approximately 1,448 Part C “person-months.” For purposes of this Complaint, defendant BCBS Michigan includes all subsidiaries and affiliates that do business with the United States.

31. Defendant Bravo Health, Inc. (“Bravo”), headquartered in Baltimore, Maryland, is an organization offering MA plans. Bravo’s MA plans cover approximately 100,000 Part C members. Between August 2006 and June 2011 Bravo health plans’ beneficiaries resided in the Western District of New York for approximately 312 Part C “person-months.” On November 30, 2010, Bravo was acquired by HealthSpring, Inc., a Delaware corporation headquartered in Franklin, Tennessee. HealthSpring, Inc., like Bravo, operates managed care plans with a focus on Medicare. For purposes of this Complaint, defendant Bravo includes all subsidiaries and affiliates that do business with the United States.

32. Defendant EmblemHealth, Inc. (“Emblem”) is a health maintenance organization and health insurance company headquartered in New York, New York. It was formed in 2006 by the merger of Group Health Incorporated and HIP Health Plan of New York, at which time it became a for-profit company. As of 2011, EmblemHealth and its subsidiaries (including HIP Health Plan of New York and ConnectiCare) served

more than 3.7 million members, including over 170,000 MA beneficiaries. Between August 2006 and June 2011, members covered by Emblem's Medicare Advantage plans resided in the Western District of New York for approximately 3,594 "person-months." For purposes of this Complaint, defendant Emblem includes all subsidiaries and affiliates that do business with the United States.

33. Defendant Managed Health, Inc., d/b/a Healthfirst New York ("Healthfirst"), is a New York non-profit corporation headquartered in New York, New York. Healthfirst operates a variety of health plans including plans that cover nearly 95,000 MA beneficiaries. Between August 2006 and June 2011 Healthfirst's Part C beneficiaries resided in the Western District of New York for approximately 589 "person-months." For purposes of this Complaint, defendant Healthfirst includes all subsidiaries and affiliates that do business with the United States.

34. Defendant Humana Inc. ("Humana") is a Delaware corporation headquartered in Louisville, Kentucky. Humana offers a wide range of health insurance products, including MA and Medicaid managed care plans. Humana's total enrollment in its medical insurance plans totals over 10.2 million members with over 1.6 million enrolled in MA plans. Between August 2006 and June 2011, Humana's Part C covered beneficiaries resided in the Western District of New York for approximately 71,549 "person-months." For purposes of this Complaint, defendant Humana includes all subsidiaries and affiliates that do business with the United States.

35. Defendant Medica Holding Company ("Medica") is a Minnesota non-profit holding company headquartered in Minnetonka, Minnesota. Its family of businesses include Medica Health Plans, Medica Health Plans of Wisconsin, Medica

Insurance Company, Medica Self-Insured, and Medica Health Management, LLC. Through its companies, Medica provides coverage to 1.6 million members, including over 126,000 members enrolled in MA plans. Between August 2006 and June 2011, Medica's Part C plan beneficiaries resided in the Western District of New York for approximately 1,813 "person-months." For purposes of this Complaint, defendant Medica includes all subsidiaries and affiliates that do business with the United States.

36. Defendant WellCare Health Plans, Inc. ("WellCare") is a Delaware corporation headquartered in Tampa, Florida. WellCare provides managed care health plans targeted to government-sponsored health care programs, including MA and Medicaid plans. As of June 30, 2011, the company served approximately 2.4 million members nationwide, including approximately 130,000 MA members. WellCare has regional offices in seven states, including New York. Between August 2006 and June 2011, WellCare represented members in the Western District of New York for approximately 171,040 Part C "person-months." For purposes of this Complaint, defendant WellCare includes all subsidiaries and affiliates that do business with the United States.

37. Defendant MedAssurant, Inc. ("MedAssurant") is a privately held company headquartered in Bowie, Maryland. MedAssurant provides risk adjustment services, including chart review and data submission, to numerous health plans that offer MA coverage. MedAssurant has numerous clients in, and routinely does business, including business involving Medicare risk adjustment, in the Western District of New York. For purposes of this Complaint, defendant MedAssurant includes all subsidiaries and affiliates that do business with the United States.

III. JURISDICTION & VENUE

38. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court for actions brought under 31 U.S.C. § 3730.

39. This Court has personal jurisdiction over the Defendants, pursuant to 31 U.S.C. § 3732(a), as one or more Defendants can be found in, reside in, transact business in, and have committed acts related to the allegations in this Complaint in the Western District of New York. For example, United's SecureHorizons Medicare Advantage plan operates in the Western District of New York. Additionally, each of the Defendant health plan issuers knowingly represented beneficiaries located in the Western District of New York.

40. Venue is proper, pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)–(c), as the Defendants can be found in, reside in, and/or transact business in the Western District of New York, and because many of the violations of 31 U.S.C. § 3729 discussed herein occurred within this judicial district.

IV. LEGAL BACKGROUND

41. Medicare is a federally-funded health care program primarily serving people age 65 or older. Initially created in Title XVIII of the Social Security Act of 1965, Medicare now has four Parts, A through D. The two original components of Medicare are Part A, which covers inpatient hospital costs and related services, and Part B, which covers outpatient health care costs, such as physicians' fees.

42. Traditionally, Medicare operates on a fee-for-service basis, meaning that Medicare directly pays hospitals, physicians and other health care providers for each service they provide to a Medicare beneficiary. Medicare beneficiaries are generally

required to pay some portion of many of these services in the form of copayments, deductibles, coinsurance, or other set fees (collectively known as the members' "out of pocket" expenses).

43. In 1997, Congress created Medicare Part C, which provides similar benefits to Medicare members, but does so based on a managed care model, rather than the traditional fee-for-service model. Under Part C, rather than pay providers directly, Medicare pays private managed care plans (later named "Medicare Advantage" or "MA" plans) a capitation rate (per member per month) and those plans are responsible for paying providers for the services they provide to members of that specific MA plan.

44. MA plans must provide Medicare beneficiaries benefits at least equivalent to those they would have received under the traditional Medicare Parts A and B. Depending on the structure of the plan, MA plans may also provide additional benefits beyond what traditional Medicare would have covered, such as dental care, or cover some or all of their members' out of pocket expenses associated with basic Medicare Parts A and B services.

45. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, creating Medicare Part D which provides prescription drug coverage. Although a limited number of Medicare Part D plans are operated under a cost-reimbursement contract, the plans are generally financed under a managed care model. These managed care model plans are provided under both Part D prescription drug plans, which offer only prescription drug coverage, and Part C plans, which integrate the prescription drug coverage with the traditional Part C health care coverage.

46. This Complaint refers, collectively, to Medicare Advantage plans with and without Part D coverage, and stand-alone managed care Medicare Part D Plans as “Medicare Advantage Plans” or “MA Plans.”

A. Calculation of MA Plan Capitation Rates

47. The capitation rates Medicare pays to MA plans are determined based on a process involving consideration of past and expected future medical expenses, the location of the plan’s actual and expected members, the health status and demographics of those members and whether the plan will include any additional benefits. That process is summarized in Medicare regulations as follows:

In short, under the bidding methodology each plan’s bid for coverage of Part A and Part B benefits (*i.e.*, its revenue requirements for offering original Medicare benefits) is compared to the plan benchmark (*i.e.*, the upper limit of CMS’ payment, developed from the county capitation rates in the local plan’s service area or from the MA regional benchmarks for regional plans). The purpose of the bid-benchmark comparison is to determine whether the plan must offer supplemental benefits or must charge a basic beneficiary premium for A/B benefits.

Medicare Managed Care Manual (“MMCM”), ch. 8, § 60.

48. In other words, it is a three-step process involving: (a) development of the MA plan’s bid rate; (b) review of the CMS benchmark rate; and (c) comparison of those two rates to develop the base capitation rate and determine whether any adjustments in the plan benefits or member premiums are required.

49. First, the MA plan develops a bid rate. This rate is the amount that the MA plan expects it will be required to pay to provide Medicare Parts A and B benefits to

a hypothetical average member of the plan. This estimate must be based on either the MA plan's prior experience covering Medicare members, or an actuarially validated data analysis of expected costs. To represent an "average" plan member, the bid rate must make adjustments to standardize the effect of expected geographic diversity (because some areas are more expensive than others) and the relative health status (*i.e.*, the number and nature of chronic conditions) of the members whose claims experience provided the basis for the bid. The bid rate also includes an amount that the MA plan expects to spend on administrative costs, and a profit margin.

50. The mechanism for standardizing the bid for individuals' demographic factors and health status is known as the "risk score." It is an artificial score that CMS assigns to every beneficiary. CMS starts with a score of zero, and then adds points for the beneficiary's demographic condition (such as age and gender) and individual disease states (such as diabetes or congestive heart failure). The average risk score is one, with most Medicare beneficiaries having scores under three. The risk score model is designed so that a population with an average risk score of two would be expected to use twice as much health care (in dollars) as a population with a score of one. The bid rate the MA plans develop must reflect the amount they will require to provide services to a hypothetical population with a risk score of one.

51. Second, the MA plan must review the Medicare benchmark rate provided by CMS. This rate is the amount that the Medicare program would spend to provide Parts A and B benefits to an average member in the geographic area covered by the MA plan's bid. The benchmark rate also includes several other adjustments, including until

recently a bonus payment to incentivize health insurance companies to enter the MA market.

52. Third, the bid rate and the benchmark rate are compared to determine whether the MA plan must charge its members a premium, or, instead, if it must offer them enhanced benefits. If the bid rate is greater than the benchmark rate, Medicare will only pay the MA plan the benchmark rate per member per month. That benchmark rate becomes the base capitation rate that CMS pays the MA plan for a member with a 1.0 risk score (described below). The MA plan must then charge the beneficiaries who join its plan a monthly premium in order to make up the shortfall between the bid rate and the base capitation rate. *See* MMCM, ch. 8, § 60.1.

53. If, on the other hand, the bid rate is less than the benchmark rate, then the bid rate becomes the base capitation rate. The difference between the benchmark rate and the bid rate is then split between the MA plan and the Medicare program. The first 25% of the difference is retained by the Medicare program as plan savings. The remaining 75% is returned to the MA plan, which must use the rebate to either provide enhanced benefits to its plan members or to cover the members' out of pocket expenses. In the end, then, in such situations, the base capitation rate equals the bid rate, plus the MA plan receives 75% of the difference between the bid rate and the benchmark rate.

54. Medicare does not, however, pay the plans the base capitation rate. Instead, when payments are actually made, the base capitation rate is adjusted, for each member, to reflect his or her actual age, gender, location, and, most important, health status.

55. MA plans must rebid their rates every year.

B. Calculation of Part D Plan Capitation Rates

56. The process of calculating the capitation rates for the Part D portion of MA plans is very similar to the process used for the base portion of the MA rate. Annually, the plan develops and submits a bid rate based on the plan's estimate of the monthly revenue requirements it will require to provide qualified prescription drug coverage for an average, eligible individual. 42 C.F.R. § 423.265(c). As for the base MA rate, a Medicare prescription drug coverage plan's average monthly bid rate is adjusted to take into account the geographic differences in pricing and the relative health status of the members on whom the bid calculation was based.

57. The risk score calculations for the Medicare Part D portion of the plans mirror the calculation for the basic MA rate, determined by each beneficiary's demographic information and health status. Each plan's bid must reflect the revenue the plan will require to provide services to a population of "average" members, *i.e.*, those with a risk score equal to one.

C. Risk Adjustment Depends on Accurate, Substantiated Health Condition Codes

58. As described above, CMS pays MA plans at a capitation rate that reflects, among other things, each member's health status. The process of adjusting the capitation rate to reflect a member's disease states is known as risk adjustment. Risk adjustment is intended to improve the accuracy of the payments CMS makes to these plans. To this end, CMS pays a higher future premium for enrollees whom the MA plan represents have been treated for certain diseases and conditions in the current year, based on the expectation that those enrollees will require treatment and/or management for the conditions in the following year. *See 2008 Risk Adjustment Training for Medicare*

Advantage Organizations Participant Guide (“Participant Guide”), at 6.4.1 (for purposes of this Complaint, “treatment” is defined as treatment and management within the meaning of the *Participant Guide*).

59. Conversely, CMS pays a lower premium for enrollees who, although they may have certain typically expensive conditions, did not require care, treatment or management for those conditions in the current year. For these patients, the risk adjustment methodology assumes that because their condition did not require treatment in the current year, it has improved or otherwise changed so that it is not expected to require treatment in the following year.

60. As a practical matter, the CMS risk adjustment model evaluates enrollee health (and establishes risk adjustment payment rates) using diagnosis classifications set forth in the International Classification of Diseases, 9th Edition, Clinical Modification (“ICD-9-CM”) system. The ICD-9 system assigns each diagnosis a specific code. Under the MA model, these individual diagnosis codes are then organized into groups, called Hierarchical Condition Categories (“HCCs”). MMCM, ch. 8, § 50. Every HCC consists of several ICD-9-CM diagnosis codes that are clinically related and are expected to require a similar level of resources to treat. *Id.* For example, there are five HCCs for patients with diabetes: HCC 15 (diabetes with renal or vascular manifestation); HCC 16 (Diabetes with Neurologic or Other Specified Manifestation); HCC 17 (Diabetes with Acute Complications); HCC 18 (Diabetes with Ophthalmologic or Unspecified Manifestation); and HCC 19 (Diabetes without Complication). Generally speaking, patients grouped in HCC 15 have the most serious manifestations associated to their diabetes, and are expected to cost the most to treat. Patients in HCC 19 have the least

cost-intensive type of diabetes, and therefore the CMS risk adjustment system provides a smaller enhanced payment for these patients.

61. CMS has used the same model for the Part D portion of risk adjustment. However, because certain diagnoses will be expected to increase liability for prescription drugs covered under Part D, but not hospital costs and physician fees covered under Part C, and vice versa, a distinct list of Hierarchical Condition Categories (“RxHCCs”) with corresponding diagnosis codes was created for Medicare’s Part D risk adjustment. *See* Participant Guide at 8.2.5.2. For example, RxHCC 75 represents Attention Deficit Disorder, a condition predicted to increase drug spending. However, because Attention Deficit Disorder is unlikely to result in hospitalization, RxHCC 75 has no corresponding HCC. On the other hand, HCC 77, Respirator Dependence/ Trachostomy Status, a condition category predictive of Medicare Part C medical costs, but not necessarily predictive of Part D drug expenses, has no RxHCC equivalent.

62. Although the HCC and RxHCC systems are not identical, they do have significant overlap. Certain HCCs have equivalent RxHCCs, meaning that the condition categories consist of identical ICD-9-CM diagnosis codes. For example, HCC 5 (Opportunistic Infections) is equivalent to RxHCC 2 (Opportunistic Infections), and HCC 37 (Bone/Joint/Muscle Infections/Necrosis) is the equivalent of RxHCC 39 (Bone/Joint/Muscle Infections/Necrosis). Even where they are not identical, most HCCs overlap with one or more RxHCCs. For example, of the thirty-seven diagnosis codes that fall within HCC 45 (Disorders of Immunity), twenty-seven fall within RxHCC 52 (Disorders of Immunity), seven fall within RxHCC 51 (Severe Hematological Disorders),

and three do not fall within any RxHCCs. Thus, the majority of ICD-9-CM diagnosis codes that capture an HCC will also capture an RxHCC.

63. An individual ICD-9-CM code included in the HCC system for a particular member corresponds on average to nearly \$3,000 in extra revenue for the plan over the course of the following year for that member. So, for example, if a MA plan like United with 2.1 million members submitted just one incremental HCC-based diagnosis code per member to CMS, it would result in approximately \$6.3 billion in additional capitation payments from CMS.

64. Because submitting incorrect diagnosis codes increases risk adjustment payments, CMS requires MA plans to follow strict guidelines when submitting codes. *See, e.g., 2008 Risk Adjustment Training for Medicare Advantage Organizations Participant Guide.*

65. CMS requires that the patient must have been treated for the relevant diagnoses during a face-to-face encounter with an eligible provider, such as a physician, physician extender, or hospital, during the year in question.

66. Only services provided by an eligible provider type may be included. CMS expressly prohibits MA plans from submitting “risk adjustment diagnoses based on any diagnostic radiology services” or laboratory services. *Participant Guide*, at 3.2.2, 4-3. The reason CMS prohibits MA plans from submitting codes based on radiology charts, for example, is that “[d]iagnostic radiologists typically *do not document confirmed diagnoses*. Confirmed diagnoses come from referring physician or physician extenders.” *Id.*, at 4-3 (emphasis added). Because radiologists generally list on their charts the diagnoses a doctor wants them to look for, not which diagnoses the patient actually has,

CMS excludes radiology services as a valid provider type (*i.e.*, source of risk adjustment data).

67. The treating provider must document the facts supporting the coded diagnosis in the patient's medical record and sign and date the record. At a minimum, the plan must record five elements for submission to CMS:

- (a) the member's Health Insurance Claim ("HIC") number; (b) the ICD-9-CM diagnosis code;
- (c) the "service from" date;
- (d) the "service through" date; and
- (e) the provider type.

68. MA plans are responsible for the content of risk adjustment data submissions to CMS, regardless of whether they submit the data themselves or through an intermediary. *Participant Guide*, at 3-13. Before submitting data to CMS, MA plans are required to filter the data "to ensure that they submit data from only appropriate data sources." *Participant Guide*, at 4-11. For example, filters should include checking that physician data comes from face-to-face encounters with patients and ensuring that data does not come from non-covered providers, such as diagnostic radiology services.

69. MA plans that filter risk adjustment claims by CPT codes must also filter the data to ensure that only diagnoses treated through approved procedure types are included. *Id.* at 4-11. MA organizations typically classify professional (*e.g.*, physician) procedures using Current Procedural Terminology ("CPT") codes and institutional procedures using revenue codes. These codes show whether the type of service in

question was a face-to-face procedure such as a physical examination, or a non-qualifying remote procedure, such as a laboratory test or radiology exam.

70. MA plans are required to correct the risk adjustment data they submit to CMS. When the MA plan learns that information in a risk adjustment claim (*i.e.*, HIC number, diagnosis code, service dates, and provider type) contains an error, it must submit a “delete record” to CMS for that claim.

71. CMS also requires that diagnosis codes used as the basis for a risk adjustment claim be substantiated through documentation in a medical record. Upon request by CMS, MA plans must provide documentation to support each diagnosis and substantiate that the provider followed proper coding guidelines. *Id.* at 6-5; 5-52.

72. In general, CMS sets risk scores based on risk adjustment data submitted for services provided during the year preceding the payment year. 42 C.F.R. §§ 422.310(g), 423.329(b)(3). The annual deadline for submitting risk adjustment data to CMS is in early September. *Id.* The data submitted by the September deadline determines members’ preliminary risk scores for the following year.

73. Despite the September deadline, CMS accepts submissions of risk adjustment data for a period after the end of service year and, through a reconciliation process, adjusts its payments to the MA plan retroactively to account for codes submitted after the September deadline. MA plans are allowed to submit risk adjustment data until after the end of the payment year. After the payment year ends, CMS recalculates the risk score for any members for whom the MA plan made a retroactive submission.

74. Thus, for example, the capitation rates for 2010 are based on the MA plans’ members’ health status (diagnosis codes) from 2009. The initial submission

deadline for the 2009 diagnosis codes was September 4, 2009 and the final submission deadline was January 31, 2011. Thus, CMS calculated members' initial risk factors for 2010 based on the September 4, 2009 data, but MA plans were allowed to continue to submit 2009 diagnoses until January 31, 2011. After that date, for every member with a newly-submitted diagnosis, CMS recalculated the risk score and reconciled the member's payments in 2010 with the amount it would have paid at the new score.

75. To test the validity of MA plan risk adjustment data, CMS conducts Risk Adjustment Data Validation ("RADV") audits after the MA plan's final deadline for submitting risk adjustment data for the payment year. During such audits, CMS "validates" some of the MA plan's HCC scores by reviewing the medical records that the plan contends support the claimed diagnosis codes. *Id.* at 7-1. To facilitate the RADV audits, MA plans are required to submit to CMS medical records and coversheets for each sampled enrollee, including the "one best medical record" supporting each HCC. *Id.* at 7-9.

76. Historically, CMS has not extrapolated RADV audit results to the plan as a whole. (CMS has recently proposed moving toward extrapolation of RADV results.) Instead, CMS has merely sought repayment for those risk adjustment claims found to be false during the RADV audit. Because RADV audits generally used relatively small samples—a few hundred risk adjustment claims—the potential risk to MA plans, should they be found to have submitted false risk adjustment claims, has been relatively small. Without meaningful financial penalties, MA organizations have generally seen little incentive to conform to CMS's risk adjustment rules. The fraudulent practices described

in this Complaint are a product of the belief, common among MA organizations, that the law could be violated without meaningful consequence.

D. CMS Requires MA Plans To Certify the Validity of Their Bid Rates and Risk Adjustment Data To Prevent Fraud

77. In recognition of the fact that the integrity of the capitation rates depends on the integrity of the actuarial information used by the MA plans in developing their bid rates, and to otherwise guard against fraud, CMS requires MA organizations to submit three separate attestations, each signed by the CEO or CFO (or their authorized, direct subordinate). These attestations are a condition that the MA plans must meet to be eligible to receive any capitation payments from CMS.

78. The first attestation, which the MA organization submits on a monthly basis, requires the MA organization to “attest based on best knowledge, information, and belief that each enrollee for whom the MA Organization is requesting payment is validly enrolled, or was validly enrolled during the period for which payment is requested, in an MA plan offered by the MA Organization.”

79. The second attestation, which is submitted annually, requires the MA organization to attest that the risk adjustment data it submits annually to CMS is “accurate, complete, and truthful.” The attestation acknowledges that risk adjustment information “directly affects the calculation of CMS payments . . . and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.” The regulations also provide that if the claims data are generated by a “related entity, contractor, or subcontractor of an MA organization,” that entity must similarly certify the “accuracy, completeness, and truthfulness of the data.” 42 C.F.R. §422.504(l)(2).

80. The third attestation is the MA organization's certification "that the information and documentation comprising the bid submission proposal is accurate, complete, and truthful and fully conforms to the Bid Form and Plan Benefit Package requirements; and that the benefits described in the CMS-approved proposal bid submission agree with the benefit package the MA Organization will offer during the period covered by the proposal bid submission."

81. MA organizations must also submit bid submission attestations, certifying "that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the [bid submission regulations]."

E. The False Claims Act Contains a Duty to Correct Known Errors

82. The False Claims Act contains an independent requirement to correct errors that will cause, or have caused, a government overpayment. The Act attaches liability to anyone who knowingly makes, uses, or causes to be made or used, a false statement or record material to an obligation to pay or transmit money to the government, or who knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money to the government. 31 U.S.C. § 3729(a)(1)(G).

83. Accordingly, MA plans not only have a duty not to submit incorrect data to CMS, but also, for data they have already submitted, must delete the records from CMS's database using a "delete code."

V. BACKGROUND

A. UnitedHealth Group

84. United is the largest provider of MA plans nationwide, covering benefits under Medicare Parts C and D in all fifty states and in most U.S. territories. United had

6.8 million individuals enrolled in its MA plans (Part C and Part D) at the end of 2010.

The MA plans are operated by UHMR and UHCS and offered to Medicare beneficiaries under such brand names as, for example, SecureHorizons, AmeriChoice, Evercare, AARP MedicareRx and UnitedHealth Rx.

85. United has expanded rapidly since its founding in 1977. The company's growth in recent years has been driven by acquisitions, nowhere more so than in its Medicare business. These acquisitions included the 2004 purchase of Oxford Health Plans, the 2005 acquisition of PacifiCare Health Systems, and the 2007 acquisition of Sierra Health Services, Inc.

86. Recently, United has also been expanding vertically by acquiring provider groups who care for many of the patients in United's MA plans. Foremost among these purchases was the 2011 purchase of WellMed, a large physician-owned practice management company located primarily in Texas.

87. United has organized its businesses into two primary segments: health plans and health services, as described above. *See* ¶¶20–22. Within the health services segment, Ingenix provides risk adjustment services (and other services) to United's MA plans and also sells those same services commercially to other MA plans.

88. Ingenix submits or previously submitted diagnosis codes for risk adjustment to CMS on behalf of UHMR and UHCS as well as on behalf of commercial clients including, for example, Health Net, Arcadian, Tufts, and Medica. United relocated its risk adjustment team from UHMR to Ingenix to enable these commercial deals, as well as to allow UHMR and UHCS to charge their risk adjustment costs with markups to CMS on their annual bids.

89. At every level, United is driven by a corporate culture that demands and rewards financial success from its employees. The risk adjustment practices described in this Complaint are attributable in large part to these demands and rewards. As to demands, United evaluated many of its employees, including Relator, until recently on their success at “maximizing revenue” by increasing risk scores. United gave Relator as well as clinical staff specific goals for increasing risk scores. Relator’s March 30, 2008 review, for example, evaluated him against United’s “business goal” of increasing risk scores by 3%. There were no similar performance goals for the overall accuracy of risk adjustment submissions. Nor was there any accountability assigned for reducing the number of false claims submitted to CMS.

90. For rewards, United tied its performance incentives directly to risk score increases. These incentives have been at the center of United’s risk adjustment practices. Relator, for example, received a \$15,000 bonus in 2010 for his work to meet UHMR’s target of \$100 million in additional internal operating income (“IOI”) from risk adjustment payments. His bonus, however, paled in comparison to the incentives offered to those higher up in the company. Optum CEO (and former CEO of UHMR) Larry Renfro received a compensation package in 2010 that included a potential bonus, called a “cash incentive award,” which tied his earnings to revenue, IOI, and provider satisfaction. Increasing risk scores met all three objectives. Mr. Renfro’s 2010 cash incentive award was \$900,000—150% of his bonus target. In 2011, Mr. Renfro received a \$1.4 million cash incentive award, which was made in consideration of his “successful execution of a major multi-track Medicare remediation initiative,” of which increasing United’s risk score was a substantial component.

91. During Mr. Renfro's term as UHMR's CEO, UHMR set revenue and IOI targets based on risk adjustment and entered into agreements with providers that offered financial rewards for increasing risk scores. As discussed below, many of the policies and practices United used to achieve these goals were fraudulent. Despite misgivings expressed by various United personnel, however, United took no action to stop its misconduct. Lack of independence contributed to the problem. For example, PSMG's Chief Compliance Officer, David Orbuch, reported not to the Board of Directors, but to Mr. Renfro.

92. United aligned the incentives of its entities, staff, and vendors to increase risk scores. Ingenix had an incentive to increase the number of risk adjustment claims (based on incremental/newly-found diagnosis codes) it submitted to CMS for payment under the terms of its Service Level Agreement with UHMR. The Agreement provided for base payments plus a significant "incentive fee" tied to risk score increases. Exhibit 2, incorporated herein.

93. In 2009, United changed to a more fixed-fee arrangement with Ingenix. Ingenix, however, continues to receive incentive fees based on risk score increases from at least one of its commercial clients, Health Net.

94. In addition, the managers responsible for Ingenix's risk adjustment program (now called CPC), including Jeff Dumcum, Paul Bihm, and Stephanie Will, had employment agreements with United that included financial incentives based on increased risk scores. Furthermore, United gave incentives to its healthcare providers and vendors. As described below, for example, United (PacifiCare at the time) entered into an agreement with WellMed, such that WellMed's data subsidiary, DataRap, would

95. United's senior management push relentlessly to increase United's revenue from risk adjustment. Tellingly, UHMR has assigned risk adjustment to its Finance Department, not one of its clinical departments. (Relator was assigned to his job despite having no clinical background.) In 2010 and 2011, UHMR has implemented projects referred to as "remediation plans", "focus area projects," or "affordability agendas" to increase IOI.

96. The remediation plan for 2010 called for \$800 million in additional IOI, \$100 million of which was to come from increased risk adjustment revenue. In 2011, the additional IOI target from risk adjustment rose to approximately \$125 million.

97. While speaking at the Citi 2011 Global Healthcare Investor conference on March 2, 2011, UHMR's CEO, Tom Paul, commented that United's 2010 affordability agenda allowed United to not raise premiums or cut benefits, while still achieving business objectives. He went on to say the affordability agenda will continue in 2011 and beyond. These remediation plans are merely United's latest effort to exploit risk adjustment's large revenue potential. As described below, United has engaged in a course of conduct since at least 2006 to maximize its risk adjustment payments from CMS. For much of the past decade, United's attitude may be summarized by an email from former UHMR CFO Jerry Knutson to Ingenix's Jeff Dumcum:

Wanted to get together with you and discuss what we can do in the short term and long term to really go after the potential risk scoring you have consistently

indicated is out there. . . . You mentioned vasculatory disease opportunities, screening opportunities, etc with huge \$ opportunities. Lets turn on the gas!

Exhibit 3, incorporated herein.

B. MedAssurant, Inc.

98. MedAssurant is a large data analytics company that offers a variety of product solutions to clients in the health care industry, including local and national health plans, care delivery networks, employers, pharmaceutical companies and government organizations. MedAssurant's earliest component was formed in Michigan in 1998, but its significant growth and expansion began in 2005 after the company launched its portfolio of data aggregation, abstraction, validation, and analysis toolsets in response to demand from the changing market. Today, MedAssurant operates in all 50 states, Puerto Rico, and the District of Columbia, in over 99.5% of counties across the U.S., and partners with nearly 200 managed care organizations touching millions of members.

99. At the heart of many of MedAssurant's solutions is the company's healthcare data warehouse which stores client data dating back to at least January 2006. As of 2008, the database held data pertaining to more than 450 million member-months of member clinical, laboratory, pharmacy, medical product utilization, and encounter data.

100. MedAssurant organizes its product solutions into four categories: (1) Clinical and Quality Outcomes; (2) Claims & Payment Integrity; (3) Care Coordination & Enhancement; and (4) Healthcare Data Insights. This Complaint addresses fraudulent practices within MedAssurant's risk adjustment and claims submission services, which fall under the "Claims & Payment Integrity" category (formerly known as "Claims Analytics and Risk Adjustment").

101. Although MedAssurant promises MA risk score improvement through a variety of its products, only its Capitation Risk Adjustment (“CARA”) solutions are marketed as complete “end-to-end” risk adjustment solutions. MedAssurant provides its CARA solution clients services that are designed to “identify, analyze, pursue, and document valid diagnoses not otherwise properly or fully captured by a plan’s primary claims systems.”

102. Broadly speaking, the CARA solution utilizes proprietary algorithms to analyze the member data and identify patients who might be ripe for the submission of additional or more intense risk adjustment claims. Among the data MedAssurant uses to identify these HCC coding “opportunities” are data for services such as radiology and laboratory services and prescription drug use that are prohibited as evidence to support HCC claims. MedAssurant calls these “opportunities” to increase the Plan’s HCC-driven reimbursement Clinical Encounter Data Incongruences (“CEDIs”).

103. MedAssurant has a nationwide employee network of chart reviewers who perform chart reviews on-location in providers’ offices and, where the on-location reviews are not feasible, in other centralized locations. MedAssurant coordinates the chart reviews with its proprietary ChartWise solution, a logic system designed to select and prioritize the medical facilities and providers holding medical records in need of review.

104. After identification of the target CEDIs, MedAssurant conducts reviews of members’ medical records to find a basis to submit a claim for each target diagnosis.

105. During these chart reviews, MedAssurant’s employees are instructed to look only for diagnosis codes that would support new HCCs. They are not instructed to

assess the accuracy of any diagnosis codes that have already been submitted for risk adjustment reimbursement. Nor are they provided a way, if they find that a previously submitted diagnosis was incorrect, to report that information to Medicare.

106. When, after a medical record review, MedAssurant decides to submit an HCC claim, it converts the necessary data about the new diagnosis into the CMS-required file format and either provides the files to the CARA client or submits the files directly to CMS.

107. MedAssurant promises significant return-on-investment (“ROI”) from its CARA solution. The company claims in its promotional material that many plans achieve reimbursement gains in excess of \$3,200 per confirmed CEDI. MedAssurant is so confident in the profitability of its services that it allows client health plans to set “ROI thresholds” requiring the achievement of specified financial gains. Overall, MedAssurant reports that ROI typically ranges from 7:1 to 12:1, but can be in excess of 27:1.

108. MedAssurant also offers a Claims Aggregation, Analysis and Submission (“CAAS”) solution, which it calls a “staple to CARA clients.” For CARA clients, the addition of the CAAS solution provides that MedAssurant will convert not only the new diagnoses, but all of the health plan’s raw data into the required format for submission to CMS.

VI. DEFENDANTS’ FRAUD AGAINST THE UNITED STATES

109. As outlined below, since at least 2006, Defendants have engaged in a deliberate scheme to defraud the United States by submitting tens or hundreds of thousands of false claims for risk adjustment payments. Defendants submitted these false claims even though they knew that the patients upon whom the claims were based did not

have the claimed diagnoses, had not been treated for those diagnoses in that year, or were otherwise ineligible for risk adjustment payments under CMS rules.

110. Defendants routinely “upcoded” the risk adjustment claims they submitted to Medicare, claiming that a patient had been treated, in the relevant time period for: (a) a diagnosis that the patient did not have; (b) a more severe diagnosis than the one the patient had; and/or (c) a diagnosis that the patient may have previously been treated for, but which was not treated in the relevant year.

111. Defendants engaged in the upcoding both directly, by creating documents to use to submit the risk adjustment claims themselves, or indirectly by paying, encouraging or otherwise convincing physicians, hospitals or others to submit upcoded data to Defendants, which upcoded data Defendants then used to submit risk adjustment claims.

112. Defendants also refused to correct previously submitted risk adjustment claims even though the Defendants knew, or should have known, that those claims were false. Defendants were on notice that certain individual risk adjustment claims or certain classes of claims were potentially or likely false, but nonetheless submitted them without attempting to ensure their accuracy.

113. In this manner, Defendants have fraudulently caused CMS to pay tens or hundreds of thousands of false claims for risk adjustment payments worth at least hundreds of millions of dollars.

A. United Knowingly Submits, and Causes To Be Submitted, False Risk Adjustment Claims and Fails to Correct Previously-Submitted False Risk Adjustment Claims

1. United Upcodes Risk Adjustment Claims

114. UHG engages in an aggressive and extensive effort to find a justification or pretext to submit risk adjustment claims for additional diagnoses—regardless of whether the patient had or was actually treated for the diagnosis in the relevant period by a qualifying provider. United’s program has some components that are broad-based, and others that target specific high value HCCs. As an overall goal, UHG attempts to reach each of its members at least once every two years through one of its programs designed to find additional risk adjustment claims.

115. United runs multiple programs designed to identify additional HCCs for submission to CMS to increase its risk scores, including: (a) reviewing medical charts, (b) paying physicians bonuses for submitting paperwork to support claims for additional diagnosis codes, (c) sending physicians forms identifying conditions that United suspects the patient has, and (d) initiatives designed to get patients to visit their doctors each year for the purpose of being “treated” for high value diagnoses.

116. These programs are designed with one primary goal – to increase UHG’s Medicare risk adjustment reimbursement. Accuracy of the claims is, at best, a secondary concern.

117. United has used its programs to promote increased coding of numerous HCCs that United knows are regularly submitted by providers when those providers should have submitted a less severe HCC code or no code at all. Notwithstanding this knowledge, United not only refuses, beyond a limited audit sample, to confirm the accuracy of these codes when submitted, but actually pushes chart reviewers, physicians,

and others to code for these problematic HCCs more often. United calls them “undercoded” HCCs.

118. Some examples of such HCCs that United knows are over-coded, but still encourages reviewers and providers to increase coding for include, but are not limited to, HCC 7 (Metastatic Cancer and Acute Leukemia), HCC 8 (Lung, Upper Digestive Tract, and Other Severe Cancers), HCC 9 (Lymphatic, Head and Neck, Brain, and Other Major Cancers), HCC 10 (Breast, Prostate, Colorectal and Other Cancers and Tumors), HCC 15 (Diabetes with Renal or Peripheral Circulatory Manifestation), HCC 16 (Diabetes with Neurological or Other Specified Manifestation), HCC 18 (Diabetes with Ophthalmologic or Unspecified Manifestation), HCC 19 (Diabetes without Complication), HCC 21 (Protein-Calorie Malnutrition), HCC 51 (Drug/Alcohol Psychosis), HCC 52 (Drug/Alcohol Dependence), HCC 55 (Major Depressive, Bipolar, and Paranoid Disorders), HCC 69 (Spinal Cord Disorders/Injuries), HCC 71 (Polyneuropathy), HCC 80 (Congestive Heart Failure), HCC 82 (Unstable Angina and Other Acute Ischemic Heart Disease), HCC 92 (Specified Heart Arrhythmias), HCC 96 (Ischemic or Unspecified Stroke), HCC 105 (Vascular Disease), HCC 108 (Chronic Obstructive Pulmonary Disease), HCC 108 (Chronic Obstructive Pulmonary Disease), HCC 112 (Pneumococcal Pneumonia, Empyema, Lung Abscess), HCC 131 (Renal Failure), HCC 132 (Nephritis), and HCC 155 (Vertebral Fractures w/o Spinal Cord Injury).

119. United trains and otherwise encourages its chart reviewers to identify diagnoses that do not qualify for risk adjustment claims. Chart reviewers are encouraged to look beyond members’ provider-reported diagnoses and identify diagnoses from

supplementary data in the medical records. United submits these additional diagnoses without seeking any confirmation from the appropriate providers.

120. For example, in January 2009, a representative of the University Physician's Network ("UPN") emailed United's executives to inform them that, because of Ingenix's illegal practices, UPN was terminating its plan to assist United with the collection of diagnosis information. The email explained that Ingenix's chart review methods result in the submission of diagnoses that were not certified by, and may not be supported by the treating physician. The UPN representative reported that Ingenix's staff attempted to assure him that the practice was legal, but that research and consultation with others confirmed that Medicare regulations do not permit a "non-treating [provider]...submitting data for the purpose of increasing the compensation to United from Medicare."

a) Chart Review

121. As described above, the vast majority of the information United uses as the basis for its risk adjustment claims comes initially from physicians, hospital or other providers in the form of claims data or other submissions. These sources are secondary to the primary records those providers hold—namely the patients' medical records, also known as charts.

122. As is common with secondary sources, the claims data and other information United receives from providers is known to have some (and at times many) errors—even when providers make good faith efforts to submit only accurate information. (As discussed in greater detail below, some providers deliberately upcode their claims information to manipulate the risk adjustment system; often because United pays them kickbacks to do so.)

123. For example, in some cases, the claims data does not include all of the diagnosis codes that it should. Providers often fail to document all diagnoses that were treated, because, historically, complete reporting of all treated diagnosis codes was generally not essential for reimbursement.

124. In other cases, the claims data erroneously indicates a patient was treated for a certain diagnosis. Sometimes this happens because of mere clerical error, but often it is the result of limitations in claims processing computer systems or a misunderstanding by coding personnel of the proper coding rules. For example, coders sometimes indicate that a patient was treated for a certain diagnosis, where, in fact, the patient only had a history of past treatment for the diagnosis, or the patient was tested to see if they had that diagnosis.

125. Moreover, there are routinely situations where the coding personnel correctly identify the patient as having been treated for a certain diagnosis, but make a mistake as to how severe the patient's illness is. Thus, the coders may either overstate or understate the severity of the diagnosis.

126. United's chart review program is designed to directly review the original documents—the patient medical records held by the providers—to correct these known problems.

127. Because United has a duty to submit accurate data, and it knows that the claims data contains substantial errors, it has a dual responsibility when conducting these reviews: it should verify that already-submitted codes are accurate and documented while it looks for codes that should have been, but were not, submitted to CMS. However, as

detailed below, United fails to meet his obligation to identify and correct previously submitted, but erroneous risk adjustment claims.

128. Ingenix conducts chart reviews on behalf of UHMR, UHCS, and commercial clients. In the retrospective chart review process, Ingenix identifies provider charts to review and arranges for the charts to be collected. It uses both internal coders and also contracts with external vendors to review and code the charts.

129. These vendors review charts using a blind review. In a blind review, the reviewer codes every condition he or she identifies from the chart without knowing what codes the provider identified from the chart previously. Thus, the reviewer works from the raw chart material and reaches independent conclusions.

130. Ingenix conducts chart reviews provider-by-provider. For each provider, members are selected for review, with a priority placed on members who have not been reviewed in the past year and members whom United believes may have a risk adjusting condition that has not been reported to CMS. Following every provider review, the reviewer submits the diagnosis codes it found to Ingenix.

131. Ingenix defrauds CMS by acting on chart review data in two very different ways: it acts on the missed codes by submitting risk adjustment claims to CMS, but takes no action on the incorrect codes.

132. When it receives the data from the reviewer, listing the diagnosis codes found during the review, Ingenix inputs the list into IRADS, its risk adjustment database (discussed in greater detail below). IRADS' design adds the reviewer's codes to the codes already in the system (*i.e.*, the provider's codes) like pouring additional water into a bucket.

133. For codes the reviewer coded but the provider did not code, IRADS will add a new entry. If this is a newly discovered diagnosis code for that patient—meaning no other provider had also reported treating the patient for that diagnosis during that time period—Ingenix will then submit a new risk adjustment claim to CMS.

134. Ingenix could easily perform a comparable comparison to look for over-coded diagnosis codes. Using either the data available from the chart reviewers or readily available additional information, Ingenix could determine whether a diagnosis code contained in IRADS was absent from the patient’s medical record for that given provider. Ingenix, however, refuses to take any steps (other than an extremely limited program described below) to determine whether the chart review data has identified over-coded claims.

135. For situations where an existing code (*e.g.*, one a provider had submitted with its claims data) was not validated by the reviewed provider’s medical records by the reviewers, IRADS does nothing. No effort is made to find other support for the diagnosis code or to delete from the IRADS system any claims that suggested the reviewed provider had treated the patient for the non-validated diagnosis.

136. United has also found high error rates in diagnoses identified by a former external chart review vendor, Outcomes, Inc., but, beyond a limited audit sample, United has not reviewed the vendor’s work in order to determine the extent of CMS’s overpayment for the vendor’s erroneous diagnoses.

137. Chart reviews have been lucrative for United. For 2006 dates of service, the first year of fully phased-in risk adjustment, United’s return on investment (“ROI”) from chart reviews was 15 to 1. Exhibit 4, incorporated herein. United spends

approximately \$30 for each chart it reviews but receives an average of \$450 per chart in additional CMS payments for the new codes it submitted. *Id.*

138. Relator believes that even if United properly conducted chart review—“looking both ways” for both helpful and harmful errors—United would still earn substantially more in newly found codes than it lost by correcting erroneous codes. However, United has steadfastly refused to take anything more than token steps to “look both ways.”

139. Unsurprisingly, UHMR and Ingenix have emphasized performing as many chart reviews as possible. UHMR reviewed approximately 600,000 charts in 2006 and approximately 600,000 in 2007. *See* Exhibit 4. On information and belief, Ingenix reviewed between 600,000 and 800,000 charts in 2008. In 2009, Ingenix reviewed approximately 800,000 charts. Exhibit 5, incorporated herein. United’s only limitation in the number of charts it can review is its providers’ dislike of the disruptions the reviews cause to their practices.

140. In 2010, United’s senior executives set a target for United’s risk adjustment programs to generate an additional \$100 million in internal operating income (“IOI”) above and beyond what was originally targeted. For 2011, United’s incremental IOI target for risk adjustment is \$125 million. Chart reviews are an important part of United’s strategy for realizing this additional IOI. United’s senior executives are fully aware that the company “looks one way” during chart reviews. *See* ¶¶191–197.

b) Patient Assessment Forms

141. In addition to the chart review program, which involves broad review of the provider medical records, United has several initiatives which are targeted to a specific subset of patients or providers. As with the chart review program, these other

initiatives are designed to “look” just one way—seeking only to add incremental codes and ignoring evidence that previously submitted risk adjustment claims may be false.

142. United’s Patient Assessment Forms (“PAF”) program targets suspected undercoded conditions, such as certain chronic conditions that a provider or group has coded less frequently than their prevalence rates would indicate. For these conditions, such as diabetes and chronic kidney disease (“CKD”), Ingenix mines patient data for episodes in which a patient with a chronic condition has not been treated for a diagnosis during the payment year.

143. The PAF program also identifies target patients by looking for situations where a patient filled a prescription for a drug that suggests the patient has a given diagnosis, or engages in a behavior (*e.g.*, smoking) that suggests a risk adjustment eligible diagnosis may be present.

144. Ingenix prepares a form for these target patients and sends the form to their doctor, so he or she can “treat” the patient for that condition. For example, if a provider diagnosed a member with diabetes in 2008 and 2009 but not 2010, Ingenix would send the provider a PAF and ask the provider to check the member for diabetes.

145. Ingenix pays providers a fee to encourage them to consult PAFs when treating their patients.

146. The program may have certain clinical benefit if and to the extent it helps ensure that members with chronic diseases receive treatment for their conditions. However, that clinical concerns are not driving this program is demonstrated by which patients are targeted. For example, PAFs are only distributed to providers for members for whom United, or one of its risk adjustment clients such as Health Net, receives risk

adjustment payments from CMS. If United were using the PAFs to improve clinical outcomes, they would include all their members, including their non-Medicare members, in the PAF program. Furthermore, as with the chart review program, the PAF program focuses solely on conditions that tend to be under-coded—and thus for which improved coding accuracy stands to increase revenue. Ingenix chooses the conditions it targets through PAFs based on revenue impact, not clinical impact, and ignores conditions that are frequently overcoded.

147. For example, United knows that cancer and stroke are often improperly coded years after the patient stopped receiving treatment. United could use the PAF program to highlight these potentially overcoded conditions to providers. For example, if a member has been coded with an acute episodic stroke for three continuous years, United can easily notify the provider that two of the three codes are probably incorrect. The member most likely had a stroke in the first year (*i.e.*, not each year) and the condition should now be coded as “history of stroke.” United could alert the provider as to its suspicion, ask the provider to assess their coding and documentation for accuracy, and submit a medical chart supporting the diagnosis. United does not include this information in its PAF reviews, however, because the provider’s poor coding habits actually increase United’s reimbursement from CMS. Therefore, though patients and providers might benefit from knowing this information, United chooses not to use it because it would decrease United’s revenue from CMS.

148. Initially, Ingenix received completed PAFs from providers and submitted the diagnoses listed on the PAF without reviewing the medical record. More recently, Ingenix has required that the medical record accompany the completed PAF—

purportedly so that diagnoses claimed on the PAF could be “validated.” Instead, United actually reviews these medical records for incremental diagnoses that the provider may have missed. In this way, the PAF program has become a one-way chart review designed to only find incremental codes to submit to CMS for reimbursement.

149. United not only skews the PAF program to focus solely on undercoded diagnoses, it prevents providers from taking the initiative on their own to focus on overcoded conditions. Ingenix maintains an online provider portal, called Insite, that “percent of premium” capitated providers (*see* ¶¶201–202) use to manage risk adjustment activities for their members.

150. Insite contains numerous reports geared towards helping providers assess, diagnose and code incremental conditions. One such report, for example, is the Central Suspect Report (“CSI”). Similar to PAFs, this report lists conditions that United suspects the member may have, but are not coded currently. Another report is the Declining RAF report. This report ranks members with risk scores that have declined period over period, a fact that highlights to providers that they may have missed one or more conditions in their coding. Some Insite reports go so far as to calculate the estimated financial impact of coding a particular condition. This allows the provider to estimate the incremental reimbursement the provider would receive from United by coding the specific condition. Similar to United’s other risk adjustment programs, Insite is designed to identify incremental diagnosis codes that United may submit to CMS for payment.

151. To Relator’s knowledge, however, Insite contains no function for providers to notify United of overcoded conditions.

152. Relator brought the discrepancy between overcoded and undercoded conditions to the attention of senior UHMR and Ingenix management. Management dismissed his concerns, however, arguing there were “better ways” to address overcoded conditions, such as chart validation, discussed below. Both UHMR and Ingenix knew, however, that the chart validation program was incredibly limited, and that the company had no plans to provide resources to address the problem of overcoded conditions through that program.

153. Instead, the PAF program is deliberately limited to seeking under-coded diagnosis codes so that United can avoid discovering over-coded diagnoses that it knows exist.

c) Clinical Operations Initiatives

154. Clinical Operations Initiatives (“COI”) is a program designed in part to “improve” the coding of conditions that United believes are frequently “undercoded.” One such COI focuses on diabetes coding. As described above, the HCC model assigns multiple HCCs to conditions, such as diabetes, that have variations in severity and cost. For instance, a patient with well-controlled diabetes is likely to incur lower medical expenses than a patient with uncontrolled diabetes and complications. CMS therefore assigns a lower-paying HCC to well-controlled diabetes and a higher-paying HCC to uncontrolled diabetes. The goal of the COI program is to increase the severity of the diagnosis codes assigned to patients with one of these target HCCs.

155. Originally, the COI program sought to improve diabetes coding by monitoring providers with high percentages of HCC 19 codes. HCC 19 is a code for diabetes without complications. The risk score associated with HCC 19 is much lower than the risk score for HCC 15, which is the code for diabetes with renal complications.

United suspected that some providers were coding HCC 19 when one of the more severe diabetes codes (HCC 15–18) would be more appropriate.

156. Under the COI program, United pays providers approximately \$100 for each diabetes patient they assess for diabetes complications, submit a supporting diagnosis via a claim, and submit a medical record with matching documentation. In addition, it pays \$200 for each doctor that receives training on the COI program and diagnosis coding. Recently, the COI program has expanded to other conditions that United suspects are frequently undercoded, such as chronic kidney disease (“CKD”), and chronic pulmonary disease (“COPD”).

157. Like the PAF program, however, United does not pay doctors to improve coding for conditions that are frequently overcoded. Again, United knows that cancer and stroke are generally overcoded. But because improving their accuracy would decrease revenue, United does not include these conditions in COI. Instead, COI is limited to conditions United believes are the most frequently undercoded, such as diabetes, CKD, and COPD, and represent large opportunities for increased reimbursement from CMS.

158. In addition, United looks one way with the medical records it receives from doctors under the COI program. Thus, when United receives a chart, it does not check whether the other diagnoses listed in the chart (such as those submitted through claims) are correct.

159. Even worse, Relator has information and believes that United does not delete its previous diagnosis when the provider submits a medical record that diagnoses the member with a *less* severe condition (such as diabetes) than before. For example,

United may send the doctor a list of diabetic members to assess. One or more members may be coded with HCC 15 (diabetes with complications). If the doctor submits a claim and medical records for that member diagnosing the member with HCC 19 (diabetes without complications), United does not submit a delete code to CMS for HCC 15. United simply assumes, without justification, that another doctor was responsible for the HCC 15 code. Similar to its chart reviews, therefore, United affirmatively solicits diagnoses from its providers but ignores them when they cast doubt on the validity of a higher-paying diagnosis.

d) Other Initiatives to Increase Risk Adjustment Payments

160. Ingenix runs several additional programs to increase risk adjustment payments, including:

161. ***Provider Attestations:*** Medical charts must be signed, credentialed and dated to be used to validate a diagnosis. When Ingenix performs chart reviews, it identifies charts that are missing one of these elements, preventing United from submitting the incremental diagnoses found in those charts to CMS for payment. To get around this obstacle, when Ingenix identifies a chart that is (1) missing an administrative element and (2) contains an incremental diagnosis that would increase United's reimbursement from CMS, Ingenix sends an attestation form to the provider to confirm the administrative elements. If it receives the attestation from the provider, Ingenix submits the incremental codes in the charts to CMS for risk adjustment payment. If it does not receive the attestation, however, Ingenix does not delete any codes that the provider previously submitted for that member, even though Ingenix knows the member's chart is invalid. Moreover, when Ingenix identifies a chart that is missing an administrative element but does *not* contain an incremental diagnosis, Ingenix does not

send an attestation form to the provider, though it knows United may have submitted diagnoses to CMS based on the invalid chart.

162. **Members without Visits:** To encourage members to visit their doctors at least once each year, Ingenix works with providers to schedule annual checkups. In some cases, this program can have clinical benefits, if the physician actually treats the patient, substantively, for the condition in question. However, in other situations, the visit is medically unnecessary if the patient is merely brought in so that the physician can “code the diagnosis” United has flagged for risk adjustment purposes.

163. **Hospital Data Capture:** Under this program, Ingenix elicits “data dumps” from hospitals to ensure it has received all of their diagnosis codes. Hospitals often enter more diagnoses for a patient than are transmitted to United. The Hospital Data Capture program is designed to retrieve the incremental codes that United did not receive so that United can submit those codes to CMS for payment.

164. **Provider Coding Training:** United trains providers on how to code “properly.” United often directs training to providers with low risk scores or with a financial incentive to increase risk scores, such as percent of premium capitated providers. Historically, however, it did not proactively offer training to providers who performed poorly in validation audits, because they routinely over-coded diagnoses. Only recently has United begun offering any such training. The reason, again, is that United’s priority is increasing code submissions.

165. United employs each of the above programs to increase its risk adjustment payments from CMS. In 2010 and 2011, United’s management directed UHMR to increase its internal operating income from risk adjustment by \$100 million and \$125

million, respectively, above and beyond what was already planned. UHMR worked to achieve the targets by increasing its risk adjustment scores by capturing past conditions (PAF), decreasing the percentage of members without visits, increasing the number of providers that use Insite, and performing more chart reviews.

166. The company monitored the progress of each program closely. The pressure to earn \$100 million in additional risk adjustment income, however, gave UHMR no incentive to identify, block, and delete incorrect codes. In fact, the company viewed the possibility that it would have to start reviewing charts for incorrect codes as a negative. In a January 2010 “Coding Accuracy Progress Report,” UHMR warned, “Potential changes to general coding accuracy strategy, including chart audits, could impact 2010 results.” Exhibit 6, incorporated herein. In other words, looking both ways in chart reviews to identify both incremental and incorrect codes would jeopardize its ability to achieve the \$100 million target.

2. United Fails To Correct (and Reimburse Medicare for) False Risk Adjustment Claims

167. United knows that much of the claims data and other information that it receives from physicians and other providers is unreliable. For this reason, United engages in extensive and expensive initiatives to review and correct that claims data, outlined in the prior section. Unfortunately—for the United States—United deliberately chooses to look only one way in its remedial efforts.

168. United designs its chart review and other corrective initiatives to seek out only errors that, if corrected, will lead to increased risk adjustment payments. With the exception of certain small programs—designed to provide the appearance of fairness—United deliberately designs these programs to avoid discovering that United’s previously

submitted risk adjustment claims are false (and thus that United should submit a “delete” code).

169. Although many of these programs could easily be used to look for both incremental and delete codes, United has deliberately structured them to look only for incremental codes. To provide cover for its scheme, United has a few limited initiatives designed to look for delete codes. However, these initiatives designed to find false claims are far smaller than their counterparts, and are subject to far stricter data validation rules.

170. Notwithstanding its efforts to avoid learning that previously-submitted claims are false, United nonetheless often generates information that gives it reason to question the accuracy of diagnosis codes it has already submitted to CMS. United, however, intentionally (and myopically) does not compare the information to the diagnoses it has already submitted to CMS. Instead, United simply submits the incremental diagnoses it finds to CMS, purposely ignoring all evidence or suggestions of invalid diagnoses that it submitted improperly in the past.

171. Perhaps the best evidence of both United’s knowledge that the underlying claims data requires verification, and United’s fraudulent refusal to correct false claims, is the disparity between its efforts to find “incremental” (new) codes and “delete” (previously submitted, but false) codes. United attempts to review a medical record for every member once every two years to try to find incremental codes, but only has a nascent, limited project to identify delete codes. For 2009 dates of service, United reviewed approximately 1.4 million charts to try to find incremental codes, but only

reviewed approximately 3,000 to 5,000 charts to try to find delete codes (and even then, only a limited portion of each chart was reviewed).

172. United has half-heartedly created a small chart validation program that is little more than a fig leaf designed to obscure its misconduct, and has been dragging its feet for years in completing a very limited pilot program designed to develop a system to look both ways.

173. Under the chart validation program, Ingenix selects providers who have coded certain HCCs at levels significantly above the condition's national prevalence rate. Ingenix audits the providers' charts for those codes to determine if the codes were properly documented and substantiated.

174. United, however, imposes four restrictions to limit the number of validation audits it performs. First, the provider who submitted the code must be a Level I provider, defined as a provider with a financial incentive contract with United, such as a capitation or gainshare agreement. This limitation excludes both large provider groups without coding incentives (Level II) and small provider groups (Level III). Second, the provider must have at least 500 United Medicare members. Third, for an HCC to qualify as "suspect," the provider must have coded it at over 300% of Ingenix's national prevalence rate. Fourth, United reviews a small number of members (initially only 30) per provider and HCC, often a tiny sample size relative to the number of codes the provider submitted.

175. Ingenix's approach to chart validation is therefore highly focused and excludes a vast majority of United's providers and risk adjustment data. None of the limits on chart validation exist for chart reviews. For example, whereas chart validation

contains safeguards to ensure diagnoses are not improperly deleted, United submits diagnoses from outside vendors' chart reviews without validating them in any way. The reason for the limits on chart validation is that chart validation is an expense that has no revenue potential.

176. Ingenix's chart validation program reviewed 4,000 charts in 2010 for the 2008 and 2009 service years. By comparison, Ingenix's chart review program reviewed approximately 1.4 million charts for the 2008 and 2009 service years. *See* Exhibit 5 (2009 chart reviews).

177. Despite their limited scope, Ingenix monitors the results of its validation audits closely. It compiles data on the validation percentages of each HCC, as well as the validation percentages for each provider group. Often, Ingenix identifies specific HCCs and specific provider groups with low validation (*i.e.*, high error) percentages. In May 2009, for instance, Ingenix's Dr. Maninder Khalsa identified five problem HCCs (with 15 to 30% error rates): HCC 10 (breast, prostate, colorectal cancers); HCC 96 (stroke); HCC 15 (diabetes with renal/circulatory complications); HCC 105 (vascular disease); and HCC 92 (arrhythmias).

178. Similarly, an Ingenix validation audit of 2008 codes from Hemet Community Medical Group reviewed 30 HCC 67 (quadriplegia) codes and validated only two. Though this was an extreme result, Ingenix identified dozens of other provider groups with low validation totals in specific HCCs.

179. Previously, United did little to nothing with the data it found during chart validation. Though it submitted delete codes for diagnoses that it could not substantiate, until recently Ingenix did not expand its search when it identified a problem area.

Recently it has enacted a policy calling for an expanded review of any HCC that validates 80% or less of the time.

180. Nor has Ingenix targeted known over-coded conditions, such as cancer or strokes, for additional scrutiny. (By contrast, in 2009 Ingenix planned a “High Value Suspects” initiative to target potentially under-coded, high-revenue members and providers.)

181. In 2010, United developed a pilot program that would look for both incremental and unsupported diagnoses during chart reviews. Though aspects of the pilot program have recently been adopted, United continues to stack the deck in favor of submitting incremental codes. The pilot, as well as United’s subsequent program, contain several limitations that do not exist in ordinary chart reviews.

182. First, the pilot was limited to members with only one provider so that United does not delete a diagnosis that some other provider’s chart might validate. This restriction does not apply to chart reviews—during chart reviews, whenever United identifies a chart that calls another provider’s diagnosis into question, it ignores the chart. United’s limited program to look both ways subsequent to the pilot continues to only review charts from members with just one provider.

183. Second, United limited the number of charts the pilot program reviewed so that it had time to validate all of them before CMS’s January 31, 2011 deadline for submitting diagnoses from 2009 dates of service. In contrast, United does not limit its efforts to find *incremental* codes before the January 31 deadline to build in time to ensure the codes are valid. On the contrary—United runs special programs up to the deadline to find as many incremental diagnoses as possible. United does not pause to check whether

it will have enough time to validate these incremental diagnoses, because it simply does not validate the diagnoses it submits.

184. United's refusal to correct errors in its risk adjustment claims is so extreme that it submits risk adjustment claims to CMS for diagnoses taken from claims that it itself refuses to pay as being fraudulent and/or abusive.

185. Through its fraud and abuse department, regular claims processing efforts, and some of the other initiatives discussed in greater detail above, United routinely learns that the claims data that was used as the basis for certain risk adjustment claims is erroneous. Nonetheless, United routinely submits risk adjustment claims—or fails to correct previously submitted claims—in purported reliance on that false data.

186. Like most insurance companies, United contains a Fraud and Abuse Prevention Unit ("F&A") in Ingenix that is responsible for identifying and resolving fraudulent claims. F&A mines claims data for anomalies that suggest a fraudulent claim. For example, F&A looks for claims for drugs that were not truly administered to patients, such as patients who supposedly received cancer drugs despite not having a cancer diagnosis. If and when F&A identifies a claim that it considers sufficiently false to be fraudulent, it takes action against the provider who submitted the claim, either by denying the claim or demanding reimbursement.

187. Ingenix, however, refuses to use this information to correct its risk adjustment database or claims submissions. Ingenix's F&A unit does not report the fraudulent claim to Ingenix's Clinical Assessment Solutions ("CAS") group; thus the CAS group cannot block submission of the claim's diagnosis codes to CMS or delete HCCs it already submitted due to the claim.

188. Ingenix knows that CAS is submitting fraudulent codes to CMS because it cannot interact with F&A, but has chosen not to fix the problem. Beginning as late as 2009, Ingenix explored improving the coordination between CAS and F&A as a way to increase coding accuracy. Dr. Maninder Khalsa of CAS stated in May 2009 that “[w]e have reached out to the INGENIX Fraud and Abuse Prevention Unit in an effort to coordinate our areas of expertise and collaborate where possible.” During that time and subsequently, Relator recommended to Ingenix that it must coordinate CAS and F&A to prevent the submission of fraudulent codes. He voiced these same concerns to his superior at UHMR, Scott Theisen. Ingenix, however, has refused to fix the problem.

189. United’s submission of fraudulent codes reflects its broader failure to coordinate its claims processing system with IRADS (the system it uses to process and submit risk adjustment claims), as discussed below. Specifically, when a claim is denied, United deliberately refuses to check whether the denial affects the validity of risk adjustment claims, *i.e.*, whether it compels United to delete any diagnosis codes.

190. There are similar problems with other programs and initiatives at United. As described above, in other situations, United learns through chart review initiatives or other programs that certain claims data or other sources of diagnosis codes used in risk adjustment claims are false. United deliberately refuses to delete those false diagnosis codes from its risk adjustment claims systems, and refuses to correct previously submitted risk adjustment claims that were based on those false diagnosis codes.

3. United Continues To Develop New Programs To Seek New Claims To Submit, While Slow-Walking Its Limited Efforts to Correct Overcoded Claims

191. Relator has spoken with senior United executives about, and has other personal knowledge that those executives are aware of, the fraudulent risk adjustment

practices discussed in this Complaint, including United's chart review practices and other risk adjustment initiatives. On this basis, Relator knows that at least the following United executives know about some or all of the problems discussed herein, and have participated in the scheme to continue submitting fraudulent claims and to refuse to correct previously submitted false claims: Stephen Hemsley, UHG Chief Executive Officer; Gail Boudreaux, UHG Executive Vice President and CEO of United Healthcare; Larry Renfro, Optum CEO; Tom Paul, UHMR Chief Executive Officer; Cindy Polich, UHMR President; Lee Valenta, Ingenix's former Chief Operating Officer (and current President of Ingenix's Life Sciences Division); Jack Larsen, former CFO of PSMG (and current CEO of UHCS); Scott Theisen, UHMR Senior Vice President of Finance; Jeff Dumcum, Senior Vice President of Ingenix; and David Orbuch, PSMG Chief Compliance Officer.

192. Although numerous United officials have acknowledged to Relator that the company should be "looking both ways" when it tests the validity of its risk adjustment data sources, United continues to focus almost exclusively on adding incremental codes. Although United has created a very limited "pilot project" to test the possibility of "looking both ways" during chart reviews, that program gets limited resources and serves primarily as a fig leaf to mask the one-sided nature of United's efforts.

193. Though the pilot is only experimental, United invokes it as justification for continuing its fraudulent chart reviews. In an email on September 9, 2010, UHMR President Cindy Polich emailed Relator that she and UHMR Chief Executive Officer Tom Paul had discussed whether to increase chart reviews despite knowing the reviews

disregarded incorrect codes, and “had resolved the issue of concern by agreeing to develop and implement a pilot.” Exhibit 7, incorporated herein. Polich told Relator that she and Paul “both agreed that this issue should not stand in the way of moving forward with additional chart audits.” *Id.* In May 2011, UHMR CFO Scott Theisen decided that UHMR should limit the number of chart reviews and PAFs it performed in 2012 to the number it performed in 2011, due to his “compliance concerns.” At or around the same time, Theisen told Relator and senior executives at Ingenix that he had discussed the chart review problem, as well as the IRADS problems discussed below, with UHG CEO Stephen Hemsley and UHG Executive Vice President Gail Boudreaux.

194. Moreover, United continues to invest significant resources toward finding incremental diagnoses while at the same time devoting significantly fewer resources to the pilot or to fixing IRADS. For example, United developed “playbooks” containing ideas for increasing its risk scores. These playbooks are garnering top-level attention at the company while the myriad problems with United’s risk adjustment programs and processes go unresolved.

195. United conceals the one-way nature of its risk adjustment programs from CMS and even its investors. For example, United’s remediation plan for 2010 that sought to increase IOI by \$800 million allocated \$100 million to “Project 7.” Project 7 was United’s codeword for initiatives to increase risk adjustment payments. The company used a codeword (as opposed to “growth,” “enrollment,” or “claims”) because it did not want CMS or other investigatory government agencies to know it had a campaign to claim an additional \$100 million through risk score increases.

196. Similarly, during its fourth-quarter earnings call on January 21, 2011, Tom Paul, CEO of UHMR, told investors that UHMR “on a year-over-year basis” was seeing “improvements” in its risk adjustment “accuracy rates.” This statement was misleading, for while UHMR had found and submitted a substantial number of incremental codes, it has no evidence that its submissions were more accurate (*i.e.*, the error rate of the data it submits has decreased). This fact is well known at United.

197. At Relator’s urging, United has changed the text of the letters it sends to providers about chart reviews to remove the word “accuracy.” The letters now say that United reviews charts to ensure it submits “complete diagnosis information” to CMS, not complete and accurate information.

4. United Encourages Providers To Uptime, and Submits False Risk Adjustment Claims Based on That Uptime

198. United encourages and provides incentives to its provider groups and risk adjustment vendors to uptime their claims data, and then uses that uptime data to submit false and/or fraudulent risk adjustment claims to Medicare. Moreover, even when it is faced with evidence that a provider or provider group is routinely uptimeing its diagnosis information, United does little or nothing to either correct the provider’s coding practices, or give that provider’s claims information special scrutiny before using it as the basis for the submission of a risk adjustment claim to Medicare.

199. United routinely provides physicians, hospitals and other providers information on diagnoses that United wants them to code more frequently. Often this information is presented as educational material designed to increase coding accuracy. Significantly, though, this information routinely focuses only on diagnoses that, if coded, would lead to increased reimbursement for United. In fact, United often pairs this coding

“advice” with information on how much money United (and, often, the providers themselves) stands to make if the diagnoses is coded more often.

200. United routinely couples such promotion of the coding of lucrative diagnosis codes with direct financial benefits (hereafter “kickbacks”) to providers to encourage them to increase the number and severity of diagnoses they submit to United. Since at least 2005, UHMR has offered providers additional payments if and when the providers’ patients’ risk scores increased.

201. United customizes its kickbacks depending on the nature of its overall reimbursement arrangement with the provider group. The providers United chooses to pay additional amounts for increased risk scores are those that do not already have an incentive to upcode diagnoses. United uses three basic payment structures for its providers: (1) percent of premium capitated providers, which receive a percent of United’s CMS premiums for its patients; (2) “fixed” capitated providers, which receive PMPM payments from United that are not tied to United’s CMS premiums; and (3) fee-for-service providers, which are paid based on the claims they submit to United.

202. “Percent of premium” capitated providers already share an incentive with United to upcode diagnosis codes, because they stand to earn a percentage of the additional revenue from CMS.

203. Flat capitated providers and FFS providers, however, have no financial incentive to upcode diagnoses. United makes up for this by paying a “bonus” (kickback) if and when such providers increase their risk scores.

204. Generally speaking, United pays fixed capitated providers a PMPM amount for its members, with the provider carrying the risk of covering the members’

healthcare costs. To encourage fixed capitated providers to maximize risk adjustment submissions, however, UHMR pays them an extra percentage of the capitation rate (or other bonus) when their patients' risk scores increase.

205. For example, a January 1, 2009 Health Services Agreement between PacifiCare and Banner Physicians Hospital ("Banner") promised to pay the hospital "an additional increase in Capitation Payment PMPM retroactive to January 1, 2009 if the increase in RAF [risk adjustment] score between July 2008 and July 2009 is in excess of 3%." Exhibit 10, incorporated herein. The amount of the increase equaled the amount of the percentage increase over 3%, such that a 4% increase in risk score would increase Banner's capitation payments by 1%. *Id.*

206. UHMR's contract with Banner reflects its policy and practice of offering providers (both capitated and fee-for-service) financial incentives to increase their risk adjustment submissions. These agreements exist across UHMR's plans, and were entered into between 2005 (or earlier) and 2010. The agreements are kickbacks that give United's providers a financial incentive to upcode the diagnoses codes they submit on their claims.

207. Similarly, WellMed's 2005 contract with PacifiCare (later United) for DataRap services included annual payments according to a payment schedule tied to increased risk scores. Exhibit 12, incorporated herein. (If risk scores fell below a 2005 benchmark, no payment was due to WellMed.)

208. Moreover, PacifiCare agreed "to pay a[n additional] contingency for *maintaining* an increased HCCRAF [*i.e.*, risk] score." *Id.* at 12 (Emphasis added.) Thus, if WellMed maintained United's high risk scores year over year, PacifiCare would pay

WellMed an *extra* amount annually on top of the payment schedule. These fees totaled \$450,000 in 2006, between \$3.1 and \$3.5 million in 2007, \$5.2 million in 2008, and \$6.4 million in 2009. For the reasons described above, WellMed's contract contains a kickback and motivated WellMed to report inflated risk scores.

209. United also enters into contracts known as gainshare agreements with certain FFS provider groups. Under these agreements, United and the provider group agree on a target benefit-cost ratio ("BCR"). If the provider group achieves a BCR lower than the target, United and the provider share the savings.

210. United also provides kickbacks to provider groups by renegotiating the terms of gainshare agreements to ensure the groups realize savings. For example, on January 24, 2011, UHMR Vice President of Finance Tim Noel told Relator that United and MedicalEdge, a provider group in Texas, entered into a gainshare agreement for a particular year in which the target BCR was 79% and any savings would be split 60/40 between MedicalEdge and United. In May of that year, United renegotiated the agreement. The new agreement raised the BCR from 79% to 82%, making it easier to attain, but changed the split from 60/40 to 50/50. Though MedicalEdge took a lower percentage, the renegotiation more or less guaranteed that it would receive a savings payment. Furthermore, the renegotiated target was applied retroactively back to January of the contract year. Because of the mid-year contract renegotiation, MedicalEdge received millions of dollars more than it otherwise would have under the terms of the original gainshare agreement.

211. UHMR enters into gainshare agreements with provider groups across its various plans and networks. On information and belief, UHMR's gainshare practices began at least as far back as 2007 (and most likely earlier) and continue to the present.

212. UHMR contracts with many capitated provider groups nationwide. As described above, percent of premium capitated providers are paid a portion of whatever premiums United receives from CMS. Consequently, such capitated providers share UHMR's incentive to submit as many diagnosis codes as possible to CMS.

213. From the inception of CMS's risk adjustment system, UHMR and Ingenix have known that many of their capitated providers are fraudulently submitting false and incorrect risk adjustment diagnoses. United's policy and practice, however, has been to continue accepting diagnoses from its capitated providers even when it knows the data from those providers is unreliable. Only in rare instances does United audit its providers, and in those instances it merely deletes whatever bad diagnoses it finds without conducting a top-to-bottom review, correcting the capitated provider's methods or terminating its relationship with the provider. Thus, UHMR and Ingenix knowingly submit, or cause the submission of, false risk adjustment claims to CMS.

214. On information and belief, UHMR's capitated providers are knowingly submitting incorrect and/or unsubstantiated codes to Ingenix, for transmission to CMS. For example, Princeton IPA of San Antonio, a capitated provider within defendant WellMed, had a risk score of 1.383 in January 2010 among its 34,163 members (by January 2011, Princeton's risk score was 1.504 among 34,902 members). Exhibit 11, incorporated herein. Such a risk score suggested that WellMed's members were substantially sicker than average (CMS sets the risk score for an average Medicare

beneficiary at 1). UHMR knows that WellMed's unusually high risk score is in large part attributable to fraud. For example, Relator learned in the fall of 2010, following an audit conducted by Ingenix, that WellMed (Princeton IPA of San Antonio) routinely submits improper diagnoses.

5. United Knows that its Risk Adjustment Claims Submission System Is Flawed, and Routinely Submits False Claims, But Has Failed to Fix that System or To Find and Fix Past False Claims

215. United knows of several significant problems with the way that its Ingenix Risk Adjustment Data System ("IRADS") processes claims data and submits risk adjustment claims to CMS. These errors always, or almost always, cause the submission of false and/or upcoded claims. Almost never do these errors cause United to fail to submit a valid claim.

216. Notwithstanding this knowledge, United has failed to fix the IRADS system, or to fix the previously submitted false claims caused by these flaws in the programming and logic of the IRADS system.

a) Background

217. The risk adjustment information United submits to CMS originates primarily from provider encounter and claims data. Providers submit encounters and claims information to United through one of several automated systems, such as the Professional Encounter System ("PES"), COSMOS, NICE, Pulse, Facets, and others.

218. United collects data from these systems and sends the data to Ingenix for incorporation into IRADS. IRADS applies multiple logic filters to the data to identify which diagnosis codes are eligible for submission to CMS, and which are not.

219. For example, when UHMR receives a claim from a provider containing an ICD-9-CM diagnosis code for diabetes, IRADS should screen that claim to ensure that all the required data elements are present, pursuant to CMS rules. If IRADS finds the Provider ID on the claim corresponds to a primary care physician, and a CPT code for a physical examination, it should then submit the code for risk adjustment. This is because the information on the claim corresponds to a face-to-face encounter between a physician and the patient. However, if the claim's Provider ID corresponds to a laboratory technician and the CPT code is for blood work, IRADS should filter out that claim because it is clear the diagnosis code is based on a lab test, not a face-to-face encounter with an appropriate provider type.

220. From these eligible codes, IRADS creates the data file that Ingenix submits to CMS's risk adjustment processing system ("RAPS"). Claims and encounter data processed through IRADS account for approximately 95% of the diagnoses United submits to CMS.

b) United Knows that the Filtering Logic Built Into IRADS is Deeply Flawed and Consistently Errs in Favor of Overcoding Risk Adjustment Claims

221. The serious problems that United has identified with IRADs include, but are not limited to:

- (1) use of "exclusion logic" to bias IRADS filters so that when in doubt they err on the side of including a diagnosis code and submitting a claim;
- (2) use of flawed logic concerning identification of provider specialties, leading to the inclusion of services provided by ineligible provider types;

- (3) failing to correct the IRADS data, and failing to correct previously submitted claims, when a provider informs United that a previously submitted claim was invalid or incorrect;
- (4) failing to properly separate information on individual service lines where one claim includes more than one separate procedure;
- (5) resubmitting previously deleted diagnoses to CMS;
- (6) submitting diagnoses from an institutional claim where the patient did not receive a face-to-face service; and
- (7) failing to update IRADS' filtering logic to include the most current CPT codes.

222. These problems are interrelated and often work in conjunction to cause erroneous submissions.

223. Relator has discussed the problems with IRADS with many of United's senior executives. In this way, Relator knows the company is aware of the problems. Although United knows about the issues with IRADS, it has allowed Ingenix to continue submitting risk adjustment data to CMS, and has not disclosed the problems to CMS. United continues to submit diagnosis codes it knows are ineligible for risk adjustment. Likewise, United has not deleted codes that IRADS improperly submitted and has limited its investigation into the extent of the errors.

224. Relator has information to believe that the problems with IRADS may also be found in its legacy risk adjustment processing systems, and thus date from the very beginning of the risk adjustment system in 2004. United has intentionally not reviewed whether its legacy systems contained an error it has identified in IRADS ("Issue 1,"

discussed *infra*) and thus whether it needs to delete any improperly-submitted codes, for example. United also has not reviewed whether its legacy systems contained any of the other errors it has identified in IRADS.

(1) Improper Use of Exclusion Logic

225. The most pervasive problem with IRADS is that it was built to use “exclusion logic” to filter diagnosis codes. As a result, the system essentially takes the position of “when in doubt, submit a claim.”

226. Generally speaking, exclusion logic compares objects in a database against a defined “exclusion list” and marks the matches (if any) for exclusion. For example, exclusion logic in an airport security system might compare travelers’ names against a list of the FBI’s Ten Most Wanted and flag any matches for security officials.

227. In IRADS, the exclusion logic filters out claims data if one or more of the data elements exactly matches a list of codes to exclude. For physician claims, the exclusion lists include, without limitation: (a) CPT codes; and (b) the provider’s specialty type. For institutional claims, the lists include, without limitation: (a) the bill type; (b) the revenue code; and (c) discharge status.

228. Thus, for example, IRADS’ exclusion list for CPT codes includes the codes for ineligible procedures such as laboratory work and diagnostic radiology. If a CPT code for the diagnosis matches a CPT code on the exclusion list, IRADS excludes the diagnosis from the data United submits to CMS for risk adjustment.

229. IRADS’ exclusion logic, however, contains a basic and devastating error—it only catches information that *matches* information on its exclusion lists *exactly*. Information that is invalid but not on the exclusion list passes through the filter.

230. Incredibly, this means that even if a key data element is left blank, or filled with a completely erroneous value, IRADS assumes that is a valid value because the blank or erroneous value does not appear on the list of codes to exclude. Thus IRADS will use that claim data when submitting risk adjustment claims.

231. This error causes Ingenix to claim payment for HCCs taken from claims data that are obviously ineligible for risk adjustment. For example, IRADS may catch and filter a diagnosis with CPT code 74150 (a radiology code). However, it will not catch a diagnosis with a CPT code field that is blank, erroneous (*e.g.*, 74x50), or even reads “this diagnosis is not eligible for risk adjustment.” So long as the field does not match the CPT codes on the exclusion list, the IRADS filter will not catch the bogus entry and the invalid diagnosis code will pass through to CMS.

232. The exclusion logic error is emblematic of United’s design for IRADS and its approach to risk adjustment in general—if United has any doubt about whether a diagnosis is eligible for risk adjustment, it submits it for payment.

(2) Flawed Provider Specialty Logic

233. United designed its claims systems and IRADS in such a way that it improperly submits claims to CMS for diagnoses made by ineligible provider types.

234. First, because of an error in the way IRADS processes provider billing identification numbers (“billing IDs”), IRADS fails to screen many diagnoses by provider type. As described above, CMS forbids MA plans from submitting diagnoses based on documents from ineligible providers such as registered nurses (“RN”) or radiologists. Thus, CMS requires MA plans to screen the diagnosis codes they submit by provider type.

235. The claims and encounter forms that United enters into IRADS each contain a billing provider identification number (“billing ID”). UHMR typically assigns billing IDs on a billing/contract basis, such that large, multi-specialty provider groups contracted with UHMR often have a single billing ID.

236. IRADS takes a shortcut in how it screens for provider types—it assumes that if a billing ID ever submits a claim or encounter with an eligible provider type, then the billing ID’s future claims and encounter forms will also have eligible provider types. When IRADS receives a claim with an eligible provider type, it adds the billing ID from that claim to its list of billing IDs associated with eligible provider types. Once the billing ID has been added to that list, IRADS treats all claims submitted by that billing ID as valid, regardless of the actual provider specialty of the provider who provided the service in question.

237. For example, if a newly-credentialed medical center submits five claims to United for a radiologist, IRADS will identify the provider specialty as “radiologist,” an ineligible provider type, and block the diagnoses from going to CMS.

238. However, the first time the medical center submits a code from an *eligible* provider (*e.g.*, internist), IRADS treats the billing ID as conclusive evidence that the medical center’s future diagnoses will likewise be made by eligible providers. From that point forward, IRADS stops filtering the medical center’s claims by provider type altogether, allowing all subsequent diagnoses from the medical center’s radiologists to be submitted to CMS for risk adjustment (assuming they pass the other filters).

239. Second, United designed its claims systems to default all unknown provider types to CMS physician specialty code 99, “unknown physician specialty.”

Generally speaking, health care providers use a different taxonomy for provider specialties than CMS. CMS requires providers to submit a valid provider type with each claim, so providers must map their taxonomy to CMS's. CMS recognizes approximately 66 physician specialty codes. Thus, a provider submitting a claim for a diagnosis made by an acute care nurse practitioner must map its code for the nurse practitioner, code 363LA2100X, to the appropriate CMS physician specialty code, code 50. United's claims systems are designed so that many provider specialty codes default to physician code 99. For some of United's claims systems, codes default when they fail to map to an eligible CMS physician specialty type. In another system, the Provider Encounter System, *all* provider specialties map to code 99. Thus, IRADS cannot filter many claims for ineligible provider specialties. United's use of code 99 as a default is improper, because to use it United has to know the provider is a *physician*. It cannot use the code whenever it knows nothing about the provider who submitted the claim.

**(3) Failure to Remove Diagnosis Codes Associated
With Claims "Voided" by the Provider**

240. When one of United's institutional providers voids a claim that was the source of a risk adjustment claim submitted to CMS, United processes the void instruction (*i.e.*, reverses the claim and recoups any claim payment) but does not delete the diagnosis code from its IRADS database or submit a delete code to CMS to reverse the risk adjustment claim. CMS therefore pays United an additional amount for diagnoses taken from cancelled claims.

241. United's general process for submitting diagnoses for risk adjustment starts with the claims and encounter data it receives from providers. Providers submit

242. The “void and replace” occurs because IRADS only collects a limited portion of the data in the claims system. For example, United receives most claims from hospitals and other institutional providers on Form UB-04. Exhibit 8, incorporated herein. Form UB-04 includes a field for the type of bill the claim represents (Item 4). The bill type is a three-digit code. The last digit of the code indicates whether the institution submitted the bill to void or replace a prior Form UB-04.

243. IRADS, however, is unable to process the bill type’s void/replace instruction. Thus when United receives instructions from a provider to void out a prior claim, and then replace it with a new claim, IRADS essentially treats this as three valid claims: (a) the original claim; (b) the “void” instruction, which looks like the original claim but for the data element that identifies it as a voiding claim; and (c) the new claim. Thus, if no filter applies, IRADS submits to CMS *both* the diagnosis from the original claim *and* the diagnosis from the replacement claim.

244. IRADS submits false data because of this error. For example, a fee-for-service provider who submits a claim (“claim #2”) on Form UB-04 (diagnosis: vascular disease) to replace a claim (“claim #1”) on Form UB-04 (diagnosis: congestive heart failure (“CHF”)) will receive payment from United based on claim #2 only. United, however, submits both the vascular disease diagnosis (HCC 105) and the CHF diagnosis (HCC 80) to CMS for risk adjustment. By doing so, United represents that its member was treated for both conditions in the present year, when in fact the member was only treated for one. United claims payment from CMS for both conditions.

**(4) Failure to Separately Filter Procedure Codes
When Multiple Services Are Included on a
Single Claim**

245. IRADS also fails to distinguish which diagnosis codes are associated with which procedures in situations where one claim form contains separate line items for two or more different procedures. Instead, IRADS assumes that all diagnosis codes on a claim are associated with each of the procedure codes. Thus, if either of the procedure codes is valid for risk adjustment purposes, IRADS uses all of the diagnosis codes for risk adjustment.

246. Both professional (*i.e.*, physician) and institutional (*i.e.*, hospital) claims forms have multiple lines in which the provider can list the multiple procedures that may have been performed for a member. At least some of United's claims systems, such as NICE (legacy PacifiCare) are capable of processing individual service lines. IRADS, however, is not programmed to treat each line separately.

247. For example, a claim may contain two service lines: (1) an office visit with a doctor who diagnosed cancer; and (2) a laboratory procedure performed by a technician to determine if the member has diabetes. The claim contains two diagnoses (cancer and diabetes) drawn separately from the two service lines. IRADS, however, *conflates* the service lines into a single data point. When checking for CPT codes, therefore, IRADS identifies the eligible CPT code (the office visit) and attributes it to both the cancer and diabetes diagnoses, even though the doctor had only diagnosed cancer. The CPT code for the laboratory procedure is effectively ignored. Consequently, IRADS submits both diagnoses to CMS, falsely representing that the doctor had diagnosed and treated the patient for two conditions, when in fact the doctor had only diagnosed one.

248. The service lines that IRADS is incapable of processing appear in United's claims forms. For example, Health Insurance Claims Form 1500 ("Form 1500"), the industry's standard claims form for professional health services, contains a field (Item 33) for the provider ID as well as a field (Item 21) for diagnosis codes. Exhibit 9, incorporated herein. Form 1500 also includes six "service lines" (each line consists of Items 24A–J) indicating, *inter alia*, the dates of service, the procedures performed (*i.e.*, CPT codes), the "diagnosis pointer," and the rendering provider identification number. The diagnosis pointer (Item 24E) relates one of the diagnoses in Item 21 to each of the service lines in Item 24 in order to document which health condition each service treated.

249. IRADS is unable to process critical information in Form 1500's service lines (Item 24) that determines the claim's risk adjustment eligibility. In addition to its inability to process CPT codes correctly, IRADS uses the field for *billing* provider number (Item 33) to determine whether an eligible provider type submitted the claim. In doing so, IRADS ignores Item 24J, which lists the *rendering* provider identification number for each service line. (The provider accumulator error is associated with this false correlation. *See* ¶¶233–239.) For example, in the prior example of a claim with two diagnoses (cancer and diabetes) from two service lines, Form 1500 lists the cancer and diabetes diagnoses in Item 21 and the doctor and the laboratory technician as rendering providers in Item 24J(1)–(2). Because IRADS relies on the billing provider (Item 33) and ignores the rendering provider (Item 24J), it does not filter the diabetes diagnosis, even though it is supported only by a lab request.

250. When United stands to have to *delete* HCCs because of an invalid CPT code, however, it finds itself quite capable of processing service lines individually. For example, in August 2009 Ingenix learned that it had submitted 257,515 diagnoses to CMS that were associated with a CPT code that was inconsistent with a face-to-face encounter with a qualifying provider. Because the CPT code was invalid, United knew it likely had to delete the diagnosis codes. In discussing the potential loss of 257,515 diagnoses, however, Ingenix's Angelo Fiorucci wrote Ingenix's Paul Bihm and Randall Myers that "I believe that we will be able to reduce the 257,515 because we have to validate that every claim line was coded as an 'Invalid CPT Code.'" Two things are clear from this response. First, United knows that just because IRADS submitted a diagnosis code to CMS does not mean that the diagnosis code is linked to a valid CPT code on the claims form. Thus, United has reason to know that IRADS submits false claims to CMS. Second, United is willing and able to process claims forms by individual service lines—in other words, to correct the mistake caused by the logic error in IRADS—only when it would otherwise have to delete a diagnosis.

251. In April 2011, Ingenix Director of Encounter Operations, Rebecca Martin, confirmed to Relator that Ingenix had in fact reviewed individual service lines when it deleted diagnoses in 2009. Martin said she suspected Ingenix had done the same when it had deleted diagnoses in 2006 as well. Relator gave Martin the hypothetical of a claim containing diagnoses of diabetes from a laboratory CPT (ineligible), cancer from a radiology CPT (ineligible), and CHF from an office visit CPT (eligible). As discussed previously, IRADS improperly submits all three diagnoses to CMS. In acknowledging

that Ingenix acts differently when it has to delete diagnoses, Martin told Relator: “In your example, we would have put diabetes and cancer on the delete list and saved CHF.”

(5) Resubmission of Previously Deleted Diagnoses

252. IRADS submits improper diagnoses to CMS because it is unable to associate a diagnosis Ingenix has deleted with a duplicate diagnosis in a resubmitted claim. When Ingenix decides to delete a diagnosis code listed in a claim, and the claim is later resubmitted by the provider, IRADS does not associate the newly-resubmitted claim with the deleted diagnosis. Therefore, Ingenix may determine that a diagnosis was improperly submitted to CMS, and yet resubmit the same code (if no filter applies) because IRADS is unable to associate the resubmitted claim with the deleted diagnosis.

(6) Submitting Institutional Claims for Non-Face-To-Face Services

253. Perhaps most egregiously, United identified and disclosed to CMS a problem in IRADS that was causing it to submit false diagnoses, but has knowingly fixed the problem in only one out of two contexts.

254. The problem, which United refers to as “Issue 1,” affects diagnosis codes that corresponded to multiple procedure codes. As discussed above, MA plans must use procedure codes to filter diagnoses codes to ensure the diagnoses were made during a face-to-face encounter with an eligible provider. The procedure codes used in professional (*e.g.*, physician) claims are known as CPT codes; the procedure codes used in institutional (*e.g.*, hospital) claims are called revenue codes.

255. For Issue 1, IRADS was inexplicably programmed to skip CPT code filtering—and essentially assume that a diagnosis was made during a face-to-face encounter with an eligible provider—as long as the diagnosis code was associated with

256. In 2008 and 2009, United investigated Issue 1 and confirmed it had caused United to submit invalid diagnoses to CMS. United notified CMS, fixed the CPT code filter, and submitted delete codes for the false diagnoses.

257. United, however, knowingly did not fix Issue 1 as it pertains to *institutional* claims. For institutional claims, IRADS continues to use the same erroneous logic such that an institutional claim with multiple non face-to-face revenue codes (the institutional equivalent to CPT codes) will pass IRADS' revenue code filter automatically. The result is that two wrongs often equal a right. A diagnosis with one bad revenue code is filtered out; a diagnosis with two bad revenue codes is submitted to CMS for payment.

(7) United Knowingly Fails to Filter Diagnoses With Current Procedure Codes

258. To ensure that it screens diagnoses based on their procedure codes properly, United is required to review the procedure codes on its exclusion list annually. Procedure codes—CPT codes and revenue codes—are regularly modified or changed year-over-year, and MA plans often determine that they need to update their risk adjustment filters to reflect the changes. United, however, fails to perform annual procedure code reviews. The exclusion logic in IRADS is therefore out of date and results in United improperly submitting to CMS diagnoses with procedure codes that are no longer associated with a face-to-face encounter with an eligible provider.

B. Ingenix and Its Commercial Customers Knowingly Submit, and Cause To Be Submitted, False Risk Adjustment Claims and Fail to Correct Previously-Submitted False Risk Adjustment Claims

259. UHG's Ingenix subsidiary performs risk adjustment services for health plans other than United's. The health plans include, without limitation, defendants Health Net, Arcadian, and Tufts. The services Ingenix provides these plans include both processing and submitting risk adjustment claims to CMS using the flawed IRADS system and performing chart reviews for incremental codes. Ingenix performs these services in the same manner as it does for United, as discussed *infra*. As such, Ingenix knowingly submits, causes to be submitted, and conspires with its commercial clients to submit false claims on behalf of its commercial clients. So too, those commercial clients submit, cause to be submitted, and conspire with Ingenix to submit false claims. Ingenix and its commercial clients also fail to correct (and reimburse Medicare for) previously submitted claims that they later learn, or should learn, are false.

260. Ingenix's commercial clients named as defendants in this Complaint know or have reason to believe that Ingenix's chart review practices are fraudulent. Their knowledge is in some instances direct.

261. For example, Ingenix told at least some clients that it was developing a system to start "looking both ways"—*e.g.*, to look for both incremental and inaccurate diagnoses during chart reviews (a limited system was adopted in July 2011). Relator has information and believes that some of Ingenix's commercial clients, having opt-out clauses in their contracts, have told Ingenix that they will cease using Ingenix to submit their risk adjustment data if Ingenix decides to start "looking both ways."

262. Health Net, meanwhile, has told Ingenix that it would simply follow United's lead, agreeing to having Ingenix review its charts for incremental and incorrect codes only if and when United implemented such reviews.

263. In a June 2011 meeting with senior UHMR executives, Jeff Dumcum said that Ingenix's commercial clients had not asked it to look both ways during chart reviews, but that they "may change their opinion when CMS releases their RADV extrapolation methodology." He noted that Health Net was the only commercial client currently willing to purchase "two way" chart reviews when United eventually implemented it. In March 2011, meanwhile, Dumcum told senior UHMR managers that he was unaware of any other large plan that looked both ways in its chart reviews. Ingenix understands from its interaction with smaller MA plans, meanwhile, that they have overwhelmingly chosen not to look both ways because, as self-perceived "small fish," they believe they stand a lesser chance of CMS singling them out for defrauding the government.

264. In addition, Ingenix's commercial risk adjustment clients have independent reason to know that Ingenix ignores incorrect diagnoses when it performs chart reviews: when Ingenix reports chart review results to its clients, it reports thousands of additional diagnoses, but no delete codes. The Defendants know the risk adjustment data they submitted to CMS was not 100% accurate and substantiated. By not identifying a single diagnosis to delete or replace, Ingenix clearly demonstrates to its clients that it disregards inaccurate and/or ineligible diagnoses.

C. WellMed Knowingly Submits, and Causes To Be Submitted, False Risk Adjustment Claims and Fails to Correct Previously-Submitted False Risk Adjustment Claims

265. WellMed, through its various affiliates and subsidiaries, is both a provider group and a managed care plan. In those joint roles, WellMed has both caused MA plans to submit false risk adjustment claims by providing those plans with false and fraudulent diagnosis information in connection with claims for physician services, and submitted false risk adjustment claims on its own in its capacity as a MA health plan. WellMed also fails to correct (and reimburse Medicare for) previously submitted claims that it later learns, or should learn, are false

266. Relator has information and believes that WellMed maintains policies and practices designed to maximize its risk adjustment submissions without regard to their accuracy or eligibility. WellMed allocates significant resources to increasing its risk adjustment payments, submitting data to IRADS through its own processing system, DataRap, which is designed to identify HCCs (and which UHMR previously used directly for a portion of its Texas membership).

267. DataRap is WellMed's system for identifying, processing, and submitting diagnosis codes to CMS for payment. WellMed developed the system now called DataRap around 2005 to allow its nurse practitioners to perform chart reviews. In 2008, WellMed expanded the system to include filtering and submitting diagnoses to CMS. Like IRADS, however, DataRap contains serious flaws that have caused WellMed and United to submit false claims to CMS. WellMed built DataRap using exclusionary logic that fails to filter diagnoses that are missing necessary information, such as CPT codes or provider specialty information. DataRap's list of CPT codes is sparse and has not been updated since the system's development in 2008, which causes it to submit diagnoses

associated with CPT codes that are no longer eligible for risk adjustment. It also cannot accommodate service line item processing and only filters for laboratory and radiology CPT codes—not other CPT codes that indicate the absence of a face-to-face encounter. Therefore, like IRADS, WellMed designed DataRap to maximize the number of claims it could submit with disregard for whether those claims were false.

268. In addition, WellMed previously conducted chart reviews on behalf of UHMR to identify codes for submission to CMS. Unlike United, WellMed's chart audits are prospective. The reviewer looks at present-year charts to check if the doctor had failed to code a diagnosis made in the prior year. The reviewer does not, however, look for invalid diagnoses in the chart. Furthermore, in July 2011, WellMed IT employee Bryan Bain told Relator that WellMed's practice is not to delete incorrect diagnoses from prior years. Thus, if a chart reviewer in 2011 found an invalid diagnosis code in a 2010 chart, he or she could not delete that diagnosis because the "delete file" that WellMed prepares for submission to CMS is designed to include only present-year diagnoses.

269. When WellMed denies a claim on grounds of fraud, waste, and abuse, it does not check whether it submitted diagnoses to CMS based on the denied claim. It thus claims payment from CMS for diagnoses taken from claims it identified as fraudulent.

270. The serious problems with DataRap, chart review, and fraud, waste, and abuse have contributed to WellMed's artificially inflated risk scores.

271. WellMed's risk adjustment practices gave it the highest projected risk score among UHMR's capitated providers with over 2,000 members in January 2010.

272. Instead of imposing a corrective action plan on WellMed or terminating its contract, UHMR bought most of WellMed's business in 2011. Thus, UHMR continues

273. Prior to its purchase by United, defendant WellMed owned two health plans, Physicians Health Choice (“PHC”) and Citrus Health Care, Inc. (“Citrus”). PHC insures or insured approximately 40,000 Part C beneficiaries in Texas, Florida, Arkansas, and New Mexico. Citrus insures or insured approximately 10,000 Part C beneficiaries and 44,000 Medicaid beneficiaries in Florida. United acquired both PHC and Citrus when it bought WellMed.

274. WellMed, through its health plans PHC and Citrus, defrauded CMS through the plans’ risk adjustment practices.

275. Both PHC and Citrus use WellMed’s DataRap system to filter and submit diagnoses to CMS. As described above, DataRap was designed to submit diagnoses so long as WellMed lacked tangible evidence the diagnosis was false, *i.e.*, it submits diagnoses that it failed to confirm, but also could not disprove, to have come from a qualifying face-to-face encounter. WellMed’s CFO, Joe Zimmerman, told Relator in April 2011 that any problems found in WellMed’s charts would logically exist in PHC’s and Citrus’s charts as well. He said “we use the same training, tools and process with our own health plans as we do in San Antonio,” *i.e.*, at Princeton IPA, which submits WellMed’s risk adjustment data to CMS through DataRap. Therefore, in addition to DataRap, PHC and Citrus share WellMed’s fraudulent chart review and fraud, waste, and abuse processes.

276. In May 2011, Relator was assigned to review PHC's and Citrus's submission systems as part of United's ongoing efforts to absorb WellMed. UHMR CFO Scott Theisen warned Relator to be careful because employees at WellMed would be paranoid on account of the many compliance issues United was finding at its new company.

D. MedAssurant Knowingly Submits, and Causes To Be Submitted, False Risk Adjustment Claims and Fails to Correct Previously-Submitted False Risk Adjustment Claims

277. Through its CARA and CAAS solutions, MedAssurant both submits risk adjustment data directly to CMS and provides data to client health care plans in the submission-ready CMS-required RAPS format. For CARA solution clients, MedAssurant submits to CMS or provides to the plan RAPS files containing the incremental codes identified through CARA's one-sided data analysis and chart reviews. For CAAS clients, MedAssurant submits to CMS or provides to the plan RAPS files for all of the diagnosis codes contained in the client's data.

278. Whether MedAssurant submits data directly to CMS or provides data to its clients with the representation that it is ready for submission to CMS, MedAssurant has a duty to provide only data that it reasonably believes to be accurate. Nevertheless, MedAssurant regularly submits data that it knows to be unreliable. The unreliability of physician submitted data is the very premise of MedAssurant's CARA solution, and yet MedAssurant looks only for incremental diagnosis codes and makes no effort to correct the over-coded and mis-coded diagnoses that it knows to be present. Thus, MedAssurant knowingly submits, and causes the submission of, false risk adjustment claims to CMS.

279. MedAssurant submits or causes the submission of false claims for many MA plans, including, but not limited to Defendants Aetna, BCBS Florida, BCBS Michigan, Bravo, Emblem, Healthfirst, Humana, Medica, and WellCare.

1. MedAssurant Upcodes Risk Adjustment Claims

280. MedAssurant's elaborate system for increasing patient risk scores includes submission of risk adjustment claims for diagnoses that it knows to be unsupported by patient's records. As explained above, ¶¶65–67, CMS guidelines dictate that ICD-9 codes may only be submitted for diagnoses that were treated in the applicable year during a face-to-face visit with an eligible provider, and recorded in the member's medical record. However, MedAssurant ignores these requirements and instructs its chart reviewers to seek out and code for conditions that were not treated in the applicable year and were otherwise undocumented and unsubstantiated.

281. MedAssurant's chart reviewers are trained to submit the codes that will result in the highest risk adjustment payments. Former reviewers reported to Relator that "MedAssurant told us which codes paid the most," and reviewers were expected to keep the reimbursement rates of the different diagnosis codes in mind during the chart reviews. As one reviewer explained, "you code for the highest that you can because that's what gets reimbursed. That's the system."

282. MedAssurant's reviewers are expected to do more than "code" the patient's medical records, they are supposed to interpret them, which means using the data to develop diagnoses that were not identified by the treating provider. MA plans are only permitted to submit codes for diagnoses that are explicitly stated in a member's medical records. However, MedAssurant trains its reviewers to go beyond reading charts for the explicitly stated diagnoses, and actually *interpret* patient's charts. Reviewers are

trained to look beyond the documented diagnoses and into the other information, including prescription drugs and diagnostic tests, and directed to form their own conclusions regarding the applicable diagnoses. Thus, for example, if a diagnostic test showed that a patient had 80% blockage of a carotid artery, the reviewer would be expected to interpret the results of the test and submit a diagnosis code for restriction of the artery. Some MedAssurant reviewers were even trained to submit diagnoses based on members' medications. For example, if a patient were taking drugs typically associated with kidney disease, a reviewer would code for it, even though the chart did not contain any such diagnosis.

283. MedAssurant has certain, specific rules regarding the appropriate way to interpret a chart in order to maximize members' risk scores. For example, if a member's medical record shows renal insufficiency for three months, MedAssurant directs its reviewers to code for chronic kidney disease, even where that diagnosis has not been documented by the treating physician. Although the prolonged renal insufficiency may provide sufficient diagnostic criteria from which a physician could determine that a patient had chronic kidney disease, it is a determination that must be made by the clinician, not a chart reviewer. CMS is very clear that only diagnoses recorded by an appropriate provider may constitute the basis for a risk score adjustment; other submissions are false.

284. MedAssurant also fraudulently upcodes depression to major depression. When a chart reflects that a patient has had depression for six or more months, MedAssurant's chart reviewers are trained to automatically submit a code for a major depressive disorder. Major depression is characterized by certain traits, which may not

be present in unspecified depression. The Fourth Edition of the Diagnostic and Statistical Manual of Mental Disorders (“DSM-IV”), which corresponds with the ICD-9 codes, lists several symptoms of depression (*e.g.*, significant weight loss when not dieting or weight gain, insomnia or hypersomnia nearly every day, fatigue or loss of energy nearly every day) and, for diagnostic purposes, defines major depressive disorder as the presence of the majority of the designated symptoms. Thus, in directing its reviewers to code major depression for members with no additional clinical symptoms, MedAssurant causes the submission of fraudulent codes for conditions that were never documented by an appropriate provider, and that the members likely did not have.

285. A further tactic used by MedAssurant is the “linking” of two separate coexisting conditions, by coding one condition as a complication of the other. MedAssurant trains reviewers to watch for instances of multiple coexisting conditions that are distinct diagnoses, but, if coded as one condition having caused or led to another, would increase a member’s risk score. MedAssurant instructs reviewers to code such conditions as linked, even where the member’s medical records do not support a causal relationship between them.

286. These fraudulent representations of causality are most often seen in the context of diabetes. For example, diagnoses of diabetes and chronic kidney disease should be represented with ICD-9-CM codes 2500.00-.03 (general diabetes) and 585.10-.90 (chronic kidney disease). These codes capture HCCs 19 and 131. HCC 19 adds .162 to the patient’s risk score and HCC 131 adds .368. MedAssurant coders however, upon finding these two distinct diagnoses in a patient’s chart, are directed to code the chronic kidney disease as a *complication* of diabetes, using ICD-9-CM code 250.40-.43 (diabetes

with renal manifestations), even where the medical record shows no evidence that the diabetes contributed to the member's chronic kidney disease. By coding chronic kidney disease as a complication, MedAssurant replaces HCC 19 (.162) with HCC 15 (.508), thus increasing the member's risk score by .346, which corresponds to approximately \$3,000 or more in extra annual revenue for a single member. Former MedAssurant employees report that the company instructs reviewers to code for HCC 15 any time a patient's medical record contains both diabetes and chronic kidney disease.

287. MedAssurant also trains its reviewers to submit codes for every chronic condition that a member patient has been diagnosed with throughout his or her medical history, including conditions that the member has neither needed nor received treatment for in the relevant, preceding year. This practice violates CMS guidelines, which dictate that even when a member has been diagnosed with a chronic condition, the condition cannot be submitted to CMS or impact a patient's risk score unless the patient was treated for it in the relevant time period. CMS reasons that even though a condition may never go away, it will only increase the insurer's costs to the extent that it requires treatment. Had CMS intended to establish permanent HCCs for "chronic" conditions, it would have done so. Instead, it deliberately created a system by which a patient must be treated for a condition within the given year to justify the higher risk score. Nevertheless, MedAssurant trains coders that once a patient has been diagnosed with a chronic disease, it should always be captured as a current condition. MedAssurant fraudulently submits these unsupported diagnoses directly to CMS and to its client health plans for submission to CMS.

2. MedAssurant Fails To Correct (and Reimburse Medicare for) False Risk Adjustment Claims

288. MedAssurant, like United, knows that the claims data it receives from providers is often unreliable. MedAssurant capitalizes on this unreliability by offering product solutions to health plans through which MedAssurant conducts extensive data analysis and chart reviews to “correct” these errors. However, MedAssurant’s CARA solution only seeks and implements the corrections that increase members’ risk scores and payments, deliberately ignoring any mistakes that were financially beneficial to a client health plan.

289. MedAssurant’s CARA solution is offered to clients as a way to “leverage a patient’s healthcare data” to “identify pertinent ‘gaps’ of applicable ROI potential.” As with United’s programs, MedAssurant’s CARA services could easily be used to look for both incremental and delete codes, however MedAssurant has deliberately designed the processes to look for incremental codes only.

290. MedAssurant’s deliberate choice to seek out and correct physician errors only where the correction will increase a client plan’s risk adjustment payments is particularly evident in two of the key CARA processes. First, the algorithms MedAssurant designed to identify CEDI gaps in member patients’ data are structured to identify suspected un-coded and under-coded diagnoses, and ignore indications that a diagnosis was improperly submitted. Second, in its chart reviews, MedAssurant looks specifically for documentation to support incremental diagnoses and makes no effort to validate the codes that have been previously submitted. Through its CARA and CAAS solutions, MedAssurant submits health plan data directly to CMS and, thus, has a duty to submit accurate data.

291. Upon information and belief, MedAssurant designed the CARA solution's proprietary algorithms to ignore any signals that a diagnosis code was incorrectly documented, if the correction of that code would decrease the client plan's risk adjustment payments. As such, MedAssurant refers to CEDIs as "reimbursement improvement opportunities" and repeatedly describes them as data suggesting the existence of "chronic, additional, worsening, or more optimally classified disease processes," all terms highlighting CEDIs use to increase members' risk scores. Additionally, in its explanations of the CARA CEDI identifications, MedAssurant provides examples of "Under-Coded," "Worsening," and "Non-Coded" conditions, but no examples of, or even suggestions that CARA identifies, over-coded or mis-coded conditions.

292. Furthermore, even if the CARA CEDI identifications included a suspected mis-coded or over-coded condition, MedAssurant's CARA solution processes would dictate that the signal be ignored, rather than confirmed through review of the patient's chart. MedAssurant evaluates each CEDI based on the financial impact to the plan if the suspected diagnosis (or mis-diagnosis) were confirmed, as well as the probability that the patient's chart will contain sufficient documentation of the suspected diagnosis. MedAssurant uses these two factors to predict each CEDI's return-on-investment, and pursues only those CEDIs that are in line with the plan's ROI goals. Thus, under the CARA solution, MedAssurant would never investigate or further pursue a CEDI with a negative financial impact to a client health plan.

293. That the program could also easily help identify false claims previously submitted is demonstrated, if nothing else, by the fact that Relator believes, and on that

basis alleges, that MedAssurant has already created algorithms that identify data incongruences signaling mis-coded or over-coded conditions, which it uses in some of its other “solutions” and it would take little to no work to include these accuracy-based algorithms in its CARA solution as well.

294. Notwithstanding the design of its databases and algorithms, MedAssurant has ample opportunity during its chart review process to identify incorrect diagnoses that were the basis for previously submitted risk adjustment claims. Yet MedAssurant fastidiously refuses to take any steps to correct such erroneous prior claims.

295. That MedAssurant’s reviews look only for new HCCs to submit, and ignore any previously submitted false claims, is well understood within the industry. For example, a newsletter sent out by a medical society addressed physician concerns about impending audits, writing:

The audit that you don’t have to worry about is the one where MedAssurant is auditing on behalf of an insurer which is a Medicare Advantage program. In this audit, MedAssurant is only trying to get more money from Medicare, which it can do if it can ‘jack up’ the intensity of the diagnosis code it finds in your charts. So, in this type of audit, MedAssurant is not looking for money from you.

See “UHC and MedAssurant Audits.” FSIPP Newsletter, Vol. IV, Issue 2 (December 2010).

296. For CARA solution clients, MedAssurant conducts chart reviews in one of two ways: Certain reviewers are given a targeted list of diagnoses for each patient, the documentation of which they are directed to seek in patients’ charts, while other, higher-level reviewers are not given a targeted list, but instead given a list of the HCC codes that

have already been assigned to each patient and trained to identify each and every opportunity to upcode, increasing patients' risk scores. For the purposes of this complaint, we will call the former method a targeted review, and the latter a comparative review.

297. A reviewer conducting a targeted review is given patient-specific sets of diagnoses that MedAssurant, through CEDI identification and ROI analysis, has determined are likely supported by documentation in the patient's chart and could substantially increase risk adjustment payments. Each diagnosis on a patient's list captures an additional or incremental HCC and the accordant increase in risk adjustment payments. These reviewers are trained to look only for the selected diagnoses, while ignoring any additional information in the chart, including evidence that diagnoses had been submitted in error. Thus, for example, if MedAssurant's CEDI analysis of a member has identified three suspected diagnoses that meet the ROI threshold, the chart reviewer will be directed to look for documentation supporting those three diagnoses only.

298. To facilitate coding of the new and incremental diagnoses in targeted chart reviews and to ensure that reviewers focus exclusively on the selected diagnoses, MedAssurant provides diagnosis-specific medical chart data templates designed to locate and fill in the information necessary to abstract the designated diagnoses. Thus, the only information that the reviewer seeks from the chart is that which will substantiate a suspected diagnosis. The reviewer is provided no templates to confirm that previously submitted diagnoses are accurate.

299. The comparative record review method utilized by MedAssurant is even more insidious. MedAssurant provides reviewers using the comparative method with lists of the HCC codes that have already been assigned to each of the members for use in their chart reviews. However, MedAssurant instructs the comparative reviewers that their reviews should be used only to look for ways to code new and incremental conditions, not to verify the legitimacy of existing HCCs.

300. A comparative review entails, by necessity, examination of the entirety of a member patient's medical record and comparison of the record with a list of HCC codes previously assigned to that member. As such, reviewers inevitably identify assigned HCC codes that are not supported by the patient's record, and are thus false. However, MedAssurant directs reviewers to ignore, rather than report, any such findings. As one former chart reviewer explained, the purpose of the reviews is "to get the insurance company more money—they look for opportunities to receive more reimbursement."

301. MedAssurant's executives and employees confirm that the company does not act on mis-coded or over-coded diagnoses in chart reviews. In a phone call with a MedAssurant representative, Relator asked whether MedAssurant's chart reviewers ever look for incorrectly-coded diagnoses, the correction of which would reduce a plans' risk adjustment payments, and the MedAssurant representative responded with silence. Likewise one of Relator's colleagues has spoken with MedAssurant regarding its chart review processes and MedAssurant conceded that the reviews are structured to look only for information to substantiate incremental diagnosis codes.

302. MedAssurant could easily use their existing reviews to confirm whether physician-submitted diagnosis are substantiated by the medical record. However, the

company is focused entirely on obtaining a maximized return-on-investment, and refuses to consider any actions that could jeopardize that goal.

E. MedAssurant's Clients Knowingly Submit False Risk Adjustment Claims and Fail to Correct Previously-Submitted False Risk Adjustment Claims

303. Defendants Aetna, BCBS Florida, BCBS Michigan, Bravo, Emblem, Healthfirst, Humana, Medica, and WellCare all have hired, used and otherwise conspired with MedAssurant, through its CARA and CAAS programs, to submit false and fraudulent risk adjustment claims.

304. Evidence of each of these Defendants' work with MedAssurant, and other efforts to submit fraudulent risk adjustment claims include, but are not limited to, the following:

305. A former MedAssurant coder reported to Relator that they reviewed charts for Aetna as part of the CARA program. Additionally, in approximately September 2008, the Michigan State Medical Society issued an alert advising providers that MedAssurant would be conducting medical chart reviews for risk adjustment purposes on behalf of several insurers, including Aetna.

306. In November of 2010, MedAssurant issued a press release announcing an expansion of the company's relationship with BCBS Florida. The release described the services that MedAssurant had provided BCBS Florida, including "risk adjustment, medical record review and claims analytics." Upon information and belief, this is a description of BCBS Florida's use of MedAssurant's CARA and CAAS solutions, through which false risk adjustment data was knowingly submitted to CMS.

307. BCBS Michigan has utilized the CARA and CAAS programs to increase the company's risk adjustment payments since at least 2008. When MedAssurant tried to

sell UHG the CARA and CAAS solutions, MedAssurant offered BCBS Michigan as a reference for the efficacy of their risk adjustment programs. BCBS Michigan gave MedAssurant a strong recommendation, citing the huge amount of money MedAssurant's programs brought the organization. In addition, in approximately September 2008, the Michigan State Medical Society issued an alert advising providers that MedAssurant would be conducting medical chart reviews for risk adjustment purposes on behalf of several insurers, including BCBS Michigan.

308. In the Fall of 2008, Bravo sent a newsletter to participating physicians, notifying them that MedAssurant would be conducting chart reviews of Medicare Advantage beneficiaries "for risk adjustment purposes."

309. Emblem has utilized the CARA and CAAS programs to increase the company's risk adjustment payments since at least 2008. When MedAssurant tried to sell UHG the CARA and CAAS solutions, MedAssurant offered Emblem as a reference for the efficacy of their risk adjustment programs. UHG contacted the company, and Emblem reported huge revenues from the programs in the form of large increases in the risk adjustment payments from CMS.

310. In addition, Emblem's subsidiaries, ConnectiCare and HIP, also use MedAssurant's CARA and CAAS solutions. On or about May of 2009, ConnectiCare sent a newsletter reminding providers that MedAssurant would be conducting medical record reviews on behalf of the company "to ensure that all applicable diagnosis codes indicated in the patient charts are reflected on claims that are submitted to ConnectiCare for payment." Similarly, in Spring 2008, HIP issued a clinician newsletter explaining the year-round "risk adjustment reviews" of HIP Medicare Advantage patients' medical

records. The newsletter explained that MedAssurant conducts these reviews, during which they are “looking back at varying dates of service periods as well as looking for different documentation to support coding standards.”

311. In the Spring of 2009, Healthfirst issued a newsletter to providers announcing an “exciting new partnership with MedAssurant.” Healthfirst explained that MedAssurant would be performing ongoing chart reviews in response to CMS requirements that MA plans “document diagnoses in order to clarify specific medical conditions and identify chronically ill members”—phrasing that is consistent with MedAssurant’s promotional material for the CARA program. Healthfirst also assured the providers that these reviews would not function as an audit of any provider’s practice.

312. In approximately September 2008, the Michigan State Medical Society issued an alert advising providers that MedAssurant would be conducting medical chart reviews for risk adjustment purposes on behalf of several insurers, including Humana. According to the alert, any providers contacted by MedAssurant were required to participate in risk adjustment audits.

313. Relator also learned from a former Humana chart reviewer that Humana conducts chart reviews using internally-trained coders. Like MedAssurant, Humana’s reviews are designed with the goal of increasing members’ risk adjustment payments, and are aggressively one-sided.

314. The former Humana reviewer reported that Humana provides its chart reviewers with a list of chronic conditions and instructs reviewers where to seek documentation for those conditions in each patient chart. Some of the conditions the

chart reviewers were instructed to seek out include history of heart attack, hypertension, and peripheral vascular disease.

315. The Humana reviewers were instructed to look at materials beyond the physician's notes, including test results and prescription drug information, when looking for additional HCCs.

316. Even more, two former Humana chart reviewers (one of whom was also a trainer for the company) reported that Humana looks only for incremental diagnoses; they do not correct any diagnoses that were incorrectly submitted.

317. In September 2009, Medica issued a "diagnosis-verification update" in which it explained that it would continue using MedAssurant to conduct chart reviews for risk adjustment purposes (*i.e.*, to "validate the diagnos[e]s submitted to CMS as well as assist providers with comprehensive diagnosis-coding practices"). The update also provided a chart-review timeline dating back to March 2008 and going forward to January 2010, and suggesting that the project may have extended back to 2007.

318. WellCare has publicly announced that it has used MedAssurant's CARA services since at least October 2010.

319. Additionally, based on Relator's experience in the industry and knowledge of the business practices of various other health plans, he believes, and on that basis alleges, that these companies are also performing one-sided chart reviews and upcoding risk adjustment claims through vendors other than MedAssurant and using internal personnel.

320. Among the experience and knowledge Relator relies upon is his belief that no health plan would hire MedAssurant to perform risk adjustment-related services

unless that plan intended to, and as a general practice did, fraudulently increase its risk adjustment claims. After reviewing MedAssurant's data analysis algorithms and chart review practice, Relator believes that MedAssurant's processes are so obviously designed to fraudulently inflate risk scores (and offer no mechanism to correct errors found) that a health plan would not hire MedAssurant unless the plan itself was already applying or planning to apply that approach to all of its MA business.

321. On this basis, Relator alleges that the named health plans have engaged in a widespread pattern of fraudulently upcoding the HCCs they have submitted, submitting HCCs that they otherwise know to be false, failing to correct previously submitted false claims, and conspiring with MedAssurant and others to do all of the same.

COUNT

Substantive Violations of the Federal False Claims Act 31 U.S.C. §§ 3729(a)(1)(A)–(C), (a)(1)(G)

322. Relator realleges and incorporates by reference the allegations made in Paragraphs 1 through 321 of this Complaint.

323. This is a claim for treble damages and forfeitures under the Federal False Claims Act, 31 U.S.C. §§ 3279–33, as amended.

324. Through the acts described above, Defendants, their agents, employees, and co-conspirators, knowingly presented, or caused to be presented, to the United States false and fraudulent claims, and knowingly failed to disclose material facts, in order to obtain payment or approval from the United States and its contractors, grantees, and other recipients of its funds.

325. Through the acts described above, Defendants, their agents, employees, and co-conspirators, knowingly made, used, and caused to be made and used false

records and statements, which also omitted material facts, in order to induce the United States to approve and pay false and fraudulent claims.

326. Through the acts described above, Defendants, their agents, employees, and co-conspirators, knowingly made, used, and caused to be made and used false records and statements material to an obligation to pay and transmit money to the United States, and knowingly concealed and improperly avoided and decreased an obligation to pay and transmit money to the United States.

327. Through the acts described above, Defendants, their agents, employees and other co-conspirators knowingly conspired to submit false claims to the United States and to deceive the United States for the purpose of getting the United States to pay or allow false or fraudulent claims.

328. The United States, unaware of the falsity of the records, statements, and claims made and submitted by Defendants, its agents, employees, and co-conspirators, and as a result thereof, paid money that it otherwise would not have paid.

329. By reason of the payment made by the United States, as a result of Defendants' fraud, the United States has suffered hundreds of millions of dollars in damages and continues to be damaged.

PRAYER

WHEREFORE, *qui tam* plaintiff Benjamin Poehling prays for judgment against Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. §§ 3279–33;
2. That the Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained as a result of

Defendants' actions in violation of the Federal False Claims Act, as well as a civil penalty of \$11,000 for each violation of 31 U.S.C. § 3729;

3. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the Federal False Claims Act;

4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That the United States and Relator receive all such other relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands trial by jury.

DATED: October 27, 2011

Respectfully submitted,

By: /s/ Brian M. Melber, Esq.
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rop@personiusmelber.com
Brian M. Melber
bmm@personiusmelber.com
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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of October, 2011, I forwarded the foregoing document via first-class mail, postage prepaid to the following:

Robert Trusiak
Assistant United States Attorney
United States Attorney's Office for the
Western District of New York
138 Delaware Avenue
Buffalo, NY 14202

Richard S. Nicholson
Trial Attorney
U.S. Department of Justice
Civil Division, Civil Fraud Section
601 D. St., NW, Room 1209
Washington, D.C. 20004

/s/ Brian M. Melber, Esq.
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Case 1:16-cv-00157-RMC Document 31-11 Filed 04/28/17 Page 1 of 3

EXHIBIT J

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

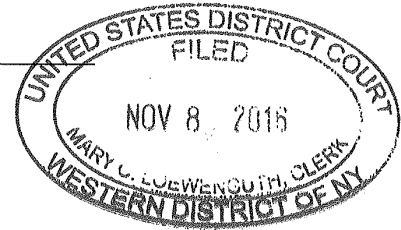
UNITED STATES OF AMERICA, ex rel.
BENJAMIN POEHLING,

Plaintiff,

-v-

UNITEDHEALTH GROUP, INC.,
WELLMED MEDICAL MANAGEMENT, INC.,
HEALTH NET, INC., ARCADIAN MANAGEMENT
SERVICES, INC., AND TUFTS ASSOCIATED HEALTH
PLANS, INC., AETNA INC., BLUE CROSS AND
BLUE SHIELD OF FLORIDA, INC., BLUE CROSS AND
BLUE SHIELD OF MICHIGAN, BRAVO HEALTH, INC.,
EMBLEMHEALTH, INC., MANAGED HEALTH, INC., d/b/a
HEALTHFIRST NEW YORK, HUMANA, INC., MEDICA
HOLDING COMPANY, WELLCARE HEALTH PLANS, INC.,
and MEDASSURANT, INC.,

Defendants.



11-CV-0258(A)

SEALED ORDER

Upon consideration of the United States' Unopposed Motion to Transfer Venue,

IT IS HEREBY ORDERED that this case be transferred to the United States
District Court for the Central District of California;

IT IS FURTHER ORDERED that in all other respects, this matter shall remain
under seal, except insofar as the seal has been partially lifted by this Court's March 8, 2012,
February 19, 2016 and September 27, 2016 Orders, until further order by the United States
District Court for the Central District of California; and

IT IS FURTHER ORDERED that the United States District Court for the Central District of California should consider whether this action should be deemed related to the *qui tam* action captioned *United States ex rel. Swoben v. United Healthcare Ins. Co. et al.*, CV 09-5013 (C.D. Cal.), either at the present time or when the remand of that action to it by the Court of Appeals from the Ninth Circuit is effectuated; and

IT IS FURTHER ORDERED that the complaint, any amended complaints, and all other filings in this matter shall remain under seal during and after the transfer, except insofar as that seal has been partially lifted by this Court.

IT IS SO ORDERED this 8 day of Nov. 2016.


HONORABLE RICHARD J. ARCARA
UNITED STATES DISTRICT JUDGE

Case 1:16-cv-00157-RMC Document 31-12 Filed 04/28/17 Page 1 of 10

EXHIBIT K

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E-mail: kathleen.lynch@usdoj.gov
Attorneys for the United States of America

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

UNITED STATES OF AMERICA *ex*
rel. [UNDER SEAL],

Plaintiff[s],

v.

[UNDER SEAL],

Defendant[s].

No. CV 16-08697 MWF (SSx)

NOTICE OF [UNDER SEAL]

**[FILED UNDER SEAL PURSUANT TO
THE FALSE CLAIMS ACT, 31 U.S.C.
§§ 3730(b)(2) AND (3)]**

**[LODGED CONCURRENTLY
HEREWITH: [PROPOSED] ORDER]**

*Lodged
Proposed
Order*

2017 FEB 14 AM 11:01
CLERK U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIF.
LOS ANGELES
BY: *[Signature]*

FILED

1 CHAD A. READLER
Acting Assistant Attorney General, Civil Division
2 EILEEN M. DECKER
United States Attorney
3 DOROTHY A. SCHOUTEN
DAVID K. BARRETT
4 LINDA A. KONTOS
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17 E-mail: kathleen.lynch@usdoj.gov
Attorneys for the United States of America

18 UNITED STATES DISTRICT COURT
19 FOR THE CENTRAL DISTRICT OF CALIFORNIA
20 WESTERN DIVISION

21 UNITED STATES OF AMERICA *ex*
22 *rel.* [UNDER SEAL],

23 Plaintiff[s],

24 v.

25 [UNDER SEAL],

26 Defendant[s].
27
28

No. CV 16-08697 MWF (SSx)

NOTICE OF [UNDER SEAL]

**[FILED UNDER SEAL PURSUANT TO
THE FALSE CLAIMS ACT, 31 U.S.C.
§§ 3730(b)(2) AND (3)]**

**[LODGED CONCURRENTLY
HEREWITH: [PROPOSED] ORDER]**

*Lodged
Proposed
order*
2017 FEB 14 AM 11:01
CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
LOS ANGELES
FILED

1 CHAD A. READLER
Acting Assistant Attorney General, Civil Division
2 EILEEN M. DECKER
United States Attorney
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Attorneys for the United States of America

18 UNITED STATES DISTRICT COURT
19 FOR THE CENTRAL DISTRICT OF CALIFORNIA
20 WESTERN DIVISION

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

23 Plaintiffs,

24 v.

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

26 Defendants.

No. CV 16-08697 MWF (SSx)

NOTICE OF ELECTION OF THE
UNITED STATES TO INTERVENE IN
PART AND DECLINE TO INTERVENE
IN PART AND STIPULATION RE
UNSEALING

**[FILED UNDER SEAL PURSUANT TO
THE FALSE CLAIMS ACT, 31 U.S.C.
§§ 3730(b)(2) AND (3)]**

[LODGED CONCURRENTLY
HEREWITH: [PROPOSED] ORDER]

Pursuant to the False Claims Act (“FCA”), 31 U.S.C. § 3730(b)(4), the United States of America (“United States”) hereby notifies the Court of its decision to intervene in part and decline to intervene in part in this *qui tam* action brought by Relator Benjamin Poehling (“Relator”). The United States hereby intervenes in the Relator’s action against UnitedHealth Group, Inc. (“United”) and WellMed Medical Management, Inc., (“WellMed”) based on their submission or causing the submission of false or fraudulent claims for and false statements relating to Risk Adjustment payments under Parts C and D of the Medicare Program and with respect to their retention of overpayments arising from those false or fraudulent claims and false statements. The United States intervenes against United with respect to Relator’s claims and allegations in his First Amended Complaint (FAC) relating to United’s Chart Review Program (e.g., FAC at ¶¶ 127-135), Claims Verification Program (e.g., FAC at ¶¶ 181-183), and Chart Validation/Risk Adjustment Coding Compliance Review (RACCR) Program (e.g., FAC at ¶¶ 173-179), and its submission of false Risk Adjustment Attestations (e.g., FAC at ¶ 79). The United States intervenes against WellMed with respect to Relator’s claims and allegations relating to the Chart Validation/RACCR Program and WellMed’s improper diagnosis coding practices which caused the submission of false or fraudulent claims for Risk Adjustment payments. The United States declines to intervene as to all remaining allegations against United and WellMed. The United States will file its Complaint against United and WellMed within the ninety-day time period following the filing of this Notice and serve its Complaint on defendants contemporaneously with its filing.

In addition, the United States hereby declines to intervene against the other defendants named by Relator in his First Amended Complaint. Although the United States declines to intervene as to those defendants and as to a portion of Relator’s claims and allegations against United, we respectfully refer the Court to 31 U.S.C. § 3730(b)(1), which allows Relator to maintain this action in the name of the United States, provided, however, that the “action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.” *Id.*

1 The United States Court of Appeals for the Ninth Circuit has held that,
2 notwithstanding this language, the United States has the right only to a hearing when it
3 objects to a settlement or dismissal of the action. *U.S. ex rel. Green v. Northrop Corp.*,
4 59 F.3d 953, 959 (9th Cir. 1995); *U.S. ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d
5 715, 723-25 (9th Cir. 1994). Therefore, the United States requests that, should Relator
6 or the defendants propose that the portion of the action in which the United States has
7 declined to intervene be dismissed, settled, or otherwise discontinued, Relator and the
8 defendants will provide the United States with notice of the same and the Court will
9 provide the United States with an opportunity to be heard before the Court rules or grants
10 its approval.

11 The United States also reserves the right to seek the dismissal of the Relator's
12 action or claim on any appropriate grounds, including under 31 U.S.C. §§ 3730(b)(5) and
13 (e)(4).

14 Furthermore, pursuant to the Stipulation re Unsealing set forth below, the United
15 States and the Relator request that the Relator's First Amended Complaint, this Notice,
16 and the attached proposed Order be unsealed. All papers on file relating to the United
17 States' motions for extensions of the intervention deadline and seal in this action,
18 however, should remain under seal because, in discussing the content and extent of the
19 United States' investigation, such papers were provided by law to the Court alone for the
20 sole purpose of evaluating whether the seal and time for making an election to intervene
21 should be extended.

22 Pursuant to 31 U.S.C. § 3730(c)(3), the United States also requests that, as to the
23 part of the action in which the United States has declined to intervene, all pleadings filed
24 in this action be served upon the United States and that all orders issued by the Court in
25 this action be sent to counsel for the United States. The United States reserves its right
26 to order any deposition transcripts. The United States also requests that it be served with
27 all notices of appeal in this action.

28 A proposed order accompanies this notice.

1 Dated: February 13, 2017

Respectfully submitted,

2 CHAD A. READLER
Acting Assistant Attorney General, Civil Division
3 EILEEN M. DECKER
United States Attorney
4 DOROTHY A. SCHOUTEN
Chief, Civil Division
5 DAVID K. BARRETT
Chief, Civil Fraud Section
6 LINDA A. KONTOS
Deputy Chief, Civil Fraud Section
7 Assistant United States Attorneys

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Attorneys, Civil Division
11 United States Department of Justice

12 JAMES P. KENNEDY, JR.
Acting United States Attorney
13 KATHLEEN ANN LYNCH
Assistant United States Attorney

14
15 

16 JOHN E. LEE
Assistant United States Attorney

17 Attorneys for the United States of America
18
19
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STIPULATION RE UNSEALING

The United States and the Relator hereby stipulate as follows:

1. The Relator's First Amended Complaint, the United States' Notice of Election of Intervention, and this Order may be unsealed.
2. All other papers or orders on file in this matter should remain under seal.
3. The seal may be lifted on all matters occurring in this action after the date of this Order.

Respectfully submitted,

Dated: February 13, 2017

CHAD A. READLER
Acting Assistant Attorney General, Civil Division
EILEEN M. DECKER
United States Attorney
DOROTHY A. SCHOUTEN
Chief, Civil Division
DAVID K. BARRETT
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United States Department of Justice

JAMES P. KENNEDY, JR.
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KATHLEEN ANN LYNCH
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JOHN E. LEE
Assistant United States Attorney

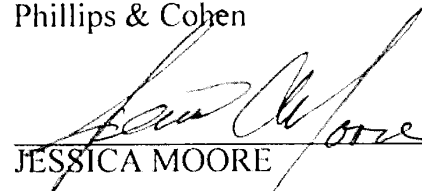
Attorneys for the United States of America

1 Dated: February 13, 2017

2 ERIC HAVIAN
3 MARY INMAN
4 JESSICA MOORE
5 HARRY LITMAN
6 Constantine Cannon LLP

7 TIM McCORMACK
8 Constantine Cannon LLP

9 STEVE HASEGAWA
10 Phillips & Cohen

11 
12 JESSICA MOORE

13 Attorneys for Plaintiff-Relator
14 Benjamin Poehling
15
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PROOF OF SERVICE BY E-MAIL

I am over the age of 18 and not a party to the above-captioned action. I am employed by the Office of United States Attorney, Central District of California. My business address is 300 North Los Angeles Street, Suite 7516, Los Angeles, California 90012.

On February 14, 2017, I served the NOTICE OF ELECTION OF THE UNITED STATES TO INTERVENE IN PART AND DECLINE TO INTERVENE IN PART AND STIPULATION RE UNSEALING on each person or entity named below by e-mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).

Date of e-mailing: February 14, 2017. Place of e-mailing: Los Angeles, California.

Person(s) and/or Entity(s) to whom e-mailed:

Jessica T. Moore
Constantine Cannon
150 California St., Suite 1600
San Francisco, CA 94111
jmoore@constantinecannon.com

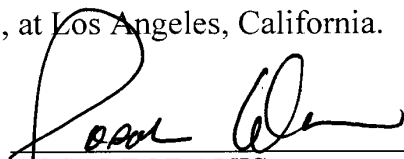
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shasegawa@pcsf.com

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 14, 2017, at Los Angeles, California.


ROSALIN DAVIS

Case 1:16-cv-00157-RMC Document 31-13 Filed 04/28/17 Page 1 of 4

EXHIBIT L

1 CHAD A. READLER
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2 SANDRA R. BROWN
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19 UNITED STATES DISTRICT COURT
20 FOR THE CENTRAL DISTRICT OF CALIFORNIA
21 WESTERN DIVISION

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

24 Plaintiffs,

25 v.

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

27 Defendants.
28

No. CV 16-08697 MWF (SSx)

ORDER ON CORRECTED NOTICE OF
ELECTION OF THE UNITED STATES
TO PARTIALLY INTERVENE

[FILED CONCURRENTLY HEREWITH:
CORRECTED NOTICE OF ELECTION
OF THE UNITED STATES TO
PARTIALLY INTERVENE]

1 The United States having filed a Corrected Notice of Election of the United States
2 to Partially Intervene in the above-captioned action (“this action”) pursuant to the False
3 Claims Act, 31 U.S.C. § 3730(b)(4),

4 IT IS ORDERED that:

5 1. The Relator’s First Amended Complaint, the Notice of Election of the
6 United States to Intervene in Part and Decline to Intervene in Part and the accompanying
7 Order, and the Corrected Notice of Election of the United States to Partially Intervene
8 and this Order shall remain unsealed.

9 2. All other papers filed or lodged in this matter shall remain under seal.

10 3. The seal shall remain lifted on all matters occurring in this action after
11 February 15, 2017.

12 4. The United States shall file and serve its Complaint in Intervention upon
13 Defendants UnitedHealth Group, Inc. and WellMed Medical Management, Inc., together
14 with this Order, by May 16, 2017.

15 5. The Relator shall file and serve a Second Amended Complaint upon
16 Defendants by May 16, 2017.

17 6. As to the part of the action in which the United States has not intervened at
18 this time, the parties shall serve all pleadings, notices, motions, orders, and other papers
19 hereafter filed in that part of the action, including any supporting memoranda, upon the
20 United States, as provided for in 31 U.S.C. § 3730(c)(3). The United States may order
21 any deposition transcripts and is entitled to intervene in that part of the action, for good
22 cause, at any time.

1 7. Should the Relator or any of the Defendants propose that the part of the
2 action in which the United States has not intervened be dismissed, settled, or otherwise
3 discontinued, the Relator and the Defendants shall provide the United States with notice
4 of the same and the Court will provide the United States with an opportunity to be heard
5 before the Court rules or grants its approval.

6
7 IT IS SO ORDERED.

8
9 Dated: March 15, 2017



UNITED STATES DISTRICT JUDGE

Case 1:16-cv-00157-RMC Document 31-14 Filed 04/28/17 Page 1 of 34

EXHIBIT M

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

United States of America, et al.,
Plaintiff,
v.
Scan Health Plan, et al.,
Defendants.

Case No. **CV09-5013-JFW (JEMx)**
**AMENDED SCHEDULING AND CASE
MANAGEMENT ORDER**

The purpose of this Order is to notify the parties and their counsel of the deadlines and the schedule that will govern this action. SEE THE LAST PAGE OF THIS ORDER FOR THE SPECIFIED DATES. Ordinarily, the dates set forth on the last page are determined after reviewing the parties' Joint Report or consultation with the parties at the Scheduling Conference. Accordingly, the dates and requirements are firm. The Court is very unlikely to grant continuances, even if stipulated to by the parties, unless the parties establish good cause through a concrete showing. **Because this Order in some respects modifies the applicable Local Rules, counsel are advised to read it carefully to avoid default on the**

1 obligations established herein. Counsel are advised to pay
2 particular attention to the requirements of the Court with
3 respect to electronic filing, the filing of motions for
4 summary judgment, and the documents to be submitted at the
5 Pre-Trial Conference and Trial.

6 **1. ELECTRONIC FILING AND COURTESY COPIES**

7 All documents that are required to be filed in an
8 electronic format pursuant to the Local Rules shall be filed
9 electronically no later than 4:00 p.m. on the date due unless
10 otherwise ordered by the Court. Any documents filed
11 electronically after 4:00 p.m. on the date due will be
12 considered late and may be stricken by the Court. Any
13 documents that counsel attempt to file electronically which
14 are improperly filed will not be accepted by the Court.

15 Counsel are ORDERED to deliver **2 copies** of all documents
16 filed electronically to Chambers. For each document filed
17 electronically, one copy shall be marked "CHAMBERS COPY" and
18 the other copy shall be marked "COURTESY COPY." The
19 "CHAMBERS COPY" and "COURTESY COPY" are collectively referred
20 to herein as "Courtesy Copies." The Courtesy Copies of each
21 electronically filed document must include on each page the
22 running header created by the ECF system. In addition, on
23 the first page of each Courtesy Copy, in the space between
24 lines 1 - 7 to the right of the center, counsel shall include
25 the date the document was e-filed and the document number.
26 The Courtesy Copies shall be delivered to Chambers no later
27 than 10:00 a.m. on the next business day after the document
28 was electronically filed. All documents must be stapled, the

1 electronic proof of service must be attached as the last page
2 of each document, and the exhibits attached to any document
3 must be tabbed. Counsel shall not staple the "COURTESY COPY"
4 and "CHAMBERS COPY" together. The "COURTESY COPY" and
5 "CHAMBERS COPY" of all documents must be three-hole punched
6 at the left margin with the oversized 13/32" hole size, not
7 the standard 9/32" hole size.

8 For any document that is not required to be filed
9 electronically, counsel are ORDERED to deliver 1 conformed
10 copy of the document, which shall be marked "COURTESY COPY,"
11 to Chambers **at the time of filing**.

12 When a proposed order accompanies an electronic filing, a
13 WordPerfect or Word copy of the proposed order, along with a
14 copy of the PDF electronically filed main document, shall be
15 e-mailed to JFW_Chambers@cacd.uscourts.gov. The subject line
16 of the e-mail shall be in the following format: court's
17 divisional office, year, case type, case number, document
18 control number assigned to the main document at the time of
19 filing, judge's initials and filer's (party) name. Failure
20 to comply with this requirement may result in the denial or
21 striking of the request or the Court may withhold ruling on
22 the request until the Court receives the required documents.

23 **2. DISCOVERY**

24 All discovery shall be completed by the discovery cut-off
25 date specified on the last page of this Order. **THIS IS NOT**
26 **THE DATE BY WHICH DISCOVERY REQUESTS MUST BE SERVED; IT IS**
27 **THE DATE BY WHICH ALL DISCOVERY, INCLUDING EXPERT DISCOVERY,**
28 **SHALL BE COMPLETED.** The Court does not enforce side

1 agreements to conduct discovery beyond the discovery cut-off
2 date.

3 Any motion challenging the adequacy of responses to
4 discovery must be heard sufficiently in advance of the
5 discovery cut-off date to permit the responses to be obtained
6 before that date if the motion is granted.

7 In an effort to provide further guidance to the parties,
8 the Court notes the following:

9 **(a) Depositions**

10 All depositions shall be scheduled to commence
11 sufficiently in advance of the discovery cut-off date to
12 permit their completion and to permit the deposing party
13 enough time to bring any discovery motions concerning the
14 deposition prior to the cut-off date.

15 **(b) Written Discovery**

16 All interrogatories, requests for production of
17 documents, and requests for admissions shall be served
18 sufficiently in advance of the discovery cut-off date to
19 permit the discovering party enough time to challenge (via
20 motion practice) responses deemed to be deficient.

21 **(c) Discovery Motions**

22 Whenever possible, the Court expects the parties to
23 resolve discovery issues among themselves in a courteous,
24 reasonable, and professional manner. If they do so, resort
25 to the Court for guidance in discovery is seldom necessary.
26 The Magistrate Judge assigned to this case will rule on
27 discovery motions and protective orders.

28 / / /

1 **(d) Expert Discovery**

2 If expert witnesses are to be called at trial, the
3 parties shall designate affirmative experts to be called at
4 trial and shall provide reports required by Fed.R.Civ.P.
5 26(a)(2)(B) not later than eight weeks prior to the discovery
6 cut-off date. Rebuttal expert witnesses shall be designated
7 and reports provided as required by Fed.R.Civ.P. 26(a)(2)(B)
8 not later than five weeks prior to the discovery cut-off
9 date. Any non-retained expert designated by a party as an
10 affirmative or rebuttal expert shall also prepare and provide
11 an expert report in the form described by Fed.R.Civ.P.
12 26(a)(2)(B). Expert witnesses will be bound by the opinions
13 expressed in their reports prepared in accordance with
14 Fed.R.Civ.P. 26(a)(2)(B) and will not be permitted to offer
15 new opinions at trial. Failure to timely comply with this
16 deadline will result in the expert being excluded at trial as
17 a witness.

18 **3. MOTIONS - GENERAL PROVISIONS**

19 All law and motion matters, except for motions in limine,
20 must be set for hearing (not filed) by the motion cut-off
21 date specified on the last page of this Order. The Court
22 will deny or strike late-filed motions. The title page of
23 all motions must state the hearing date and time for the
24 motion, the Pre-Trial Conference date, and the Trial date.

25 Once a party has noticed a motion for hearing on a
26 particular date, the hearing shall not be continued without
27 leave of Court. If the Court concludes that a motion can be
28 / / /

1 resolved without argument, the Court will notify the parties
2 in advance.

3 If counsel does not intend to oppose a motion, counsel
4 shall immediately inform the Courtroom Deputy by e-mail and
5 immediately file a Notice of Non-Opposition in accordance
6 with the Local Rules. The parties should note that failure
7 to timely respond to any motion shall be deemed by the Court
8 as consent to the granting of the motion. See Local Rules.

9 Ex parte practice is strongly discouraged. The Court
10 will require strict adherence to proper ex parte procedures
11 for any ex parte application filed with the Court. See Local
12 Rules and the Court's Standing Order.

13 **(a) Applications and Stipulations to Extend Time**

14 No applications or stipulations extending the time to
15 file any required document or to continue any date are
16 effective unless and until the Court approves them.
17 Applications and/or stipulations to extend the time to file
18 any required document or to continue any hearing, Pre-Trial
19 date, or the Trial date must set forth the following:

20 (i) the existing due date or hearing date, as well
21 as all dates currently set by the Court in this Order,
22 including the discovery cut-off date, the Pre-Trial
23 Conference date, and the Trial date;

24 (ii) the new dates proposed by the parties;

25 (iii) specific, concrete reasons supporting good
26 cause for granting the extension; and

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1 (iv) whether there have been prior requests for
2 extensions by any party, and whether those requests were
3 granted or denied by the Court.

4 All applications and stipulations must be accompanied by
5 a separate and independent proposed order which must be
6 submitted to the Court in accordance with the Local Rules and
7 this Order. Failure to submit a separate proposed order may
8 result in the denial of the application or stipulation or the
9 Court may withhold ruling on the application or stipulation
10 until the Court receives a separate proposed order.

11 **(b) Joinder of Parties and Amendment of Pleadings**

12 The deadline for joining parties and amending pleadings
13 is sixty days from the date of this Order. Any motions to
14 join other parties or for leave to amend the pleadings shall
15 be filed within twenty days of the date of this Order so that
16 they can be heard and decided prior to the deadline.

17 In addition to the requirements of the Local Rules, all
18 motions to amend the pleadings shall: (1) state the effect of
19 the amendment; (2) be serially numbered to differentiate the
20 amendment from previous amendments; and (3) state the page,
21 line number(s), and wording of any proposed change or
22 addition of material. The parties shall deliver to Chambers
23 a redlined version of the proposed amended pleading
24 indicating all additions and/or deletions of material.

25 **(c) Withdrawal or Substitution of Counsel**

26 The Court will not grant a request for approval of
27 substitution of counsel after an action has been set for
28 trial unless: (1) counsel files the request using the most

1 recent version of the appropriate forms provided on the
2 Court's website; and (2) the request is accompanied by a
3 declaration signed by a substituting attorney indicating that
4 such attorney has been advised of the trial date and will be
5 prepared to proceed with trial as scheduled. Any request for
6 substitution of counsel which is not on the proper form or is
7 not accompanied by a declaration signed by a substituting
8 attorney as set forth above will be denied.

9 Counsel who wish to withdraw and substitute their client
10 *pro se* must file a regularly noticed motion to withdraw which
11 demonstrates good cause for the request to withdraw. The
12 Court will not consider such a motion unless: (1) the motion
13 is accompanied by a declaration signed by the client
14 indicating that the client consents to the withdrawal, has
15 been advised of the time and date of trial, and will be
16 prepared to represent themselves *pro se* on the scheduled
17 trial date; or (2) the Court is otherwise satisfied for good
18 cause shown that the attorney should be permitted to
19 withdraw.

20 **4. SUMMARY JUDGMENT MOTIONS**

21 The Court will only entertain ONE summary judgment motion
22 by a party. In the event a party believes that more than one
23 summary judgment motion is necessary to expedite the
24 resolution of issues in the action, the party must obtain
25 leave of court to file more than one summary judgment motion.
26 The Court will require strict adherence to the following
27 requirements:

28 / / /

1 **(a) Statement Of Uncontroverted Facts and Conclusions of**
2 **Law and Statement of Genuine Disputes of Material**
3 **Fact**

4 The Statement of Uncontroverted Facts and Conclusions of
5 Law is to be prepared in a two column format. The left hand
6 column should set forth the allegedly undisputed fact or
7 conclusion or law. The right hand column should set forth
8 the evidence that supports the factual statement or
9 conclusion of law. The factual statements and conclusions of
10 law should be set forth in sequentially numbered paragraphs.
11 Each paragraph should contain a narrowly focused statement of
12 fact or conclusion of law. Each numbered paragraph should
13 address a single subject in as concise a manner as possible.

14 The opposing party's Statement of Genuine Disputes of
15 Material Fact must track the movant's Statement of
16 Uncontroverted Facts exactly as prepared. The document must
17 be in two columns; the left hand column must restate the
18 allegedly undisputed fact, and the right hand column must
19 restate the moving party's evidence in support of the fact,
20 and indicate either undisputed or disputed. The opposing
21 party may dispute all or only a portion of the statement, but
22 if disputing only a portion, must clearly indicate what part
23 is being disputed. Where the opposing party is disputing the
24 fact in whole or part, the opposing party must, in the right
25 hand column, set forth the evidence controverting the fact.
26 Where the opposing party is disputing the fact on the basis
27 of an evidentiary objection, the party must cite to the
28 evidence alleged to be objectionable and state the ground of

1 the objection and nothing more. Counsel are reminded that
2 unwarranted factual denials made in the context of a Summary
3 Judgment Motion are subject to Rule 11 sanctions. **No**
4 **argument should be set forth in this document.**

5 The opposing party may submit additional material facts
6 that bear on or relate to the issues raised by the movant,
7 which shall follow the format described above for the moving
8 party's Statement of Uncontroverted Facts. These additional
9 facts shall follow the movant's facts, shall continue in
10 sequentially numbered paragraphs (*i.e.*, if movant's last
11 statement of fact was set forth in paragraph 30, then the
12 first new fact will be set forth in paragraph 31), and the
13 evidence that supports the new fact shall be set forth in the
14 right hand column.

15 The moving party, together with its reply, shall file a
16 separate document entitled "Combined Statement of Facts" that
17 (1) restates the entirety of the opposing party's Statement
18 of Genuine Disputes of Material Fact and (2) responds to any
19 additional facts in the same manner and format that the
20 opposing party must follow in responding to the Statement of
21 Uncontroverted Facts, as described above.

22 **(b) Supporting Evidence**

23 No party should submit any evidence other than the
24 specific items of evidence or testimony necessary to support
25 or controvert a proposed statement of undisputed fact. Thus,
26 for example, entire sets of interrogatory responses, or
27 documents that do not specifically support or controvert
28 material in the Statements should not be submitted in support

1 of or in opposition to a motion for summary judgment. Any
2 such material will not be considered.

3 Evidence submitted in support of or in opposition to a
4 motion for summary judgment should be submitted either by way
5 of stipulation or as exhibits to declarations sufficient to
6 authenticate the proffered evidence, and should not be
7 attached to the memorandum of points and authorities. The
8 Court will accept counsel's authentication of deposition
9 transcripts, written discovery responses, and the receipt of
10 documents in discovery if the fact that the document was in
11 the opponent's possession is of independent significance.
12 Documentary evidence as to which there is no stipulation
13 regarding foundation must be accompanied by the testimony,
14 either by declaration or properly authenticated deposition
15 transcript, of a witness who can establish its authenticity.

16 All exhibits submitted in support of, and in opposition
17 to, a motion for summary judgment shall be consecutively
18 numbered; no two exhibits shall bear the same number. For
19 example, if the moving party submits one declaration and one
20 request for judicial notice, with four exhibits attached to
21 each document, the exhibits attached to the declaration shall
22 be marked 1 through 4, and the exhibits attached to the
23 request for judicial notice shall be marked 5 through 8. The
24 opposing party's exhibits shall then commence with number 9.
25 Immediately above or below the page number on each page of an
26 exhibit, the parties shall mark "[Party Name]'s Summary
27 Judgment Exhibit No. ____".

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1 In addition to the foregoing, any party who offers
2 deposition testimony in support of or in opposition to a
3 motion for summary judgment shall prepare and file a separate
4 document for each deponent which contains only those
5 questions and answers, and any objections made at the time of
6 the deposition to those questions, that a party is relying on
7 to support their motion, with a citation to the appropriate
8 page and line number(s) in the deposition transcript.

9 The parties shall also deliver to chambers (but not file)
10 one copy of the entire deposition transcript (single-sided
11 condensed transcript including the word index) of each
12 deposition referenced. The deposition transcripts shall be
13 placed in a slant D-ring binder with each transcript
14 separated by a tab divider on the right side and three-hole
15 punched at the left margin with the oversized 13/32" hole
16 size, not the standard 9/32" hole size. The deposition
17 transcript binder shall include a Table of Contents and the
18 spine of each binder shall be labeled with its contents.

19 The Court's Courtesy Copies of all evidence in support of
20 or in opposition to a motion for summary judgment shall be
21 submitted in a separately bound compendium and shall include
22 a Table of Contents. If the supporting evidence exceeds
23 fifty pages, each Courtesy Copy of the supporting evidence
24 shall be placed in a slant D-ring binder with each item of
25 evidence separated by a tab divider on the right side. All
26 documents contained in the binder must be three-hole punched
27 with the oversized 13/32" hole size, not the standard 9/32"

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1 hole size. The spine of each binder shall be labeled with its
2 contents.

3 In addition to the foregoing, the parties shall meet and
4 confer and prepare two binders, one binder containing a joint
5 set of all exhibits relied on by the parties in support of
6 and in opposition to the motion for summary judgment ("Joint
7 Exhibit Binder"), and the other binder containing a joint set
8 of all declarations relied on by the parties in support of
9 and in opposition to the motion for summary judgment ("Joint
10 Declarations Binder"). The parties shall file the Joint Set
11 of Exhibits with a cover page titled "Joint Set of Exhibits"
12 and the Joint Set of Declarations with a cover page titled
13 "Joint Set of Declarations" with the Reply. The parties
14 shall also deliver to Chambers two copies of both the Joint
15 Exhibit Binder and Joint Declarations Binder in accordance
16 with paragraph 1 of this Order, one set of which shall be
17 marked "CHAMBERS COPY," and the other set of which shall be
18 marked "COURTESY COPY."

19 The Joint Exhibit Binder and Joint Declarations Binder
20 shall include a Table of Contents, and the spine of each
21 binder shall be labeled with its contents. The Table of
22 Contents for the Joint Exhibit Binder and Joint Declarations
23 Binder shall specifically describe each summary judgment
24 exhibit or declaration and include a citation to each
25 paragraph number in the Combined Statement of Facts that
26 refers to the exhibit or declaration (e.g. Plaintiff's
27 Summary Judgment Exhibit No. 1 - Letter from John Doe to Jane
28 Doe dated January 1, 2007 Re: Reasons for Jane Doe's

1 termination) (Combined Statement of Facts Nos. 2, 8, 10). In
2 preparing the Table of Contents, counsel should not create a
3 new set of exhibit numbers. Counsel shall use the same
4 exhibit numbers that were used to identify the documents in
5 the Motion for Summary Judgment.

6 **(c) Objections to Evidence**

7 If a party disputes a fact based in whole or in part on
8 an evidentiary objection, the ground for the objection, as
9 indicated above, should be stated in the Statement of Genuine
10 Disputes of Material Fact or Combined Statement of Facts but
11 not argued in that document. Evidentiary objections are to
12 be addressed in a separate memorandum to be filed with the
13 opposition or reply brief of the party. This memorandum
14 should be organized **to track the paragraph numbers of the**
15 **Statement of Genuine Disputes of Material Fact or Combined**
16 **Statement of Facts in sequence**. It should identify the
17 specific item of evidence to which objection is made, or in
18 the case of deposition testimony it should quote the relevant
19 testimony, the ground for the objection, and a very brief
20 argument with citation to authority as to why the objection
21 is well taken. The following is an example of the format
22 contemplated by the Court:

23 Combined Statement of Facts Paragraph 10: Objection to
24 the supporting deposition testimony of Jane Smith [quote
25 testimony] at 60:1-10 on the grounds that the statement
26 constitutes inadmissible hearsay and no exception is
27 applicable. To the extent it is offered to prove her
28

1 state of mind, it is irrelevant because her state of mind
2 is not in issue. Fed. R. Evid. 801, 802.

3 **DO NOT SUBMIT BLANKET OR BOILERPLATE OBJECTIONS TO THE**
4 **OPPONENT'S STATEMENT OF FACTS. THESE WILL BE DISREGARDED AND**
5 **OVERRULED.**

6 **(d) The Memorandum of Points and Authorities**

7 The movant's memorandum of points and authorities should
8 be in the usual form required under Local Rules and should
9 contain a narrative statement of facts as to those aspects of
10 the case that are before the Court. All facts should be
11 supported with citations to the paragraph number in the
12 Statement of Uncontroverted Facts that supports the factual
13 assertion and not to the underlying evidence.

14 Unless the case involves some unusual twist, the motion
15 need only contain a brief statement of the Fed.R.Civ.P. 56
16 standard; the Court is familiar with the Rule and with its
17 interpretation under *Celotex* and its progeny. If at all
18 possible, the argument should be organized to focus on the
19 pertinent elements of the claim(s) for relief or defense(s)
20 in issue, with the purpose of showing the existence or non-
21 existence of a genuine issue of material fact for trial on
22 that element of the claim or defense.

23 Likewise, the opposition memorandum of points and
24 authorities should be in the usual form required by the Local
25 Rules. Where the opposition memorandum sets forth facts,
26 those facts should be supported with citations to the
27 paragraph number in the Statement of Genuine Disputes of
28 Material Fact and not to the underlying evidence.

1 **(e) Proposed Statement of Decision**

2 Within two days of the filing of the Reply, each party
3 shall lodge a Proposed Statement of Decision, which shall
4 contain a statement of the relevant facts and applicable law
5 with citations to case law and the record. The Proposed
6 Statement of Decision shall not exceed ten pages and shall be
7 in a form that would be appropriate for the Court to enter as
8 its final order on the motion. The Proposed Statement of
9 Decision shall be submitted to the Court in accordance with
10 the Local Rules.

11 **(f) Timing**

12 Parties should not wait until the motion cut-off date to
13 bring motions for summary judgment or partial summary
14 judgment. Early completion of non-expert discovery and
15 filing of motions for summary judgment may eliminate or
16 reduce the need for expensive expert depositions which are
17 normally conducted in the last stages of discovery.

18 **Caveat: Failure of the moving party to comply with these**
19 **procedures regarding summary judgment motions will result in**
20 **the denial of the Motion for Summary Judgment. If a party**
21 **fails to respond to a Motion for Summary Judgment, the Court**
22 **will assume that the material facts as claimed and adequately**
23 **supported by the moving party are admitted to exist without**
24 **controversy, which will likely result in the granting of the**
25 **Motion for Summary Judgment.**

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1 **5. MOTIONS IN LIMINE**

2 The Court will only entertain a maximum of five motions
3 in limine by a party. In the event a party believes that
4 more than five motions in limine are necessary, the party
5 must obtain leave of Court to file more than five motions in
6 limine. The Court will not hear or resolve motions in limine
7 that are disguised summary judgment motions. No application
8 to file under seal will be granted with respect to a motion
9 in limine or any documents submitted with the motion in
10 limine.

11 Before filing any motion in limine, counsel for the
12 parties shall confer in a good faith effort to eliminate the
13 necessity for hearing the motion in limine or to eliminate as
14 many of the disputes as possible. It shall be the
15 responsibility of counsel for the moving party to arrange for
16 this conference. The conference shall take place in person
17 within ten calendar days of service upon opposing counsel of
18 a letter requesting such conference, but in no event later
19 than twenty-one days before the Pre-Trial Conference. Unless
20 counsel agree otherwise, the conference shall take place at
21 the office of the counsel for the moving party. If both
22 counsel are not located in the same county in the Central
23 District, the conference may take place by telephone. The
24 moving party's letter shall identify the testimony, exhibits,
25 or other specific matters alleged to be inadmissible and/or
26 prejudicial, shall state briefly with respect to each such
27 matter the moving party's position (and provide any legal
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1 authority which the moving party believes is dispositive),
2 and shall specify the terms of the order to be sought.

3 If counsel are unable to resolve their differences, they
4 shall prepare and file a separate, sequentially numbered
5 Joint Motion in Limine for each issue in dispute which
6 contains a clear caption which identifies the moving party
7 and the nature of the dispute (e.g., "Plaintiff's Motion in
8 Limine #1 to exclude the testimony of Defendant's expert").
9 Each Joint Motion in Limine shall consist of one document
10 signed by all counsel. The Joint Motion in Limine shall
11 contain a clear identification of the testimony, exhibits, or
12 other specific matters alleged to be inadmissible and/or
13 prejudicial and a statement of the specific prejudice that
14 will be suffered by the moving party if the motion is not
15 granted. The identification of the matters in dispute shall
16 be followed by each party's contentions and each party's
17 memorandum of points and authorities. The title page of the
18 Joint Motion in Limine must state the Pre-Trial Conference
19 date, hearing date for the motions in limine, and Trial date.

20 Joint Motions in Limine made for the purpose of
21 precluding the mention or display of inadmissible and/or
22 prejudicial matter in the presence of the jury shall be
23 accompanied by a declaration that includes the following:
24 (1) a clear identification of the specific matter alleged to
25 be inadmissible and/or prejudicial; (2) a representation to
26 the Court that the subject of the motion in limine has been
27 discussed with opposing counsel, and that opposing counsel
28 has either indicated that such matter will be mentioned or

1 displayed in the presence of the jury before it is admitted
2 in evidence or that counsel has refused to stipulate that
3 such matter will not be mentioned or displayed in the
4 presence of the jury unless and until it is admitted in
5 evidence; and (3) a statement of the specific prejudice that
6 will be suffered by the moving party if the motion in limine
7 is not granted.

8 Unless ordered by the Court, no supplemental or separate
9 memorandum of points and authorities shall be filed by either
10 party in connection with any motion in limine.

11 The Court's Courtesy Copies of all evidence in support of
12 or in opposition to a motion in limine, including
13 declarations and exhibits to declarations, shall be submitted
14 in a separately bound volume and shall include a Table of
15 Contents. If the supporting evidence exceeds fifty pages,
16 each Courtesy Copy of the supporting evidence shall be placed
17 in a slant D-ring binder with each item of evidence separated
18 by a tab divider on the right side, and the spine of the
19 binder shall be labeled with its contents. All documents
20 contained in the binder must be three-hole punched with the
21 oversized 13/32" hole size, not the standard 9/32" hole size.

22 The Court will not consider any motion in limine in the
23 absence of a joint motion or a declaration from counsel for
24 the moving party establishing that opposing counsel: (a)
25 failed to confer in a timely manner; (b) failed to provide
26 the opposing party's portion of the joint motion in a timely
27 manner; or (c) refused to sign and return the joint motion
28 after the opposing party's portion was added.

1 Unless otherwise ordered by the Court, motions in limine
2 should be filed and will be heard on the dates specified on
3 the last page of this Order. Unless the Court in its
4 discretion otherwise allows, no motions in limine shall be
5 filed or heard on an ex parte basis, absent a showing of
6 irreparable injury or prejudice not attributable to the lack
7 of diligence of the moving party.

8 The failure of any counsel to comply with or cooperate in
9 the foregoing procedures will result in the imposition of
10 sanctions, including a resolution of the issue against the
11 party refusing to cooperate.

12 **6. PRE-TRIAL CONFERENCE AND LOCAL RULE 16 FILINGS**

13 **(a) General Provisions**

14 The Pre-Trial Conference ("PTC") will be held on the date
15 specified on the last page of this Order, unless the Court
16 expressly waived a PTC. If adjustments in the Court's
17 calendar to accommodate congestion become necessary, the
18 Court may re-schedule the PTC instead of the trial date.
19 Therefore, the parties should assume that if the PTC goes
20 forward, the trial will go forward without continuance,
21 although some brief period of trailing may prove necessary.

22 The lead trial attorney on behalf of each party shall
23 attend both the PTC and all meetings of the parties in
24 preparation for the PTC, unless excused for good cause shown
25 in advance of the PTC.

26 A continuance of the PTC at the parties' request or by
27 stipulation is highly unlikely. **Specifically, failure to**
28 **complete discovery is not a ground for continuance.** In the

1 unlikely event that the Court agrees to continue the PTC, the
2 trial date is likely to be delayed as a result. If a change
3 in the trial date is necessitated or likely because of the
4 Court's calendar or otherwise, modifications of that date
5 will be discussed at the PTC.

6 At the PTC, the parties should be prepared to discuss
7 means of streamlining the trial, including, but not limited
8 to: bifurcation; presentation of foundational and non-
9 critical testimony and direct testimony by deposition
10 excerpts; narrative summaries and/or stipulations as to the
11 content of testimony; presentation of testimony on direct
12 examination by affidavit or by declaration subject to cross-
13 examination; and qualification of experts by admitted
14 resumes. The Court will also discuss settlement.

15 **(b) Form of Pre-Trial Conference Order ("PTCO")**

16 The proposed PTCO shall be filed by the date specified on
17 the last page of this Order. Adherence to this time
18 requirement is necessary for in-chambers preparation of the
19 matter. The form of the proposed PTCO shall comply with
20 Appendix A to the Local Rules and the following:

21 (i) Place in "ALL CAPS" and in **bold** the separately
22 numbered headings for each category in the PTCO (e.g., "**1.**
23 **THE PARTIES**" or "**7. CLAIMS AND DEFENSES OF THE PARTIES**").

24 (ii) Include a Table of Contents at the beginning.

25 (iii) In specifying the surviving pleadings, state
26 which claims or counterclaims have been dismissed or
27 abandoned (e.g., "Plaintiff's second cause of action for
28 breach of fiduciary duty has been dismissed."). Also, in

1 multiple party cases where not all claims or counterclaims
2 will be prosecuted against all remaining parties on the other
3 side, specify to which party each claim or counterclaim
4 is directed.

5 (iv) In drafting the PTCO, the Court expects that
6 the parties will attempt to agree on and set forth as many
7 uncontested facts as possible. A carefully drafted and
8 comprehensively stated stipulation of facts will assist the
9 Court in preparing for the Pre-Trial Conference.

10 **(v) In specifying the parties' claims and defenses**
11 **in Section 7 of the PTCO, each party shall closely follow the**
12 **examples set forth in Appendix A of the Local Rules.**

13 (vi) The Court may submit fact issues to the jury in
14 the form of findings on a special verdict form. The issues
15 of fact should track the elements of a claim or defense on
16 which the jury will be required to make findings.

17 (vii) If expert witnesses are to be called at trial,
18 each party must list and identify its respective expert
19 witnesses, both retained and non-retained. Failure of a
20 party to list and identify an expert witness in the PTCO
21 shall preclude the party from calling that expert witness at
22 trial.

23 **(c) Rule 16 Filings; Memoranda; Witness Lists; Exhibit**
24 **Lists**

25 The parties must comply fully with the requirements of
26 Local Rule 16. They shall file carefully prepared Memoranda
27 of Contentions of Fact and Law (which may also serve as the
28 trial brief), along with their respective Witness Lists and

1 Exhibit Lists, all in accordance with the Local Rules. See
2 the last page of this Order for applicable dates.

3 **(d) Summary of Witness Testimony and Time Estimates**

4 Counsel shall prepare a list of their witnesses,
5 including a brief summary (two to three paragraphs) of each
6 witness's expected testimony, an estimate of the length of
7 time needed for direct examination, and whether the witness
8 will testify by deposition or in person. Counsel shall
9 exchange these lists with opposing counsel. **Counsel shall**
10 **jointly file a single list of witness testimony summaries,**
11 **including estimates for direct examination of their own**
12 **witnesses and estimates for cross-examination of opposing**
13 **witnesses.** The joint witness testimony summaries shall be
14 filed at the same time counsel submit the PTCO. If a party
15 intends to offer deposition testimony into evidence at trial,
16 the party shall comply with the Local Rules.

17 **(e) Pre-Trial Exhibit Stipulation**

18 The parties shall prepare a Pre-Trial Exhibit Stipulation
19 which shall contain each party's numbered list of all trial
20 exhibits, with objections, if any, to each exhibit including
21 the basis of the objection and the offering party's response.
22 All exhibits to which there is no objection shall be deemed
23 admitted. The parties shall also identify each witness they
24 anticipate will testify about and/or lay the foundation for
25 the exhibit. All parties shall stipulate to the authenticity
26 of exhibits whenever possible, and the Pre-Trial Exhibit
27 Stipulation shall identify any exhibits for which

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1 authenticity has not been stipulated to and the specific
 2 reasons for the party's failure to stipulate.

3 The Pre-Trial Exhibit Stipulation shall be substantially
 4 in the following form:

5 Pre-Trial Exhibit Stipulation

6 Plaintiff(s)' Exhibits

7 Number Description Witness If Objection, State Grounds Response to Objection

8 Defendant(s)' Exhibits

9 Number Description Witness If Objection, State Grounds Response to Objection

10 The Pre-Trial Exhibit Stipulation shall be filed at the
 11 same time counsel file the PTCO. Failure to comply with this
 12 paragraph shall constitute a waiver of all objections.

13 **DO NOT SUBMIT BLANKET OR BOILERPLATE OBJECTIONS TO THE**
 14 **OPPOSING PARTY'S EXHIBITS. THESE WILL BE DISREGARDED AND**
 15 **OVERRULED.**

16 **(f) Jury Instructions, Verdict Forms, Special**
 17 **Interrogatories**

18 Fourteen days before the required Local Rule 16-2
 19 meeting, the parties shall exchange proposed jury
 20 instructions, verdict forms, and, if necessary, special
 21 interrogatories. Seven days before the meeting, counsel
 22 shall exchange written objections, if any, to the proposed
 23 jury instructions, verdict forms, and special
 24 interrogatories. At the required meeting, lead counsel
 25 shall confer with the objective of submitting one set of
 26 agreed upon instructions, a verdict form, and, if necessary,
 27 special interrogatories.

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1 If lead counsel agree upon one complete set of jury
2 instructions, they shall file a joint set of proposed jury
3 instructions, arranged in a logical sequence with each
4 instruction sequentially numbered, and identified as
5 "Stipulated Instruction No. __ Re _____," with the blanks
6 filled in as appropriate. If the parties cannot agree upon
7 one complete set of jury instructions, they shall file the
8 following two joint documents with the Court:

9 (i) A joint set of proposed jury instructions
10 arranged in a logical sequence with each instruction
11 sequentially numbered. If undisputed, an instruction shall
12 be identified as "Stipulated Instruction No. __ Re _____,"
13 with the blanks filled in as appropriate. If disputed, each
14 alternate version of the disputed instruction shall be
15 inserted together (back to back) in their logical place in
16 the overall sequence. Each such disputed instruction shall
17 be identified as "Disputed Instruction No. __ Re _____
18 Proposed By _____," with the blanks filled in as
19 appropriate. All disputed versions of an instruction shall
20 bear the same instruction number. If a party does not have a
21 counter-version of an instruction and simply contends no such
22 instruction should be given, then that party should so state
23 (and explain why) on a separate page inserted in lieu of an
24 alternate version; and

25 (ii) A joint memorandum of law in support of each
26 party's disputed instructions, organized by instruction
27 number. The joint memorandum of law shall quote the text of
28 each disputed instruction and shall set forth each party's

1 respective position and legal authority, immediately after
2 the text of each disputed instruction.

3 Each proposed instruction, whether agreed upon or
4 disputed, shall (a) be set forth in full on a separate page;
5 (b) embrace only one subject or principle of law; (c) cite to
6 the legal authority for or source of the instruction; and (d)
7 reference the claim for relief to which the instruction
8 relates with a citation to Section 7 of the PTCO.

9 **A Table of Contents shall be included with all jury**
10 **instructions submitted to the Court.** The Table of Contents
11 shall set forth the following:

- 12 (i) The number of the instruction;
- 13 (ii) A brief title of the instruction;
- 14 (iii) Whether it is undisputed or disputed;
- 15 (iv) The source of the instruction; and
- 16 (v) The page number of the instruction.

17 For example:

18 <u>Number</u>	<u>Title</u>	<u>Source</u>	<u>Page No.</u>
19			
20 1	Burden of Proof (Undisputed)	9th Cir. Man. of Model Jury Instr. 5.1	5

22 The Court directs counsel to use the instructions from
23 the Ninth Circuit Manual of Model Jury Instructions (West
24 Publishing, most recent edition) where applicable. Where
25 California law is to be applied and the above instructions
26 are not applicable, the Court prefers counsel to use the
27 Judicial Council of California Civil Jury Instructions
28 ("CACI") (LexisNexis Matthew Bender, most recent edition).

1 If neither of these sources is applicable, counsel are
2 directed to use the instructions from O'Malley, Grenig and
3 Lee, Federal Jury Practice and Instructions (West Group, most
4 recent edition). Any modifications made to the original form
5 instruction from the foregoing sources (or any other form
6 instructions) must be specifically identified, along with the
7 authority supporting the modification. **Counsel shall not**
8 **submit proposed preliminary instructions to be given to the**
9 **jury prior to opening statements.**

10 If the parties agree upon a verdict form and/or special
11 interrogatories, they shall file a joint verdict form and/or
12 special interrogatories, with the questions arranged in a
13 logical sequence. If the parties cannot agree upon a verdict
14 form and/or special interrogatories, they shall file a joint
15 document containing each party's alternative version along
16 with a brief explanation of each party's respective position.

17 The joint set of proposed jury instructions, the joint
18 memorandum of law, and verdict form(s) and/or special
19 interrogatories are to be filed with the PTCO and other Local
20 Rule 16 documents. Courtesy Copies shall be provided to the
21 Court in accordance with Section 1 of this Order. **In**
22 **addition, the parties shall e-mail the joint set of proposed**
23 **jury instructions, joint memorandum of law, and verdict**
24 **form(s) and/or special interrogatories in WordPerfect or Word**
25 **format to the Chambers' e-mail address**
26 **(JFW_Chambers@cacd.uscourts.gov) at the time of filing.**

27 Immediately after the Court's final ruling on the
28 disputed jury instructions, counsel shall file one final

1 "clean set" of jury instructions, which shall be sent into
2 the jury room for the jury's use during deliberations. The
3 "clean set" shall contain only the text of each instruction
4 set forth in full on each page, with the caption "Court's
5 Instruction No. ____" (eliminating supporting authority,
6 citations to the PTCO, etc.). Counsel shall also e-mail the
7 final "clean set" of jury instructions in WordPerfect or Word
8 format to the Chambers' e-mail address
9 (JFW_Chambers@cacd.uscourts.gov) at the time of filing.

10 **Caveat: The failure of any counsel to comply with or**
11 **cooperate in all of the foregoing procedures regarding jury**
12 **instructions and/or verdict forms will constitute a waiver of**
13 **all objections to the jury instructions and/or verdict form**
14 **used by the Court.**

15 **(g) Real-Time Reporting Requirement**

16 Each party must file with the Court, at the same time
17 counsel submit the PTCO, a document for the Court Reporter
18 which contains proper names, unusual or scientific terms, or
19 any foreign or uncommon words that are likely to be used by
20 the parties during the PTC and the Trial. Each party shall
21 also e-mail a copy of the document to the Chambers' e-mail
22 address (JFW_Chambers@cacd.uscourts.gov) at the time of
23 filing.

24 **(h) Joint Statement of the Case and Requests for Voir**
25 **Dire**

26 Two days prior to the Pre-Trial Conference, the parties
27 shall file their proposed voir dire questions and their joint
28 statement of the case which the Court shall read to all

1 prospective jurors prior to the commencement of voir dire.
2 The statement should be not longer than two or three
3 paragraphs.

4 The Court conducts voir dire of all prospective jurors.
5 The parties need not submit requests for standard voir dire
6 questions, such as education, current occupation, marital
7 status, prior jury service, etc., but should include only
8 proposed questions specifically tailored to the parties and
9 issues of the case.

10 **7. COURT TRIALS**

11 **(a) Declarations of Witness Direct Testimony**

12 Counsel in non-jury trials shall submit the direct
13 testimony of their witnesses in writing in a declaration
14 executed under penalty of perjury. These declarations shall
15 be in admissible form with an appropriate foundation
16 established for the declarant's statements. Paragraphs in
17 each declaration shall be numbered consecutively to
18 facilitate the identification of paragraphs for evidentiary
19 objections. Any exhibits which are attached to a witness
20 declaration shall be numbered consistently with the number of
21 the exhibit on the Joint Exhibit List.

22 Counsel are to exchange and file these declarations at
23 least fourteen calendar days before trial, unless otherwise
24 ordered by the Court. Courtesy Copies shall be provided to
25 the Court in accordance with Section 1 of this Order.
26 Courtesy Copies shall be submitted to the Court in a slant D-
27 ring binder with each declaration separated by a tab divider
28 on the right side. All documents must be three-hole punched

1 with the oversized 13/32" hole size, not the standard 9/32"
2 hole size. The binders shall also contain a Table of
3 Contents listing the declarations contained therein, and the
4 spine of the binder shall be labeled with its contents.

5 Eight calendar days before trial, counsel may file
6 evidentiary objections to those declarations. Counsel shall
7 prepare a separate document for each declaration for which
8 they have an evidentiary objection in which they shall quote
9 the specific language from the declaration to which they
10 object, followed by the objection and any relevant argument.
11 Counsel shall file any reply or response to the objections by
12 noon on the fifth calendar day before trial. Courtesy Copies
13 shall be provided to the Court in accordance with Section 1
14 of this Order. **DO NOT SUBMIT BLANKET OR BOILERPLATE**
15 **OBJECTIONS TO THE OPPOSING PARTY'S WITNESS DECLARATIONS.**
16 **THESE WILL BE DISREGARDED AND OVERRULED.**

17 At trial, the Court will rule on the evidentiary
18 objections and, depending upon the ruling, the declarations
19 will be received in evidence, either in whole or in part, or
20 rejected. Counsel will then conduct the cross-examination
21 and re-direct examination at trial.

22 Failure to comply with the terms of this Order will
23 result in sanctions or the Court may refuse to allow that
24 witness to testify.

25 **(b) Trial Briefs**

26 Counsel for each party shall file and serve a trial
27 brief, not to exceed 15 pages in length, fourteen calendar
28 days before trial.

1 **(c) Findings of Fact and Conclusions of Law**

2 Counsel for each party shall file and serve initial
3 proposed findings of fact and conclusions of law fourteen
4 calendar days before trial. Counsel for each party shall
5 also e-mail a copy of their proposed findings of fact and
6 conclusions of law to the Chambers' e-mail address
7 (JFW_Chambers@cacd.uscourts.gov) on the date due. Counsel
8 for each party shall then:

9 (i) Underline in red the portions which it
10 disputes;

11 (ii) Underline in blue the portions which it
12 admits; and

13 (iii) Underline in yellow the portions which it does
14 not dispute, but deems irrelevant.

15 Counsel may agree with a part of a finding or conclusion,
16 disagree with a part of it, and/or consider a part of it
17 irrelevant.

18 Two marked copies of opposing counsel's proposed findings
19 of fact and conclusions of law shall be filed with the Court
20 seven calendar days before trial and one marked copy shall be
21 served on opposing counsel. Courtesy Copies shall be
22 provided to the Court in accordance with Section 1 of this
23 Order.

24 **8. SETTLEMENT**

25 This Court will not conduct settlement conferences in
26 non-jury cases which the Court will try unless counsel for
27 all parties and their respective clients agree either in

28 / / /

1 writing or on the record. In jury cases, the Court will
2 conduct a settlement conference at the parties' joint request
3 if three conditions exist:

4 (a) The parties are satisfied that the fact issues in
5 the case will be tried to a jury;

6 (b) All significant pre-trial rulings which the Court
7 must make have been made; and

8 (c) The parties desire the Court to conduct the
9 conference, understanding that if settlement fails, the Court
10 will preside over trial of the case.

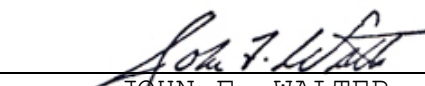
11 The parties must file a Status Report re: Settlement at
12 the time they lodge the Proposed Pre-Trial Conference Order.
13 The Status Report shall include the name and phone number of
14 the Settlement Officer who assisted the parties with their
15 settlement conference.

16 **Caveat: If counsel fail to cooperate in the preparation**
17 **of the required Pre-Trial documents, fail to file the**
18 **required Pre-Trial documents, or fail to appear at the Pre-**
19 **Trial Conference and such failure is not otherwise**
20 **satisfactorily explained to the Court: (a) the cause shall**
21 **stand dismissed for failure to prosecute if such failure**
22 **occurs on the part of the plaintiff; (b) default judgment**
23 **shall be entered if such failure occurs on the part of the**
24 **defendant; or (c) the Court may take such action as it deems**
25 **appropriate.**

26 IT IS SO ORDERED.

27 DATED: April 26, 2017

28



JOHN F. WALTER
UNITED STATES DISTRICT JUDGE

JUDGE JOHN F. WALTER
SCHEDULE OF TRIAL AND PRE-TRIAL DATES

Matter	Time	Weeks before trial	Plaintiff(s) (Request)	Defendant(s) (Request)	Court Order
Trial (jury) Estimated length: <u>10</u> days	8:30 am				11/27/18
[Jury trial] Hearing on Motions in Limine; Hearing on Disputed Jury Instructions	10:00 am				11/16/18
[Court trial] Hearing on Motions in Limine	10:00 am				X
Pre-Trial Conference; File Proposed Voir Dire Qs and Agreed-to Statement of Case	10:00 am				11/9/18
Submit Pre-Trial Conf. Order; File Motions in Limine; Memo of Contentions of Fact and Law; Pre-Trial Exhibit Stipulation; Summary of Witness Testimony and Time Estimates; File Status Report re: Settlement; File Agreed Upon Set of Jury Instructions and Verdict Forms; File Joint Statement re Disputed Instructions, Verdicts, etc.					10/18/18
Last day for hearing motions *	1:30 pm				8/27/18
Discovery cut-off					7/17/18

**ADDITIONAL MATTERS TO BE DETERMINED AT SCHEDULING
CONFERENCE**

Last day to conduct Settlement Conference					2/6/18
Last day to file Joint Report re: results of Settlement Conference					2/13/18

* Motions for class certification shall be filed in accordance with Local Rule 23-3.

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EXHIBIT N

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

UNITED STATES OF AMERICA *ex*
rel. JAMES M. SWOBEN,

Plaintiffs,

v.

SECURE HORIZONS, a business
entity, form unknown, *et al.*,

Defendants.

No. CV 09-5013 JFW (JEMx)

**JOINT REPORT PURSUANT TO
FED. R. CIV. P. 26, LOCAL RULE
26-1, AND THE COURT'S
FEBRUARY 21, 2017 ORDER**

SCHEDULING CONFERENCE:
DATE: May 1, 2017
TIME: 8:30 am
COURT: Hon. John F. Walter

1 Plaintiff United States of America, Relator James Swoben, and Defendants
2 UnitedHealth Group, Inc., UnitedHealthcare Insurance Company, United HealthCare
3 Services, Inc., Pacificare Health Plan Administrators, Inc., Pacificare of California,
4 Pacificare Life and Health Ins. Co., and Pacificare Health Systems (“UnitedHealth”) and
5 HealthCare Partners, LLC and HealthCare Partners Medical Group, Inc. (“HCP”), by
6 their attorneys, respectfully submit the following joint report.

7 *UnitedHealth’s Position:* The United States has not yet filed its Complaint-in-
8 Intervention, which is due May 1, 2017 (ECF No. 254). Without an operative complaint,
9 there is inherent uncertainty as to many issues in the Joint Report and some positions are
10 subject to change based on the allegations and claims in the forthcoming pleading.
11 Nevertheless, the parties endeavored to engage in a meaningful meet-and-confer process
12 on April 4, 2017 and subsequent drafting of the Joint Report.

13 **1. JURISDICTION, VENUE, AND SERVICE**

14 *United States’ and Relator’s Position:* The basis for this Court’s subject matter
15 jurisdiction is 28 U.S.C. § 1345 (U.S. plaintiff) and § 1331 (federal question), as this is
16 an action under the federal False Claims Act (“FCA”), 31 U.S.C. § 3729-3733. Personal
17 jurisdiction and venue are proper under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)(1)
18 & (b)(2). The United States will file and serve its Complaint-in-Intervention by May 1,
19 2017 in accordance with this Court’s March 17, 2017 Order (ECF No. 254).
20 UnitedHealth anticipates waiving service under FRCP 4(d) and answering or otherwise
21 responding to the United States’ Complaint-in-Intervention by June 30, 2017 and HCP
22 will respond to Relator’s Fourth Amended Complaint by the same date.

23 *Defendants’ Position:* Defendants do not intend to challenge service of Swoben’s
24 complaints, except to the extent that Swoben has named as a defendant and attempted to
25 serve “Secure Horizons,” “UnitedHealth,” and “Healthcare Partners Independent
26 Physician Association,” which are not actual corporate entities. UnitedHealth is unable
27 to assess whether any issues exist regarding jurisdiction or venue until the Complaint-in-
28 Intervention is filed, but anticipates that it may file motions on these issues.

1 **2. CHRONOLOGY AND STATEMENT OF PRINCIPAL FACTUAL ISSUES**
2 **IN DISPUTE**

3 Relator James Swoben commenced this litigation by filing a sealed complaint
4 under the *qui tam* provisions of the FCA in July 13, 2009 against SCAN Health Plan and
5 Senior Care Action Network, adding UnitedHealth and HCP in his First Amended
6 Complaint and Third Amended Complaint, respectively. The defendants moved to
7 dismiss Relator's Third Amended Complaint in June 2013 and the Court dismissed this
8 action. Relator appealed. The Ninth Circuit remanded, issuing its mandate on February
9 7, 2017. On March 13, 2017, Relator filed his Fourth Amended Complaint against
10 UnitedHealth and HCP. On March 24, 2017, the United States filed its notice of partial
11 intervention, intervening as to UnitedHealth.

12 *United States' and Relator's Position:* The key factual issues in dispute concern
13 the medical record reviews (also known as chart reviews) that were conducted by or on
14 behalf of HCP (and possibly other capitated providers in California) from the mid-2000s
15 and for a number of years thereafter for the purpose of identifying diagnoses to submit to
16 the Medicare Program for risk adjustment payments under Parts C and D of the Program;
17 UnitedHealth's encouragement of, involvement in, design of and knowledge about these
18 chart reviews (*e.g.*, its financial support for these reviews); and whether UnitedHealth
19 and HCP acted "knowingly," as that term is defined by 31 U.S.C. § 3729(b)(1) and used
20 in 31 U.S.C. §§ 3729(a)(1)(A), (B), (C), and (G), when they did not also identify and
21 withdraw from the Medicare Program previously submitted diagnosis codes that were
22 unsupported by the reviewed medical charts and return to the Program the overpayments
23 based on these invalid diagnoses.

24 *Defendants' Position:* Defendants anticipate the following disputed factual issues:
25 (1) whether Defendants designed retrospective reviews of patient records deliberately to
26 avoid identifying erroneously submitted diagnosis codes that might otherwise have been
27 identified with reasonable diligence; (2) whether HCP implemented record-review
28 procedures specifically designed not to reveal unsupported diagnosis codes; (3) whether

Defendants engaged in reasonable efforts to identify and withdraw unsupported diagnosis codes; (4) whether HCP's retrospective reviews resulted in knowingly false certifications of accuracy of plan data under 42 C.F.R. § 422.504(l); (5) whether Defendants knowingly presented to CMS certifications that falsely represented the accuracy of plan data or otherwise "knowingly" violated the FCA; and (6) whether risk scores were inflated as a result of the chart review practices employed by HCP.

UnitedHealth's Position: In addition to the factual disputes identified above, UnitedHealth anticipates additional factual disputes will include: UnitedHealth's transparency and disclosures to the Government regarding its risk adjustment processes and the role if any of UnitedHealth in the design and execution of HCP's chart reviews.

3. DISPUTED POINTS OF LAW

United States' and Relator's Position: Key disputed points of law will include: The interpretation of *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1167-69 (9th Cir. 2016), the obligation of Medicare Advantage Organizations such as UnitedHealth and providers such as HCP to submit valid diagnoses to the Medicare Program for risk adjustment payments and to correct prior submissions of invalid diagnoses and return the overpayments, and their liability under the FCA.

Defendants' Position: Key disputed points of law will include the fundamental question that will be decided in the Administrative Procedure Act suit pending in the D.C. District Court: whether it violates the statutory mandate of "actuarial equivalence" in the Medicare Act, 42 U.S.C. § 1395w-23(a)(1)(C)(i), to require MA plans to exercise "reasonable diligence" to identify and delete unsupported diagnostic codes or to delete diagnosis codes that they identified, or should have identified, as allegedly unsupported by medical charts. *See UnitedHealthcare Insurance Co. v. Price*, No. 1:16-cv-00157-RMC, Slip op. at 6 (*citing* 79 Fed. Reg. at 29,923). Additional key disputed points include: (1) whether a physician's subjective clinical judgment regarding diagnostic coding may give rise to a false claim under the FCA; (2) whether the government's theory of liability is consistent with the Court of Appeals' opinion; (3) whether

UnitedHealth submitted any certifications that are “false” under the FCA; (4) whether UnitedHealth violated the FCA for insufficient supervision of its capitated providers’ coding practices; (5) whether Defendants “knowingly” violated the FCA in light of the regulatory landscape and the government’s knowledge of UnitedHealth’s chart review processes; (6) whether any alleged noncompliance was material to payment; and (7) whether the acts of Defendants resulted in damages actionable under the FCA. HCP anticipates an additional legal dispute as to whether some or all of Relator’s claims are barred by the applicable statutes of limitations.

4. PRIOR, PENDING, AND ANTICIPATED MOTIONS

Prior: In March 2017, this Court granted the United States’ unopposed request for leave to intervene against UnitedHealth in this *qui tam* action. (ECF No. 254)

Pending: United States’ Motion to Consolidate this action with *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, CV 16-8697-MWF (SSx) (“*Poehling*”) as to UnitedHealth and HCP set for hearing on May 1, 2017. (ECF No. 271)

Anticipated: All parties anticipate filing dispositive motions (including motions for summary judgment) before a trial in this action. All parties reserve the right to file other pretrial motions, including but not limited to motions to dismiss, motions related to discovery disputes, motions *in limine*, and motions to exclude experts.

5. ADDITIONAL PARTIES, CLAIMS, DEFENSES, OR AMENDMENTS

United States’ Position: The United States and HCP are currently discussing a resolution of potential claims related to risk adjustment. If a resolution with HCP fails, the United States may move for leave to intervene as to HCP and, if granted, amend its Complaint-in-Intervention to add claims against HCP. If the United States is able to resolve the claims against HCP, it may move to dismiss that defendant from this action. Additionally, if this Court or Judge Fitzgerald concludes that *Swoben* was the first-to-file with respect to UnitedHealth’s national Chart Review Program from 2007 to present, the United States will either amend its Complaint-in-Intervention in *Swoben* or file its own FCA action against UnitedHealth relating to UnitedHealth’s national Chart Review

1 Program. Given the uncertainty of the timing of the aforementioned, the United States
2 proposes a December 31, 2017 tentative deadline for amending pleadings.

3 *UnitedHealth's Position:* While UnitedHealth is unable to meaningfully assess its
4 claims and defenses because the Complaint-in-Intervention has not been filed and Judge
5 Fitzgerald has not yet had occasion to assess motions in the *Poehling* case, UnitedHealth
6 anticipates that it may assert equitable affirmative defenses including without limitation
7 waiver, ratification and estoppel, and counterclaims including without limitation breach
8 by CMS of its MA contracts. *HCP's Position:* HCP does not intend to add parties,
9 claims, or amendments. HCP intends to include various defenses in its Answer to
10 Relator's Fourth Amended Complaint.

11 **6. INITIAL DISCLOSURES**

12 The parties anticipate exchanging initial disclosures required by FRCP
13 26(a)(1)(A) by August 1, 2017.

14 **7. DISCOVERY**

15 *Status:* The United States and Relator anticipate serving UnitedHealth and HCP
16 with document requests before May 1 or very soon thereafter. HCP anticipates serving
17 Relator with document requests before May 1, 2017 or very soon thereafter.
18 UnitedHealth anticipates serving discovery in the near future, though believes that
19 discovery issued by the United States before it has filed its complaint would be
20 premature and subject to objection or possibly a protective order.

21 *United States' Expectations:* The United States and Relator anticipate discovery,
22 including third party discovery, regarding HCP's chart reviews (*e.g.*, who and how
23 conducted and the results); UnitedHealth's knowledge of and involvement in those chart
24 reviews; the use of the Industry Collaborative Effort for Healthcare's ("ICE's")
25 diagnosis code reporting template for reporting the results of chart reviews; Defendants'
26 knowledge concerning the validity of diagnosis codes reported by physicians or their
27 administrative support staffs; Government Risk Adjustment Data Validation Audits and
28 other similar audits or reviews; HCP's process for reporting diagnosis codes to

1 UnitedHealth and for deleting or correcting unsupported, inaccurate, and untrue codes;
2 UnitedHealth's process for submitting provider-reported codes to the Medicare Program
3 and for deleting or correcting invalid codes; and damages. The United States disagrees
4 with UnitedHealth's characterization of the anticipated discovery, below, particularly
5 regarding the anticipated discovery needs of the United States.

6 The United States and Relator expressly reserve the right to conduct discovery on
7 additional subjects and from additional persons or entities as necessary and appropriate,
8 and to make appropriate objections to discovery requests.

9 *Defendants' Position:* Unlike in many cases where the plaintiff is the United
10 States, here a vast amount of necessary information is in possession of the government.
11 Defendants anticipate needing extensive discovery from the United States in order to
12 prepare their defenses, including discovery relating to: the manner in which risk
13 adjustment factors are calculated; CMS' knowledge of Defendants' chart reviews and its
14 awareness of industry-wide diagnostic coding error rates during the relevant time period;
15 any attempts by the United States to calculate a Medicare fee-for-service error rate; the
16 meaning of the "reasonable diligence" standard; the decision not to finalize the medical
17 record review rule; meetings and communications between UnitedHealth and CMS
18 regarding its obligations to perform a "two-way-look" in light of this proposed rule; and
19 the May 2014 and February 2015 overpayment rules. Defendants will also seek
20 discovery, including third party discovery, to identify what information, if any, Relator
21 possesses, how Relator obtained that information, and the source of that information.

22 Defendants expressly reserve the right to conduct discovery on additional subjects
23 and from additional persons or entities as necessary and appropriate, and to make
24 appropriate objections to discovery requests.

25 *UnitedHealth's Position:* UnitedHealth does not anticipate the United States needs
26 significant additional discovery in this matter. The United States contends that this case
27 is related to the *Poehling* case and has argued repeatedly that it only became convinced
28 that Relator's earlier claims were meritorious after it began investigating Poehling's

1 later complaint. The *Poehling* case remained under seal in the Western District of New
2 York for more than five years to allow the United States to conduct an investigation in
3 which UnitedHealth provided extensive documentary and testimonial submissions to the
4 United States and, based on the parties' meet-and-confer, UnitedHealth anticipates that
5 the Government's Complaint-in-Intervention will narrowly focus on California-based
6 reviews by HCP.

7 *Discovery Plan and Limitations on Discovery:*

8 Prior to the production of documents, the parties will meet to negotiate a proposed
9 Stipulated Protective Order Regarding Confidential Information and a proposed
10 Stipulated Order Pursuant to Federal Rule of Evidence 502(d). The United States will
11 provide Defendants with its specifications for the production of electronically stored
12 information and digitized images.

13 The parties propose the following schedule:

- 14 • Complete Fact Witness Depositions: December 31, 2018
- 15 • Complete Expert Disclosures: April 2, 2019
- 16 • Complete Expert Witness Depositions: August 1, 2019

17 *United States' and Relator's Position:* The United States and Relator propose
18 phased discovery whereby document production is completed before depositions begin,
19 with document production completed by June 1, 2018. The United States proposes that
20 the parties may, without taking leave of Court, serve up to thirty (30) interrogatory
21 requests each, and that the parties may, without taking leave of Court, take up to fifteen
22 (15) fact witness depositions each in addition to the depositions of each witness listed in
23 the Rule 26(a)(1) disclosures submitted by each party.

24 Should this Court grant the United States' Motion to Consolidate, the United
25 States reserves the right to request additional discovery for the purpose of litigating the
26 much larger *Poehling* action. Also, if this Court or Judge Fitzgerald disagrees with the
27 United States about the first-to-file issue and concludes that the claims and allegations in
28 *Poehling* relating to UnitedHealth's national Chart Review Program were first asserted

1 in *Swoben*, the United States may seek leave to amend its Complaint-in-Intervention in
2 *Swoben* to include its claims and allegations relating to UnitedHealth's national Chart
3 Review Program (if it does not file its own action) and request permission to conduct the
4 additional discovery relating to those additional claims and allegations.

5 *Defendants' Position:* Defendants do not agree with a multi-phase discovery
6 approach. Rather, discovery should be conducted in one phase, and each party is
7 responsible for ensuring that it accomplishes what is required during the discovery
8 period as a whole. A phased approach is not contemplated under the Federal Rules of
9 Civil Procedure, and Defendants do not see any reason to deviate from the standard
10 discovery procedure. *UnitedHealth's Position:* While UnitedHealth anticipates needing
11 extensive discovery from the Government, the United States already has requested and
12 received extensive documentary and testimonial submissions from UnitedHealth in the
13 lengthy *Poehling* investigation that the United States contends is related to this matter.
14 UnitedHealth does not see the need for extensive discovery from Defendants and
15 anticipates seeking a protective order if necessary to avoid producing duplicative
16 discovery in this case.

17 **8. RELATED CASES OR PROCEEDINGS**

18 *United States' Position:* *United States ex rel. Poehling v. UnitedHealth Group,*
19 *Inc.*, CV 16-8697-MWF (SSx).

20 *UnitedHealth's Position:* *UnitedHealthcare Insurance Co. v. Price*, No. 1:16-cv-
21 00157-RMC (D.D.C. 2016).

22 **9. RELIEF SOUGHT**

23 *United States' Position:* After UnitedHealth and HCP produce the results of the
24 chart reviews at issue, the United States will determine the risk adjustment claims that
25 were false and the diagnosis codes that should not have been submitted to the Medicare
26 Program and quantify the overpayments based on these invalid codes. In order to
27 perform this damages analysis, the United States also may need to obtain documents and
28 other information from one or more third-party coding vendors which performed the

1 chart reviews at issue.

2 *Defendants' Position:* Defendants will have an alternate theory as to how damages
3 should be calculated if liability is established in light of the contracts and
4 reimbursement methodology. Although Defendants' position is too preliminary to fully
5 articulate prior to the filing of the Complaint-in-Intervention, Defendants anticipate
6 challenging the propriety of sampling and extrapolation and asserting that a fee-for-
7 service adjustor must be applied to account for unsupported codes in the diagnostic data
8 of fee-for-service beneficiaries.

9 **10. CERTIFICATIONS AS TO INTERESTED PARTIES**

10 Each party filed the Certification as to Interested Parties or Persons required by
11 Local Rule 7.1-1 on the following dates and each party restates, below, the contents of
12 its certification:

13 UnitedHealth: UnitedHealth filed its Certifications on April 25, 2013, and restate
14 that UnitedHealthCare Services Inc., United HealthCare Group, H&W Indemnity (SPC)
15 Ltd., UHC of California, and UHIC Holding Inc. may have a direct, pecuniary interest in
16 the outcome of this case.

17 HCP: Defendant HealthCare Partners, LLC, which is now known as DaVita
18 Medical Management, LLC (sued as "HealthCare Partners") and Defendant HealthCare
19 Partners Medical Group, Inc., which is now known as DaVita Medical Group California,
20 P.C. (sued as "HealthCare Partners Medical Group") filed their Certification on February
21 22, 2017, and restate that DaVita Inc., DaVita Medical Management, LLC, DaVita
22 Medical Group California, P.C., Dr. Chan-Chou Chuang, MD, and Dr. Robert Tseng,
23 MD may have a direct, pecuniary interest in the outcome of the case.

24 **11. PROPOSED SCHEDULE**

25 The Parties propose the following schedule:

26 Completion of Fact Discovery	December 31, 2018
27 Completion of Expert Discovery	August 1, 2019
28 File Dispositive Motions	November 1, 2019

Motion Hearing Date January 6, 2020

Final Pre-Trial Conference April 6, 2020

Trial Date May 5, 2020

12. JURY/TRIAL

United States' and Relator's Position: The United States and Relator request a jury trial. The United States estimates that the trial will take approximately two to four weeks if *Swoben* is not consolidated with *Poehling*. If consolidated, the trial will likely take a minimum of four weeks (and likely over four weeks if the consolidated trial also includes the other claims against UnitedHealth in *Poehling* that are unrelated to its national Chart Review Program). Also, if this Court or Judge Fitzgerald concludes that the claims and allegations in *Poehling* relating to United's national Chart Review Program were first asserted in *Swoben*, the trial will likely take at least four weeks.

UnitedHealth's Position: UnitedHealth is unable to estimate the time required for trial until the Complaint-in-Intervention is filed.

HCP's Position: HCP opposes consolidation and estimates that trial of claims and disputes between HCP and Relator will take approximately two weeks.

13. SETTLEMENT EFFORTS

The parties select ADR Procedure No. 3, a private dispute resolution proceeding, as best suited to the circumstances of the case. L.R. 16-15.4

United States' Position: The United States and HCP have discussed a possible resolution of various claims related to risk adjustment issues but unrelated to the claims before this Court. Recently, the claims against HCP regarding the chart review allegations raised by Relator have been added to these discussions. The prospects of settlement with HCP can be enhanced by focusing discovery in this case on the scope of the chart reviews at issue and an assessment of damages.

United Health's Position: Based on earlier discussions with the United States, UnitedHealth respectfully believes that settlement discussions would not be productive at this time, and will not be productive at least until after the Court has resolved any

1 preliminary motions and the parties exchange information through discovery, if
2 Plaintiff's case proceeds.

3 *HCP's Position:* HCP is engaged in discussions with the United States regarding
4 a potential plan and framework for proceeding to a possible resolution of various claims
5 related to risk adjustment issues, including allegations raised on the face of the Fourth
6 Amended Complaint in *Swoben*. It is difficult to predict whether the parties will be able
7 to reach a settlement. HCP has not discussed settlement with Relator.

8 **14. CASE COMPLEXITY**

9 *United States' Position:* The United States believes consolidation is appropriate as
10 set forth in its March 24, 2017 motion. (ECF No. 271)

11 *Defendants' Position:* As set forth in their respective oppositions to the United
12 States' motion, Defendants oppose consolidation (ECF Nos. 277 and 279).
13 UnitedHealth is unable to make a determination on whether the manual on complex
14 litigation should be utilized before seeing the Complaint-in-Intervention. However,
15 particularly if the claims here are not consolidated with the *Poehling* action, the manual
16 of complex litigation will not be applicable.

17 **15. DISPOSITIVE MOTIONS**

18 The parties anticipate filing cross-motions for summary judgment on liability and
19 possibly also damages.

20 **16. UNUSUAL LEGAL ISSUES**

21 The meaning and significance of the term "actuarial equivalence" in the Medicare
22 Advantage statute. 42 U.S.C. § 1395w-23(a)(1)(C)(i).

23 **17. SEVERANCE, BIFURCATION, ORDER OF PROOF**

24 *United States' Position:* The United States opposes ordering of proof or
25 bifurcation as to liability and damages.

26 *UnitedHealth's Position:* As to order of proof, UnitedHealth proposes that the
27 issue of liability, if any, be resolved before any damages trial.

28 *HCP's Position:* If the United States' Motion for Consolidation is granted, HCP

1 will seek severance of the claims asserted by Relator against HCP from the remainder
2 of the case for purposes of trial.

3
4 Dated: April 17, 2017

Respectfully submitted,

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1 Dated: April 17, 2017

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6 Dated: April 17, 2017

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LOCAL RULE 5-4.3.4 ATTESTATION

I attest that all other signatories listed, and on whose behalf this filing is submitted,
concur with the filing's content and have authorized the filing.

Dated: April 17, 2017

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney

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EXHIBIT O

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No. 13-56746

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff,

and

JAMES M. SWOBEN, Qui Tam Relator,
Plaintiff-Appellant,

v.

UNITED HEALTHCARE INSURANCE COMPANY, a Connecticut Corporation;
UNITED HEALTHCARE SERVICES, INC., a Minnesota Corporation; UHIC;
UNITEDHEALTH GROUP; UNITEDHEALTHCARE; UNITEDHEALTH;
PACIFICARE HEALTH PLAN ADMINISTRATORS, INC.; UHC OF
CALIFORNIA, FKA PacifiCare of California; PACIFICARE LIFE & HEALTH
INSURANCE CO.; PACIFICARE HEALTH SYSTEMS; HEALTH NET;
WELLPOINT; AETNA; HEALTHCARE PARTNERS, LLC; HEALTHCARE
PARTNERS MEDICAL GROUP, INC.; HEALTHCARE PARTNERS
INDEPENDENT PHYSICIAN ASSOCIATION,
Defendants-Appellees.

On Appeal from the United States District Court
for the Central District of California
Case No. 2:09-cv-05013-JFW-JEM

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Case 1:16-cv-00157-RMC Document 31-16 Filed 04/28/17 Page 3 of 21

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California (f.k.a. PacifiCare of

California), PacifiCare Life and

Health Insurance Company,

PacifiCare Health Systems

(collectively, “United Health”), and

Health Net

(complete list of counsel on signature page)

Dated: February 24, 2016

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INTRODUCTION AND SUMMARY OF ARGUMENT

Swoben alleges that Defendants submitted false claims for reimbursement by conducting retrospective chart reviews to look for diagnosis codes that may have been missed by a provider's coders, without also validating the codes separately submitted by those providers through claims. The Court has asked whether engaging in such reviews could cause Defendants' certifications to CMS to be false. The answer is "no."

When an MA plan certified, based on its "best knowledge, information, and belief," that data created by third-party medical providers were "accurate, complete, and truthful" under 42 C.F.R. § 422.504(*l*), it was attesting only that, as far as the MA plan knew, it was faithfully submitting an accurate, complete, and truthful set of diagnosis codes received from those providers. During the time period alleged in the complaint, no statute, regulation, or guidance from CMS indicated that a certification could only be "accurate, complete, and truthful" if an MA plan validated for itself that the millions of diagnosis codes submitted to it by third-party providers were supported by the underlying medical charts—*i.e.*, that the plan was required to attest to the accuracy of someone else's work. Nor did any authority indicate that a plan was obliged to undertake affirmative steps to unearth potentially unsupported codes before it could certify the third-party risk adjustment data based on its "best knowledge, information, and belief." In fact, the

regulations and CMS' own procedures indicated just the opposite. *See infra* at 6-7. An MA plan's independent and voluntary decision to engage in snapshot reviews, and its awareness of general risk adjustment data validation ("RADV") error rates, thus had no bearing on the truthfulness of a plan's certification.

Moreover, even assuming Swoben were correct that a certification could only be "accurate, complete, and truthful" if an MA plan took some proactive steps to ensure that diagnosis codes were supported by medical charts, he still could not establish that, by conducting retrospective reviews that did not seek to validate prior codes, the plans submitted a false certification. Retrospective chart reviews are not the only means for an MA plan to identify unsupported codes. Indeed, even when CMS adopted the "reasonable diligence" standard in 2014, years after the relevant time period for this complaint, it expressly *declined* to mandate that MA plans design retrospective chart reviews to look for codes that would trigger negative payment adjustments.

Finally, at a minimum, Swoben's allegations fail to demonstrate that the defendants' certifications were *knowingly* false. During the relevant time period, there was no basis for any MA plan to conclude that undertaking a limited review of a subset of a beneficiary's medical charts (without seeking to validate all diagnosis codes that may have been reported via myriad patient encounters) would somehow render its certification false. At worst, the certification was ambiguous,

and this alone precludes as a matter of law the possibility that any MA plan knowingly submitted false certifications.

ARGUMENT

I. CONDUCTING RETROSPECTIVE REVIEWS WOULD NOT CAUSE THE DEFENDANTS' CERTIFICATIONS TO BE FALSE

A. The Certifications Did Not Attest That Plans Affirmatively Double Checked the Validity of Codes Submitted By Providers

Swoben's proposed fourth amended complaint alleges that from about 2005 to about 2012 some Defendants submitted false claims to CMS by conducting retrospective reviews of a subset of their beneficiaries' medical encounters designed to look for diagnosis codes that had not previously been submitted, without undertaking the additional step of validating codes separately submitted by providers through claims. *See* 3ER312. He contends that conducting such reviews rendered false Defendants' certifications that their risk adjustment data were "accurate, complete, and truthful." *See* Swoben Suppl. Br. 1-3.

As an initial matter, Swoben's proposed fourth complaint—even if viewed as offering a certification theory—remains woefully insufficient under Rule 9(b) because it fails to identify *any* specific facts regarding *any* false claims or fraudulent schemes by particular Defendants. Swoben's entire complaint, including his false-certification theory, is premised on the speculative and unsupported possibility that some third-party providers reported unsupported

diagnosis codes, that “defendants” passed them along to CMS thereby supposedly making their certifications false, and that subsequent reviews performed by “defendants” were too limited to find these unidentified unsupported diagnosis codes and delete them. 3ER309. These speculative and generalized assertions fail to satisfy Rule 9(b).

In any event, Swoben’s contention that conducting snapshot retrospective reviews rendered Defendants’ certifications false is meritless. Under 42 C.F.R. § 422.504(*l*), MA plans certify that, based on the certifier’s “best knowledge, information, and belief,” the plan’s risk adjustment data are “accurate, complete, and truthful.” No statute, regulation, or guidance from CMS during the relevant period indicated that, by executing that certification, an MA plan warranted that all diagnosis codes submitted by third-party medical providers were supported by beneficiaries’ medical charts—as opposed to attesting that the codes were, in fact, an accurate, complete, and truthful set of diagnosis codes those plans received from those providers. And nothing indicated that “best knowledge, information, and belief” implicitly warranted that plans had undertaken affirmative steps to find such alleged “inaccuracies”—as opposed to attesting that the plans did not *know* of any unsupported diagnosis codes.¹

¹ Swoben has never alleged that Defendants were aware that any unsupported diagnosis codes were submitted. In fact, he alleges the *opposite*. See, e.g.,

Neither an MA plan's decision to conduct snapshot retrospective reviews, nor its awareness of general RADV error rates, could possibly affect the truth of its certification. Any additional accurate codes submitted by the MA plan had no bearing on the plan's independent certification that the set of third-party diagnosis codes it submitted to CMS accurately reflected the set it received from those third-party providers. Swoben has never alleged—much less with particularity—that *any* diagnosis code that *any* plan submitted as a result of such reviews was inaccurate. And if, as Swoben contends, awareness of general RADV error rates were sufficient to trigger a duty to undertake affirmative steps to verify third-party codes, then that would be true for every MA plan in the country—whether or not the plan conducted retrospective chart reviews. Yet, at oral argument (at 3:48-3:53), Swoben renounced such a result when he conceded that plans that do not conduct such reviews have no duty to verify the accuracy of provider diagnosis codes.

Swoben points out (at 4) that knowledge under the False Claims Act also includes deliberate ignorance or reckless disregard of the truth, and argues (at 7-8) that “[n]umerous courts have held that submitting a certification without adequate investigation constitutes deliberate ignorance or reckless disregard.” But that argument assumes the answer to the question posed by the Court: whether the

3ER310 (“[T]he results of the coders’ reviews did not identify [any] diagnosis codes unsupported by proper documentation of the reviewed medical charts....”).

certifications were false at all. Here, the certifications did not attest directly to the accuracy of provider submitted codes; moreover, the attestation was “based on best knowledge, information, and belief.” “In certifying the truth of ... information ... ‘to the best of its knowledge and belief’ [the defendant does] no more than assert that it had no knowledge of, nor intention to make, misrepresentations”; it is *not* an “unqualified assertion of fact” that would require the certifier “to verify the information.” *United States v. Ekelman & Assocs.*, 532 F.2d 545, 549-50 (6th Cir. 1976). A certification “based on best knowledge, information and belief” thus does not warrant that plans have undertaken affirmative steps to find unsupported codes. Absent such a guarantee, the certifications cannot be false, let alone knowingly false.

Contemporaneous CMS regulations and statements cement Defendants’ reading of the certification. From 2005 to 2012, the most relevant regulation provided that MA plans were required to submit to CMS risk adjustment data “equivalent to [the] Medicare fee-for-service data” CMS relied on to determine the relative health of the average traditional Medicare beneficiary for purposes of establishing an MA plan’s payment. 42 C.F.R. § 422.310(d); *see* Defendants-Appellees Br. 7-11 (describing risk adjustment). CMS has *never* purported to verify *any* of the diagnosis codes submitted to *it* by third-party medical providers for its traditional FFS beneficiaries. To the contrary, it has acknowledged that its

risk-adjustment model determines the average health of an FFS beneficiary based on claims data that have not been audited against medical charts. *See CMS, Final RADV Methodology*, at 4 (Feb. 24, 2012).² Accordingly, CMS’ own data reflect the natural occurrence of inadvertent coding mistakes by medical providers—indeed, often the very same third-party medical providers. “[E]quivalent” data from an MA plan may reflect the same.

The RADV process also bolsters this conclusion. In that process, CMS does not attempt to recover for all unsupported codes in the audited plan’s submissions. Instead, CMS applies a so-called FFS “adjuster” to account for similar unsupported codes in CMS’ own data. *Id.* If the audited plan’s error rate is no higher than the error rate in CMS’ data, then *no* contract payment adjustment occurs. *Id.* CMS therefore recognizes that unsupported codes are an incidental part of the system.

Against this statutory and regulatory background that existed at the time of the relevant submissions and certifications, statements by CMS made in connection with the 2014 promulgation of a *prospective* regulation, 42 C.F.R. § 422.326(c), cannot establish the meaning of certifications signed and submitted years before. *See Swoben Suppl. Br.* 5-6 (citing 79 Fed. Reg. 29,844, 29,923 (May 23, 2014)). Tellingly, the 2014 preamble did not cite a single pre-2014 pronouncement by

² Available at <http://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/radvmethodology.zip>.

CMS on the meaning of the certifications. And the “reasonable diligence” standard adopted in 2014 reflects CMS’ implementation of an unrelated, recently-enacted statutory provision, 42 U.S.C. § 1320a-7k(d),³ which Swoben’s allegations do not implicate.⁴

A certification based on “best knowledge, information, and belief” that data submitted by someone else were “accurate, complete, and truthful” means exactly what it says—as far as the certifier knows, the data are what they purport to be—not that the certifier has taken unspecified steps to investigate further. Neither snapshot retrospective reviews, nor general RADV error rates about a *different* set of codes, can affect the truth of that assertion.

B. Snapshot Reviews Do Not Demonstrate That a Plan Is Not Taking Affirmative Steps to Verify Third-Party Diagnosis Codes

Moreover, even assuming Swoben were right that a certification can be true only if an MA plan exercised reasonable diligence to ensure that submitted

³ Swoben’s related description (at 6-7) of CMS’ statements as “comport[ing] with the FCA’s definition of ‘knowing’ violations” is wrong. Although CMS proposed implementing § 1320a-7k(d) by adopting a “reckless disregard or deliberate ignorance” standard, in the final rule it *rejected* that standard in favor of the “reasonable diligence” standard. 79 Fed. Reg. 29,923. It expressly disclaimed any attempt to “interpret the terms ‘knowing’ or ‘knowingly,’ which are defined in the Civil False Claims Act.” *Id.* at 29,924.

⁴ Even if these 2014 statements were relevant, both the validity of the “reasonable diligence” standard and the requirement that plans delete all unsupported codes they identify is currently being challenged in the U.S. District Court of the District of Columbia as inconsistent with the Medicare Act and the APA. *UHC v. Burwell*, No. 1-cv-16-157 (D.D.C. complaint filed Jan. 29, 2016).

diagnosis codes were supported by medical charts, he still could not establish that the MA plans' certifications were false. The fact that MA plans conducted reviews of a *subset* of medical encounters for a *subset* of a plan's beneficiaries does not remotely demonstrate (or plausibly allege) that a plan is not undertaking *other* reasonable steps to meet such an obligation.

There are myriad ways a plan could exercise reasonable diligence to discover unsupported codes. Plans could seek to identify whether particular third-party providers have aberrational patterns of coding. They could choose to separately audit all diagnosis codes submitted during a given year for a sample of their beneficiaries (not focused on beneficiaries whose charts were previously reviewed). And there are many more. The fact that a plan conducted snapshot retrospective reviews to identify unreported diagnoses says absolutely nothing about whether the plan executed other procedures to unearth unsupported codes (whether or not the certification actually required it).

Indeed, there are good reasons for an MA plan *not* to use the same process to serve both ends. As Swoben acknowledges (at 8), using retrospective reviews to find unsupported codes would require that such reviews *not* be blind. Only by providing reviewers a list of previously submitted codes can those reviewers determine whether previously submitted codes are adequately documented in the reviewed medical chart, which—even if practicable—risks undermining the

objectivity of that review. The primary purpose of a retrospective review is to obtain an *independent* judgment of the codes supported by a particular medical chart. Suggesting to the reviewer what he or she *should* look for would diminish that independence.

Swoben’s alternative contention—that MA plans are somehow required to perform a reconciliation of the snapshot review with earlier coding results to remove codes not found in the second review—is equally problematic. As Defendants previously explained, identifying a code that may be unsupported by the medical chart for a *particular* encounter does not establish that a plan has submitted a false claim for payment because a diagnosis code may be supported by *any* medical record from *any* encounter with *any* medical provider for a beneficiary in a given year. *See* Defendants-Appellees Br. 35-37 & n.18. Without reviewing every chart and every encounter in that year, the fact that a code is unsupported by *one* chart cannot possibly establish that the code should be deleted. Swoben has not alleged that any plan structured its retrospective reviews in a manner that was designed to review, and then ignore, the entire medical record of a beneficiary—nor could he plausibly do so.

The same 2014 rulemaking on which Swoben relies provides the most powerful evidence that retrospective reviews are not the only way to exercise “reasonable diligence” to find unsupported codes. Although Swoben insists that

the preamble to this rulemaking proves that MA plans have always been required to exercise such reasonable diligence, CMS quite clearly left it to plans to determine what specific steps might constitute reasonable diligence. CMS announced that “reasonable diligence” would require *some* “proactive compliance activities conducted in good faith.” 79 Fed. Reg. at 29,923. But that does not come close to a requirement that plans specifically utilize *retrospective chart review programs* to do so.

In fact, CMS explicitly declined to adopt such a requirement. In the notice of the very same proposed rulemaking, CMS also proposed “strengthening [its] existing regulations” by “requir[ing] that any medical record reviews conducted by an MA organization ... be designed to determine the accuracy of diagnoses [previously] submitted ... [and not] designed *only* to identify diagnoses that would trigger additional payments by CMS.” *Id.* at 29,925. But after considering comments by numerous MA plans pointing out the problems with such a requirement, CMS declined to “finalize” that proposal. *Id.* at 29,926.

There is no basis for a court to retroactively impose such a requirement on MA plans from *2005 through 2012* under the heavily punitive FCA, when CMS declined to “strengthen” its existing regulations by imposing that very requirement on a prospective basis *in 2014*.

**II. AT A MINIMUM, CONDUCTING RETROSPECTIVE REVIEWS
WOULD NOT CAUSE THE DEFENDANTS' CERTIFICATIONS TO
BE KNOWINGLY FALSE**

For all these reasons, Swoben cannot establish that the mere fact that Defendants allegedly conducted snapshot reviews rendered their certifications false. The Court should affirm the district court on that basis alone. But even if the Court were to adopt a different interpretation today, at a minimum from 2005 to 2012 it was objectively *reasonable* to conclude that snapshot retrospective reviews would not render their certifications false. And that alone is sufficient as a matter of law to preclude a finding that the plans knowingly or recklessly submitted false certifications. *See United States ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (“To take advantage of a disputed legal question, ... is to be neither deliberately ignorant nor recklessly disregardful.”); *cf. Safeco Ins. Co. v. Burr*, 551 U.S. 47, 70 n.20 (2007) (“Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator ... whatever their subjective intent may have been.”).

CONCLUSION

The district court's judgment should be affirmed.

Dated: February 24, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing Joint Supplemental Brief of Defendants-Appellees complies with the Order dated January 27, 2016. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6). This brief is 2,748 words, excluding the portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

Dated: February 24, 2016

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9th Circuit Case Number(s) 13-56746

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CERTIFICATE OF SERVICE

When All Case Participants are Registered for the Appellate CM/ECF System

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on (date) February 24, 2016 .

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Signature (use "s/" format) s/ David J. Schindler

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I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on (date) .

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Signature (use "s/" format)

Case 1:16-cv-00157-RMC Document 31-17 Filed 04/28/17 Page 1 of 12

EXHIBIT P

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

UNITED STATES OF AMERICA
and STATE OF CALIFORNIA *ex rel.*
JAMES M. SWOBEN,

Plaintiffs,

v.

SCAN HEALTH PLAN, *et al.*,
Defendants.

CASE NO. CV 09-5013 JFW (JEMx)

Statement of Decision Denying the
United States of America's Motion to
Consolidate

INTRODUCTION

The United States (the “Government”) filed a motion to consolidate this case (“*Swoben*”) with a separate case recently transferred from the Western District of New York: *United States ex rel. Poehling v. UnitedHealth Group et al.*, 2:16cv8697 (C.D. Cal.) (“*Poehling*”). The Government has not filed its complaint-in-intervention in either case. Defendant UnitedHealth opposed the motion on grounds that it is premature. Defendant HCP also opposed the motion. Because the Government has not met its burden in demonstrating that consolidation should occur at this early stage of the litigation, the Government’s motion to consolidate is denied.

FACTS

There are three separate actions relevant to the Government’s motion to consolidate: (1) the *Swoben qui tam* action, (2) the *Poehling qui tam* action, and (3) an Administrative Procedure Act action pending in the United States District Court for the District of Columbia. Each case addresses whether UnitedHealth has an obligation to actively seek out and delete diagnosis codes associated with the medical condition of its beneficiaries in certain circumstances.

I. The *Swoben* Action

Relator James Swoben filed his original complaint in 2009 under seal in the Central District. (Docket No. 1.) Initially, he alleged violations of the False Claims Act arising from billing practices by two defendants who are no longer parties, Scan Health Plan and Senior Care Action Network (“SCAN”), where he was an employee from 2004-2006. (*Id.* at 3-7; Docket No. 133 at 9.)

Through a series of amended complaints, Swoben later added allegations against UnitedHealth arising from a retrospective review process of patient medical charts that UnitedHealth employed to ensure it was receiving proper payment from the federal government under the Medicare Advantage (“MA”) program (*i.e.*, a review of the patient medical charts done at some point after the

1 provider initially provided diagnosis codes to the Medicare Plan). (See Docket No.
2 37 at 23-27.) In essence, Swoben alleged that the process used to perform the
3 retrospective reviews in California was “biased” in favor of adding information
4 which might enhance reimbursement to UnitedHealth without simultaneously
5 reviewing the medical charts to see whether any diagnosis codes previously
6 submitted by physicians were adequately documented.

7 The Government initially opted not to intervene in support of Swoben’s
8 claims against UnitedHealth, and the action was dismissed with prejudice in 2013.
9 (See Docket No. 133 at 10.) Swoben appealed, and the parties briefed and argued
10 the case before the Ninth Circuit. The United States did not initially participate in
11 the appeal, but after oral argument, it filed an amicus brief arguing that the
12 certification required UnitedHealth to exercise “due diligence” to identify and
13 delete from its claims data diagnostic codes that were not supported in the
14 underlying medical charts. See Brief of United States 6-7, *United States ex rel.*
15 *Swoben v. United Healthcare Ins. Co.*, No. 13-56746 (9th Cir. Apr. 18, 2016).

16 In August 2016, the Ninth Circuit reversed the dismissal of Swoben’s claims
17 against UnitedHealth, and remanded the case to this Court. See [*United States ex*](#)
18 [*rel. Swoben v. United Healthcare Ins. Co.*, 832 F.3d 1084 \(9th Cir. 2016\)](#), *amended*
19 *on rehearing*, 848 F.3d 1161 (9th Cir. 2016). On March 13, 2017, Swoben filed
20 his Fourth Amended Complaint. (No. 09-5013 (C.D. Cal.), Docket No. 251.) That
21 complaint repeats his earlier allegations about UnitedHealth’s chart review efforts.
22 (*Id.* at 3-15.) According to the Government, Swoben’s claims properly extend only
23 to UnitedHealth’s Medicare Advantage plan in California, and not to separate chart
24 review efforts for other UnitedHealth plans throughout the country. (See U.S. Mot.
25 20 n.13.) The Government has also indicated that Swoben’s claims are properly
26 limited to the 2005-2006 time period. (See Docket No. 259 ¶ 4.)

27 In March, the Government moved to intervene in the case and this Court
28 ordered it to file its complaint-in-intervention by May 1, 2017.

1 **II. The *Poehling* Action**

2 The second action relevant to this motion was filed under seal in the Western
3 District of New York in 2011. In that case, Relator Benjamin Poehling, a former
4 UnitedHealth employee, alleges that the national Chart Review Program that he
5 helped to develop and operate for UnitedHealth starting in 2007 had resulted in the
6 submission of false claims. (*See, e.g., Poehling* Compl. ¶¶ 16-17, 109, 114-66, No.
7 11-cv-258 (W.D.N.Y.), at Ex. 3 to Docket No. 271-2.)

8 Poehling's case remained under seal in the Western District of New York for
9 more than five years while the Government investigated his allegations. The
10 Government did not seek transfer, however, until November 2016, when it filed an
11 *ex parte* motion to have the case transferred to the Central District of California,
12 which was granted. Because the case remained under seal, UnitedHealth was not
13 given the opportunity to respond to that motion. (No. 16-cv-8697 (C.D. Cal.),
14 Docket No. 50.) The Government moved to intervene in *Poehling* after it was
15 transferred. (*See id.*, Docket No. 78.) Judge Fitzgerald has ordered the
16 Government to file its complaint-in-intervention in that case by May 16, 2017, and
17 has authorized Poehling to file an amended complaint by that date. (*Id.*, Docket
18 No. 93.)

19 **III. The APA Action**

20 In January 2016, while *Poehling* was still under seal and *Swoben* was
21 pending before the Ninth Circuit, UnitedHealth filed an action in the U.S. District
22 Court for the District of Columbia. *See* [UnitedHealthcare Ins. Co. v. Price, No. 1:16-cv-00157-RMC, slip op. \(D.D.C. Mar. 31, 2017\), Docket No. 25](#). This action
23 concerns a new regulation (known as the "Overpayment Rule") promulgated by the
24 Centers for Medicare and Medicaid Services in 2014, purporting to implement a
25 provision added to the Medicare Act by the Affordable Care Act of 2010. (*Id.* at 5-
26 6.) The new statutory provision requires Medicare Advantage plans that identify
27 an overpayment to report and return it to CMS no later than sixty days after the
28

1 overpayment was identified. 42 U.S.C. § 1320a-7k(d). To enforce the new
2 requirement, the statute provides that any overpayment that is not returned within
3 the sixty-day period is an “obligation” under the False Claims Act, which can serve
4 as the basis for a reverse false claims action. *See* 31 U.S.C. § 3729(a)(1)(G). In
5 the Overpayment Rule, CMS has provided that the rule applies to overpayments
6 that result from errors in MA plans’ diagnostic codes. *See* 42 C.F.R. § 422.326(a).

7 In the APA action, UnitedHealth contends that the Overpayment Rule
8 violates CMS’s statutory mandate to “‘ensure[] actuarial equivalence’ between
9 Medicare and Medicare Advantage plans.” *Price*, slip op. at 2 (quoting 42 U.S.C.
10 § 1395w-23(a)(1)(C)(i)). By requiring MA plans to exercise “reasonable
11 diligence” to identify and delete diagnostic codes that are unsupported by
12 underlying medical charts, without accounting for the fact that CMS does not itself
13 exercise such diligence to identify and delete unsupported diagnostic codes from
14 the diagnostic data of FFS beneficiaries, UnitedHealth contends that CMS is
15 failing to ensure actuarial equivalence. (*See, e.g.*, Compl. ¶ 4, *UnitedHealthcare*
16 *Ins. Co. v. Burwell*, No. 16-cv-157 (D.D.C. Jan. 29, 2016).) Accordingly,
17 UnitedHealth has requested that the Overpayment Rule be set aside, and that the
18 court grant a declaratory judgment that it is not required to undertake “reasonable
19 diligence” efforts unless CMS imposes the same validation standard on itself.

20 On March 31, 2017, the district court denied the Government’s motion to
21 dismiss, holding that UnitedHealth had standing to challenge the Overpayment
22 Rule’s direct regulation of its conduct and that the 2014 Overpayment Rule’s
23 requirement that MA plans exercise “reasonable diligence” to identify and delete
24 unsupported diagnostic codes “imposes (for good reason or not) new obligations”
25 that did not previously exist in any other regulation or statute. (*See Price*, slip op.
26 at 13.) Accordingly, the district court will soon be hearing UnitedHealth’s
27 challenge to the legal underpinnings of the Government’s arguments in this case—
28 namely, that UnitedHealth was required to review and analyze the accuracy of

1 codes submitted by providers under a “due diligence” standard that the
2 Government allegedly does not undertake itself.

3 DISCUSSION

4 I. Consolidation At This Time Would Be Premature

5 Federal Rule of Civil Procedure 42(a) gives a district court discretion to
6 consolidate actions that “involve a common question of law or fact.” That
7 discretion is “broad,” [Pierce v. County of Orange](#), 526 F.3d 1190, 1203 (9th Cir.
8 2008), and is to be exercised in a manner that “balance[s] the efficiency of
9 consolidation against the possible inconvenience, delay or prejudice to the
10 parties,” [Avetisyan v. Equifax Info. Servs. LLC](#), No. CV 14-00161-AB (ASx),
11 2015 WL 12669875, at *2 (C.D. Cal. May 13, 2015). Thus, “[a] common nucleus
12 of operative facts between . . . two cases only addresses the threshold issue of
13 consolidation” and a court “must still weigh the administrative issues that may
14 emerge and any prejudice to the parties.” *Id.*

15 A. *The Extent To Which The Swoben And Poehling Matters Will* 16 *Involve Common Questions Is Presently Unknown*

17 The Government has yet to file its complaints-in-intervention in either
18 *Poehling* or *Swoben*, which will determine the scope and focus of both lawsuits.
19 As the Ninth Circuit has recognized, a relator cannot “have a claim separate from
20 the government’s.” [United States ex rel. Barajas v. Northrop Corp.](#), 147 F.3d 905,
21 910 (9th Cir. 1998). Accordingly, the parties recently agreed that once the
22 Government files its complaint-in-intervention in this case, its “complaint-in-
23 intervention will then be the operative pleading for those claims against
24 UnitedHealth to the extent such claims overlap those in Swoben’s complaint.”
25 (Docket No. 268 at 3.) The same will be true in the *Poehling* case, where the
26 Government has been ordered to file its complaint-in-intervention by May 16,
27 2017.

1 Although the Government's complaints-in-intervention, and UnitedHealth's
2 defenses, may share some commonalities, at this stage it is premature to determine
3 whether that will *in fact* be true and how significant any potential overlap might be.
4 As an initial matter, the Government concedes that Poehling's current complaint
5 names more than a dozen other defendants who are not parties to the *Swoben*
6 matter, and acknowledges that it "does not know whether Poehling will continue to
7 pursue his FCA claims against" those defendants. (U.S. Mot. 10.) If Poehling
8 does, his claims against them would not be superseded by the Government's
9 complaint-in-intervention against UnitedHealth, but would need to be litigated
10 alongside it. The presence of more than a dozen parties in one case but not the
11 other would significantly complicate the prospect of consolidation.

12 It is not just Poehling's complaint that remains uncertain. Because the
13 Government's complaints-in-intervention have yet to be filed, it is impossible for
14 this Court to review them in order to assess the overlap between the cases.
15 Moreover, based on the Government's statements to date, it appears that the
16 complaints might have far less in common than they have differences: the
17 Government has indicated that it believes the *Swoben* case is limited to chart
18 reviews by HCP in California for a relatively short period beginning in 2005, while
19 the *Poehling* case is about a national Chart Review Program that started at a later
20 date.

21 The conventional way of evaluating factual overlap for purposes of a
22 consolidation motion is to compare filed complaints, not compare the parties'
23 predictions about what they might allege in complaints they plan to file in the
24 future. See, e.g., [Gerber Plumbing Fixtures, LLC v. Amerifreight, Inc., Nos. 2:15-](#)
25 [cv-04146-ODW\(RAO\), 2:15-cv-02926-ODW\(GJS\), 2015 WL 7259717, at *3](#)
26 [\(C.D. Cal. Nov. 16, 2015\)](#) (consolidating actions because "the respective
27 complaints involve common issues of law and fact, and . . . the two actions share
28 key witnesses and evidence"); [Angeletti v. Lane, No. 12-00503-BAJ-SCR, 2013](#)

1 [WL 4546828, at *3 \(M.D. La. Aug. 28, 2013\)](#) (denying motion to consolidate
2 because “a review of *all* eleven complaints reveals more differences than
3 similarities”); [In re Facebook Privacy Litig., Nos. C 10-02389-JW, C 10-05301-](#)
4 [BZ, 2010 WL 5387616, at *1 \(N.D. Cal. Dec. 21, 2010\)](#) (consolidating cases
5 “[u]pon review of the Complaints in both Actions”); [Grainger v. Solomon, No.](#)
6 [3:07-cv-91, 2008 WL 3823734, at *2 \(E.D. Tenn. Aug. 12, 2008\)](#) (consolidating
7 cases after “examination of the complaint”).¹ The Government has identified no
8 persuasive reason to depart from that convention here.

9 ***B. Consolidating The Matters At This Time Would Create***
10 ***Inefficiencies and Complications***

11 In addition to the uncertainty created by the unavailability of the relevant
12 complaints, UnitedHealth has identified persuasive reasons why consolidating now
13 would affirmatively create complications that outweigh any theoretical benefits
14 consolidation might bring over the next few months. First, *Swoben* and *Poehling*
15 are at different stages of litigation: *Swoben* was unsealed nearly four years ago,
16 and has already gone through a round of motion-to-dismiss briefing, an appeal, and
17 a remand. In contrast, *Poehling* was unsealed less than three months ago, shortly
18 after being transferred to this district via an *ex parte* transfer motion, and involves
19 claims that have never been briefed in any court. As a result, the Court may need
20 to address preliminary issues in *Poehling* that have already been completed in
21 *Swoben*, which favors deferring consolidation until preliminary motions can be
22

23 ¹ In arguing that the Court should not wait to consider the filed complaints, the
24 Government cites four New York state cases from the 1920s to the 1950s, none of
25 which even involved Federal Rule of Civil Procedure 42(a). U.S. Reply, 5. And in
26 the one federal case the Government cites, the court specifically relied on the fact
27 that “[t]he complaints are based upon the same allegations of fraud and
28 conspiracy.” [Schultz v. Manufacturers & Traders Trust Co., 29 F. Supp. 37, 38](#)
[\(W.D.N.Y. 1939\)](#). The case—like the treatise to which the Government also
points—simply stands for the proposition that consolidation based on common
questions of law or fact is sometimes appropriate even before “[i]ssue has been
joined” on those common questions. *Id.* It does not undermine the wisdom of
waiting until the complaints have been filed.

1 resolved. See, e.g., Thompson v. City of St. Peters, No. 4:15CV404 RLW, 2016
2 WL 1625373, at *2 (E.D. Mo. Apr. 21, 2016) (noting that “judicial efficiency is
3 best served by deciding the pending motions [for judgment on the pleadings and
4 summary judgment] prior to any consolidation”); Rock v. NCAA, No. 1:12-cv-
5 1019-JMS-DKL, 2014 WL 4722527, at *3 (S.D. Ind. Sept. 23, 2014) (denying
6 consolidation based in part on a “forthcoming motion to dismiss [the other case] on
7 alleged legal defects not present” in the case before the court); Oliver v. Dow, Civ.
8 No. 10-1542 (DMC)(JAD), 2012 WL 1883921, at *2 (D.N.J. May 22, 2012)
9 (noting prior denial of motion to consolidate as “premature in light of the . . .
10 pending Motion to Amend the Complaint in the present action”).

11 Second, UnitedHealth has indicated that it anticipates filing two motions that
12 might be more efficiently addressed if the *Swoben* and *Poehling* cases remain
13 separated. The first motion UnitedHealth may file is a motion to transfer the
14 *Poehling* matter. *Poehling* was initially brought in the Western District of New
15 York in 2011 and has minimal connections to the Central District of California.
16 *See supra* at 4-5. The transfer of *Poehling* to the Central District of California
17 occurred *ex parte* and without UnitedHealth’s input, which this circuit strongly
18 disfavors. United States v. Thompson, 827 F.2d 1254, 1258-59 (9th Cir. 1987)
19 (“*ex parte* proceedings are anathema in our system of justice.”); *see also* Granny
20 Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers Local No. 70, 415
21 U.S. 423, 439 (1974). UnitedHealth has stated that once it has seen the operative
22 complaints in that case, it will request that Judge Fitzgerald determine which venue
23 would be most appropriate for hearing its nationwide claims.

24 UnitedHealth alleges that none of the policy decisions and certifications at
25 issue in the *Poehling* action’s nationwide allegations were made in the Central
26 District of California. Instead, UnitedHealth argues that the District of Columbia
27 or Minnesota may be more appropriate venues given that the contracts and
28 certifications at issue in *Poehling* were submitted in the Washington, D.C. area, the

1 policy decisions implicated by this case were reached primarily in or around those
2 locations, and the vast majority of likely witnesses and documents are located in or
3 near Washington, D.C. and Minnesota. In addition, transferring litigation of the
4 Government’s nationwide claims to Washington, D.C. would allow them to be
5 consolidated with the pending APA action about whether it would violate the
6 statutory mandate of “actuarial equivalence” in the Medicare Act to require MA
7 plans to exercise “reasonable diligence” to identify and delete unsupported
8 diagnostic codes, without accounting for unsupported codes in the diagnostic data
9 of fee-for-service beneficiaries.

10 Whether to grant a transfer is a question properly left to the sound discretion
11 of Judge Fitzgerald, and this Court makes no determination about whether
12 transferring *Poehling* to the District of Columbia will conserve judicial resources,
13 avoid inconsistent judicial decisions, and serve the interests of justice. However,
14 in the event the motion was ultimately granted, consolidating the cases before that
15 transfer motion is heard would create a myriad of difficulties because the Court
16 and parties would then have to unravel the administrative interconnections created
17 by consolidation. The fact that the Government has not asked this Court to
18 formally “merge” the cases does not eliminate this concern, because the very
19 object of consolidation is to combine aspects of multiple cases—a combination that
20 must be undone if one of those cases is transferred out of the district.

21 The second motion that UnitedHealth anticipates filing is a motion to
22 dismiss *Poehling*. *Poehling* was unsealed less than three months ago, and it
23 implicates programs and time periods that were not directly at issue in the earlier
24 *Swoben* complaints. (See U.S. Mot. 20 & n.13.) UnitedHealth has not yet had a
25 chance to test the legal sufficiency of the allegations about those programs in
26 *Poehling*’s complaint or the Government’s upcoming complaint-in-intervention. If
27 that motion is granted, the issue of consolidation will be moot. And if the cases
28

1 have *already* been consolidated when that motion is granted, it will again create
2 additional complications and administrative burdens as the parties and the Court
3 are forced to sort through which aspects of the consolidated proceeding remain
4 unchanged and which aspects have been dismissed.

5 **II. The Government Has Not Justified Immediate Consolidation**

6 Given the complications that immediate consolidation would produce, the
7 Government bears the burden to persuade the Court that there are significant
8 advantages to be gained from consolidating the cases now rather than waiting and
9 revisiting the issue in a few months. The Government has not met that burden.

10 The Government claims immediate consolidation is warranted because this
11 Court is moving the *Swoben* action quickly and consolidating it with *Poehling* will
12 allow the Court to continue at its pace and because certain pre-trial activities may
13 need to be repeated if *Swoben* is not stayed. (U.S. Mot. 18.) The Court disagrees.
14 Consolidating *Swoben* and *Poehling* might actually slow the pace of *Swoben* while
15 the Court works to resolve any preliminary motions in *Poehling*.

16 **CONCLUSION**

17 For the foregoing reasons, the Government's request for immediate
18 consolidation is **DENIED without prejudice** to a new motion to consolidate after
19 the complaints-in-intervention have been filed and the preliminary motions
20 discussed above have been resolved.

21 IT IS SO ORDERED.

22
23 Dated: April 27, 2017

24 
UNITED STATES DISTRICT JUDGE

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE
COMPANY, *et al.*,

Plaintiffs,

v.

THOMAS E. PRICE, M.D., in his official
capacity as Secretary of the Department of Health
and Human Services, *et al.*,

Defendants.

No. 1:16-cv-00157-RMC

[PROPOSED] ORDER

Upon consideration of United's Opposition to Defendants' Motion to Stay and Motion for Extension of Time, it is **ORDERED** that the motion to stay and motion for extension of time are hereby **DENIED**. It is **FURTHER ORDERED** that Defendants file their answer to Plaintiffs' complaint and certified list of the contents of the administrative record within 7 days of this Order.

Dated: _____

Hon. Rosemary M. Collyer
United States District Court Judge

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Pursuant to LCvR 7(k), the following is a list of the names and addresses of all attorneys to be notified of entry of the Proposed Order.

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EXHIBIT 56

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

_____	)	
UNITEDHEALTHCARE INSURANCE	)	
COMPANY, <i>et al.</i>,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 16-cv-157 (RMC)
	)	
THOMAS E. PRICE, M.D.,	)	
Secretary, Department of Health	)	
And Human Services, <i>et al.</i>	)	
	)	
Defendants.	)	
_____	)	

MEMORANDUM OPINION AND ORDER

The parties to this action, which challenges a new rule under the Administrative Procedure Act (APA), 5 U.S.C. § 702, are simultaneously engaged in two other cases and the Department of Health and Human Services (HHS) asks to stay this one. HHS is the Defendant in the immediate case and the Plaintiff in the other two, both brought under the False Claims Act, 31 U.S.C. § 3729. UnitedHealthCare Insurance Company (United), the lead Plaintiff in this action and the Defendant in the two False Claims Act cases (FCA Cases), opposes. In addition, America's Health Insurance Plans (AHIP), an industry group, has submitted an *amicus* brief supporting United's opposition and distinguishing the suits. HHS has replied to both United and the *amicus*, and, in the alternative, moved for a 90-day extension of time to file its Answer. Both motions are ripe for review.

While the two FCA Cases may involve many of the same parties, lawyers, and otherwise serve as other fronts in a legal conflict between HHS and United, the question before the Court is not whether the immediate matter grows out of strategic thinking by one or more

parties, or occurs within the context of other litigation, but rather, more simply, whether the issues in the two FCA Cases are so similar as to render the matter before the Court duplicative or potentially confusing. The Court concludes, for the reasons stated below, that this lawsuit is neither and it will therefore deny the Government's motion to stay. The Court will, however, grant the Government's motion for an extension of time to answer the Complaint until July 14, 2017, as requested.

BACKGROUND

In this matter, United seeks review of an administrative rule, promulgated in 2014 and codified at 42 C.F.R. § 422.326 (the 2014 Overpayment Rule), that applies to insurers participating in the Medicare Advantage (MA) program. MA insurers provide Medicare benefits to eligible beneficiaries who elect to participate in an MA program instead of the traditional Medicare program. The Centers for Medicare and Medicaid Services (CMS), a constituent agency of HHS which administers traditional Medicare, reimburses MA insurance providers for services rendered to Medicare beneficiaries. The 2014 Overpayment Rule concerns MA providers' obligations to report and repay any overpayments made by the CMS to an MA provider. United argues that the 2014 Overpayment Rule, which it says imposes a stricter standard on MA providers than on CMS itself when paying Medicare benefits, is inconsistent with the Medicare statute's requirement that CMS "ensure actuarial equivalence" between traditional Medicare and MA programs and thus violates the APA. United filed suit in January 2016, and the Court denied an HHS Motion to Dismiss on March 31, 2017. *See* Mem. Op. [Dkt. 25].

Simultaneously, United and HHS are engaged in the FCA Cases: *United States ex rel. Swoben v. Secure Horizons*, No. 09-5013 (C.D. Cal) (*Swoben*), and *United States ex rel. Poehling v. UnitedHealth Group*, 11-cv-258 (W.D.N.Y) (*Poehling*). Both cases allege, *inter*

alia, that United knowingly misreported or knowingly caused other parties to misreport overpayments as part of a scheme to inflate its Medicare reimbursements. *See* Reply Ex. A [Dkt. 36-1] (*Swoben* Complaint) ¶¶ 8-9; *Poehling* Complaint [Dkt. 37-1] ¶¶ 8-12. While both suits were originally brought by private plaintiffs, HHS has recently intervened in both, filing its *Swoben* Complaint on May 1, 2017 and its *Poehling* Complaint on May 16, 2017.

All parties agree that the allegedly fraudulent conduct in *Poehling* and *Swoben* predates the 2014 Overpayment Rule, and that the Rule is not at issue in either FCA Case. *See* Mot. to Stay [Dkt. 28] at 5; Opp. [Dkt. 31] at 5. However, part of the HHS planned argument in both *Poehling* and *Swoben* is that United’s alleged activities violated its obligations to perform due diligence as required under the Medicare statute. Mot. to Stay at 4. United, in turn, intends to defend in part on its interpretation of the CMS obligation to treat MA providers with “actuarial equivalence.” *Id.* at 5.

Because of the potential common questions of defining actuarial equivalence and the diligence obligations of MA providers, HHS asks the Court to stay this matter until the FCA Cases are resolved.

ANALYSIS

Courts disfavor duplicative litigation; it has the potential to waste judicial resources, muddy legal waters with conflicting rulings, and can strain the capabilities of litigants. *See Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976); *UtahAmerican Energy, Inc. v. Dep’t of Labor*, 685 F.3d 1118, 1124 (D.C. Cir. 2012). A court’s ability to stay proceedings flows from its inherent authority to manage its own docket. While no firm rule governs a court’s decision to stay a matter, it must balance “equitable considerations” when assessing whether a stay is warranted. *Handy v. Shaw, Bransford, Veilleux & Roth*, 325

F.3d 346, 350 (D.C. Cir. 2003).¹ “The factors relevant to wise administration here are equitable in nature [and] an ample degree of discretion . . . must be left” to the district courts. *Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183 (1952).

The Government asserts that equitable considerations favor a stay here. The private plaintiffs in the FCA Cases filed their complaints under seal before United filed this suit, although HHS did not intervene in the FCA Cases until after this action was filed. HHS contends the FCA Cases will develop a full factual record that will allegedly “show UnitedHealth’s knowledge of its due diligence obligations, its implementation of compliance programs relating to ensuring the validity of the diagnoses it submitted to Medicare for risk adjustment payments, and its decision to terminate those compliance efforts.” Mot. to Stay at 7.

The Court is not convinced these considerations warrant a stay here. This APA case is limited to whether CMS acted beyond its authority when promulgating its 2014 Overpayment Rule. It does not concern the actions of United in any way, and any analysis by the Court would be limited to the administrative record behind the 2014 Overpayment Rule and the statute. Any factual record developed in the FCA Cases would have very limited relevance, if any, to this APA review of the 2014 Overpayment Rule.

Similarly, judicial resolution of the FCA Cases will inevitably involve a highly fact-specific analysis of United’s actions, only part of whose defense would involve Medicare’s

¹ One rule of thumb is the “first-filed” rule, which counsels that, “[w]here two cases between the same parties on the same cause of action are commenced in two different federal courts, the one which is commenced first is to be allowed to proceed to its conclusion first.” *UtahAmerican Energy*, 685 F.3d at 1124 (quoting *WMATA v. Ragonese*, 617 F.2d 828, 830 (D.C. Cir. 1980) and predecessors). While the first-filed rule implicates the same equitable considerations relevant here, the first-filed rule is not applicable in this situation, firstly because the causes of action in the FCA Cases are different from those found in this matter, and secondly because HHS intervened in both FCA Cases after this matter was filed. See *id.*; *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009).

requirement of actuarial equivalence. The complexity of the FCA cases means their resolution could take a number of different forms, including resolution without any reference to questions potentially common to this action.

In short, it is highly unlikely that a future decision in the FCA Cases would address, much less resolve, the APA challenge here. Similarly, any decision in this matter will not answer the most relevant questions in the FCA Cases. Whether a government contractor knowingly engaged in fraud, and whether a government agency appropriately promulgated a rule several years later, are simply too different from one another to warrant a stay, even if such lawsuits may touch upon similar questions of statutory interpretation. The equitable considerations are not so strong that all matters potentially implicating similar legal issues, with otherwise separate facts and claims, should be heard sequentially throughout the federal court system. And a difference of opinion among district court judges is not so unusual as to foreclose timely consideration of this matter.

Because United's alleged behavior in the FCA Cases is distinct from HHS's actions in promulgating the 2014 Overpayment Rule, the fact that the same parties are in all three actions is only a distraction. Further, as the *amicus* indicates, the question of the 2014 Overpayment Rule has industry-wide implications, which, clearly, the FCA Cases do not. *See Amicus Curiae* Br. of America's Health Insurance Plans [Dkt. 35].

HHS suggests, however, that it is not mere coincidence that United is a party in all three actions, and that this lawsuit is merely a strategic attempt by United to end run the FCA Cases. United retorts that HHS only intervened in the FCA Cases because United filed this APA challenge. Motivated reasoning may well have influenced either—or both—parties in their litigation decisions; however, the Court is not here to referee the strategic decisionmaking

process that goes into any complex litigation. Neither party has given the Court reason to believe that the other has acted in bad faith; it has been presented with a live legal controversy and will treat it as such.

In sum, the Court disagrees with HHS that the cases and issues are sufficiently alike to warrant a stay in this review of a new administrative rule. The two FCA Cases will require considerable discovery and take much longer to bring to conclusion. In stark contrast, the 2014 Overpayment Rule will rise or fall on the administrative record that preceded it. The relevant facts and legal standards will be entirely different. In addition, the Secretary did not join either FCA Case until after this suit was filed, although each was filed by a relator years ago.

CONCLUSION

For the foregoing reasons, it is hereby

ORDERED that Defendants' Motion to Stay, Dkt. 28, is **DENIED**; and it is

FURTHER ORDERED that Defendants' Motion for Extension of Time to Answer the Complaint, Dkt. 30, is **GRANTED**. Defendants' Answer shall be filed no later than July 14, 2017.

Date: June 14, 2017

/s/
ROSEMARY M. COLLYER
United States District Judge

EXHIBIT 57

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

	)	
UNITEDHEALTHCARE INSURANCE	)	
COMPANY, <i>et al.</i>,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 16-cv-00157 (RMC)
	)	
THOMAS E. PRICE, M.D.,	)	
Secretary of the Department of Health	)	
and Human Services, <i>et al.</i>	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION

The case before the Court is an action brought by a collection of insurers operating under the UnitedHealthcare Insurance Company umbrella (United) which are participating in the Medicare Advantage Program. Under Medicare Advantage, insurers provide Medicare insurance coverage in lieu of the government itself. Defendants are (1) the Secretary for Health and Human Services in her official capacity; (2) the Centers for Medicare and Medicaid Services (CMS), a constituent agency of HHS, which administers the Medicare Advantage program; and (3) the United States of America. The Plaintiffs challenge a recent CMS rulemaking concerning the obligations of Medicare Advantage insurers.

Defendants have moved to dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). *See* Defs.' Mot. to Dismiss [Dkt 12] (Mot. to Dismiss). Plaintiffs have opposed, *see* Pls.' Opp. [Dkt. 14] (Opp.), and Defendants have replied, *see* Defs.' Reply [Dkt. 17] (Reply). Plaintiffs sur-replied, *see* Pls.' Sur-Reply [Dkt. 19] (Pls.' Sur-Reply), and Defendants sur-sur-replied, *see* Defs.' Sur-Reply [Dkt. 21] (Defs.' Sur-Reply).

Finally, Defendants submitted a Notice of Supplemental Authority [Dkt. 23], to which Plaintiffs have submitted a Response [Dkt. 24].

Despite the extensive briefing, the overarching questions before the Court can be summarized as follows: (1) Has CMS's new rule imposed a novel legal obligation on Plaintiffs, and, if so, (2) under the existing circumstances, may Plaintiffs challenge the rule in this Court without waiting for Defendants to bring an enforcement action? For the reasons stated below, the Court answers yes to both questions. It therefore concludes that Plaintiffs have standing and will deny Defendants' Motion to Dismiss. At this point, the merits are not addressed.

I. BACKGROUND

The Medicare Advantage (MA) program allows Medicare-eligible individuals to receive healthcare benefits through private insurance plans that have contracted with CMS. Compl. [Dkt. 1] ¶ 24. A Medicare Advantage insurer must provide, at a minimum, the same level of benefits provided by Medicare itself. *Id.* ¶ 26. Medicare Advantage insurers reimburse healthcare providers for services to Medicare beneficiaries covered by a Medicare Advantage insurer; the Medicare Advantage insurers are reimbursed themselves by CMS on a pre-set, per-member-per-month basis. *Id.*

Congress requires CMS to pay Medicare Advantage insurers in a manner that “ensures actuarial equivalence” between Medicare and Medicare Advantage plans. *Id.* ¶ 32, *see* 42 U.S.C. § 1395w-23(a)(1)(C)(i). To do this, CMS first calculates the average monthly expenditure for the average Medicare beneficiary. Compl. ¶ 30. However, because not all Medicare beneficiaries are the same, CMS then adjusts these baseline repayments according to the beneficiary profile of particular Medicare Advantage plans. *Id.* ¶ 32. To make these adjustments, CMS gathers demographic data as well as health history data, the latter of which are primarily provided to CMS by the Medicare Advantage insurer. *Id.* ¶ 33. Specifically, health

history data relies on specific diagnostic codes submitted by the healthcare providers to the Medicare Advantage insurers. *Id.* ¶ 34. These diagnostic codes can vary in granularity and content, and serve as a rough guide to what services have been provided by healthcare professionals to a patient. *Id.* The diagnostic codes are designated by healthcare providers to reflect patient conditions and medical needs and then sent to the Medicare Advantage insurers as part of the billing process. *Id.* The Medicare Advantage insurers compile these codes and submit them to CMS, which uses the data to make adjustments to its monthly payment based on the relative health of a particular Medicare Advantage insurer's enrollees. *Id.* In theory, if a Medicare Advantage insurer's enrollee had diagnosis codes that suggested a 20% higher annual coverage cost than the average Medicare beneficiary, the monthly payment to that Medicare Advantage insurer would be adjusted upwards to cover that cost. *Id.* ¶ 36.

Unfortunately, diagnostic codes in healthcare records are often miscoded, inappropriately added, or otherwise faulty. Medical professionals often cite incorrect diagnostic codes when preparing their billing, and Plaintiffs suggest that the error rate can be as high as 20%. *Id.* ¶ 38. In the past, neither CMS nor the Plaintiffs made efforts to review categorically the diagnostic codes assigned by healthcare providers to individual patients. *Id.* ¶ 40. As a result, CMS has treated the diagnostic codes as conclusively valid for its own payment purposes. *Id.* Regulations oblige Medicare Advantage insurers to certify “based on best knowledge, information and belief” that the information they provide to CMS, including the diagnostic codes included in the Medicare Advantage insurers' risk adjustment data, are “accurate, complete and truthful.” *Id.* ¶ 41; 42 C.F.R. § 422.504(l)(2). However, Plaintiffs allege that neither this pre-existing regulation, nor any other regulation, has in the past obligated Medicare Advantage insurers to validate diagnostic codes independently. Compl. ¶ 42. They assert that Medicare

Advantage providers have not heretofor reviewed the underlying medical information from which particular diagnostic codes arose, and neither has CMS. *Id.* ¶ 42.

Nonetheless, it is widely known that the entry of diagnostic codes by medical professionals is often faulty. In order to adjust for mistakes—as well as fraud—CMS conducts what are known as Risk Adjustment Data Validation (RADV) audits. *Id.* ¶ 45. Every year, CMS selects a group of Medicare Advantage insurers for audit, *id.*, and reviews the underlying medical charts for a sample of each insurer’s beneficiaries to determine whether the medical charts justify the diagnostic codes. *Id.* ¶¶ 46, 47. To the extent these adjustments result in a corrected risk score, monthly payments are adjusted accordingly. *Id.* ¶ 47. The results of these audits are extrapolated for Medicare Advantage insurers generally to calculate an average estimated error rate for the year. *Id.* ¶ 47. If the error rate is positive—if a Medicare Advantage insurer is being reimbursed for more services than were provided—the insurer is responsible for returning any overpayment to CMS. *Id.* ¶ 48.

In the past, CMS proposed requiring overpayment returns on an absolute basis, which would have meant that any errors found by an audit would be subject to return by the Medicare Advantage insurer if it resulted in an overpayment. *Id.* ¶ 49. Ultimately however, CMS included a “Fee-For-Service adjuster” (FFS adjuster) arising from CMS payments to Medicare beneficiaries, which reflects the expected error rate in the use of diagnostic codes relied upon by Medicare. The FFS adjuster reflects CMS’s own estimate of the average error in diagnostic codes for its Medicare participants and essentially acts as a buffer for overpayments; Medicare Advantage providers are thereby only responsible for overpaying for any errors above and beyond CMS’s own estimated error rate. Medicare Advantage plans run the risk of needing

to return overpayments if the diagnostic codes they submit are unusually error-prone compared to Medicare's reliance on diagnostic codes.

Plaintiffs state that the FFS adjuster works to counteract the fact that initial payments to Medicare Advantage insurers are based on a less precise set of data than that which is reviewed during an audit. Plaintiffs also state that the FFS adjuster was added at the urging of the American Academy of Actuaries to ensure that CMS would fulfill its statutory obligation to treat Medicare Advantage insurers with "actuarial equivalence."¹ *Id.* ¶ 50.

Within this context, Congress passed the Affordable Care Act (ACA) in 2010. Pub. L. No. 111-148, 124 Stat. 119 (2010). As relevant here, the ACA imposed an obligation on insurers that receive federal payments to report and return overpayments that the insurers discover on their own. *See* Pub. L. No. 111-148, § 6402, 124 Stat. at 755-56, codified at 42 U.S.C. § 1320a-7k(d)(1) (2012). This section of the ACA defines "overpayment" as "any funds that a person receives or retains under [Medicare] to which the person, after applicable reconciliation, is not entitled." *Id.* § 1320a-7k(d)(4)(B). It further requires that any "overpayment . . . be reported and returned [within] 60 days after the date on which the overpayment was identified." *Id.* § 1320a-7k(d)(2). Under the law, if a Medicare Advantage insurer fails to return an overpayment within 60 days of identifying it, that failure would render the insurer's initial but faulty claim for payment a violation of under the False Claims Act (FCA). *Id.* § 1320a-7k(d)(3) ("Any overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation (as defined in section 3729 (b)(3) of title 31) for purposes of section 3729 of such title."); *see* False Claims Act, 31 U.S.C. § 3729 *et*

¹ While the full context of "actuarial equivalence" has not been discussed by the parties at this stage of the litigation, it presumably includes circumstances in which insurance companies process payments directly for Medicare.

seq. (2012). False Claims Act claims carry with them the potential for treble damages and civil penalties, and can result in disbarment from Medicare. *See* Compl. ¶ 58. Further, non-government *qui tam* plaintiffs may bring FCA claims in federal court. *Id.* ACA § 6402 lays out a basic statutory framework, but leaves several terms undefined. For example, it does not define what “identified” means for triggering the 60-day clock, *see* Compl. ¶ 57, nor state explicitly whether “overpayments” are intended to incorporate an FFS adjustor threshold as do RADV audits.

In order to implement ACA § 6402, CMS issued a notice of proposed rulemaking in January 2014. Compl. ¶ 59; *see* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014). CMS proposed a new regulation, 42 C.F.R. § 422.326, titled “Reporting and Returning Overpayments,” that was intended to “clarify the statutory definition of overpayment.” 79 Fed. Reg. at 2055-56, 1996; *see* Compl. ¶ 59.

After engaging in notice and comment, CMS published the final rule in May 2014, which finalized 42 C.F.R. § 422.326 concerning overpayments (the CMS Rule). *See* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014). Under the CMS Rule, any inadequately documented diagnostic code not supported by underlying medical documentation will result in an overpayment. *Id.* at 29,921. Further, the CMS Rule specified that any overpayment would be considered “identified” when a Medicare Advantage insurer determined, or *should have determined* through reasonable diligence, that it had received an overpayment. *Id.* at 29,923. CMS further stated that reasonable diligence would require “at a minimum . . . proactive compliance activities conducted in good faith by qualified

individuals to monitor for the receipt of payments.” *Id.* Plaintiffs allege that these obligations apply a negligence standard for purposes of False Claims Act liability. *See* Compl. ¶ 78. They allege further that this is a lower standard than that actually required by the FCA, which contains a recklessness standard. *Id.*; *see* False Claims Act, 31 U.S.C. § 3729(b) (defining “knowing” and “knowingly”).

Plaintiffs also contend that the CMS Rule, which does not adopt the “FFS adjuster” buffer that exists in RADV audits, violates the statute’s requirement that Medicare Advantage insurers be treated with “actuarial equivalence” to CMS and, instead, subjects them to a more searching form of scrutiny than CMS applies to its own enrollee data. Compl. ¶ 80. By requiring Medicare Advantage insurers to confirm diagnostic codes through review of underlying medical charts—while not conducting such reviews under Medicare proper—CMS allegedly will systematically underpay for beneficiaries’ care to Medicare Advantage insurer plans compared to payments if that same beneficiary were in a traditional Medicare plan. *Id.* ¶ 81. Plaintiffs also argue that, by applying what amounts to a “negligence” standard of liability, the CMS Rule “cannot be squared with the language of the Act.” *Id.* ¶ 78.

The merits of the case are not before the Court at this time. The present issue is whether the Plaintiffs, as Medicare Advantage insurers, have standing to challenge the CMS Rule.

II. LEGAL STANDARD

Under Rule 12(b)(1) of the Federal Rules of Civil Procedure, a defendant can move to dismiss a complaint, or any portion thereof, for lack of subject matter jurisdiction in federal court. Fed. R. Civ. P. 12(b)(1). No action by the parties can confer subject matter jurisdiction on a federal court because subject matter jurisdiction is both a statutory requirement and an Article III requirement. *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir.

2003). The party claiming subject matter jurisdiction bears the burden of demonstrating that such jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008); *see Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (noting that federal courts have limited jurisdiction and that “[i]t is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction”). When reviewing a motion to dismiss for lack of jurisdiction under Rule 12(b)(1), a court must construe the complaint liberally, giving the plaintiff the benefit of all inferences that can be derived from the facts alleged. *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004). Nevertheless, “the court need not accept factual inferences drawn by plaintiffs if those inferences are not supported by facts alleged in the complaint, nor must the Court accept plaintiffs’ legal conclusions.” *Speelman v. United States*, 461 F. Supp. 2d 71, 73 (D.D.C. 2006).

III. ANALYSIS

Defendants have moved to dismiss, asserting that Plaintiffs lack both Article III and statutory standing to bring their suit before a court.

A. Article III Standing

Standing is part and parcel of Article III’s limitation on the judicial power of the United States, which extends only to “cases or controversies.” U.S. Const. Art. III, § 2. “No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 37 (1976). “The ‘core component’ of the requirement that a litigant have standing to invoke the authority of a federal court ‘is an essential and unchanging part of the case-or-controversy requirement of Article III.’” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). “At bottom, ‘the gist of the question of standing’ is whether petitioners have ‘such

a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination.” *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007) (quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962)). The strictures of Article III standing are by now “familiar.” *United States v. Windsor*, 133 S. Ct. 2675, 2685 (2013). Standing requires (1) the plaintiff to have suffered an injury in fact that is both (a) concrete and particularized and (b) actual or imminent, as opposed to conjectural or hypothetical; (2) the injury to be traceable to the defendant’s actions; and (3) the injury to be redressable by a favorable decision of the court. *See id.* at 2685-86 (citing *Lujan*, 504 U.S. at 559-62).

“The Supreme Court has stated that ‘there is ordinarily little question’ that a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated.” *State Nat. Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (quoting *Lujan*, 504 U.S. at 561-62). In *Big Spring*, the United States Circuit Court for the District of Columbia Circuit found that a bank subject to regulation by the Consumer Financial Protection Bureau had standing to bring a claim against the CFPB because CFPB regulations “impose[] disclosure requirements on institutions” such as the bank and the bank “must now monitor [a relevant part of its business], and the monitoring program causes it to incur costs.” 795 F.3d at 53.

Plaintiffs have asserted that, as Medicare Advantage insurers, they are the intended objects of the CMS Rule and therefore have standing to challenge it.² *Opp.* at 19-21.

² In support of this position, Plaintiffs have predominantly cited cases dealing with the doctrine of ripeness. *See Opp.* at 19, 20 (citing, *inter alia*, *Nat’l Ass’n of Home Builders v. U.S. Army Corps of Eng’rs*, 417 F.3d 1272 (D.C. Cir. 2005)). While the two are similar, it is important to emphasize that the doctrines are different, with separate analyses and occasionally different outcomes. *See AT&T Corp. v. FCC*, 349 F.3d 692, 702 (D.C. Cir. 2003) (finding Article III

The Court agrees that the text and character of the CMS Rule establish the kind of obligation contemplated by *Lujan* and *Big Spring*. The CMS Rule itself requires Medicare Advantage insurers to undertake “reasonable diligence” in certifying that diagnostic code information is supported by underlying medical charts. 42 C.F.R. § 422.326. In its response to notice and comment on the rule, the government stated that it expects “reasonable diligence” to require “at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments.” 79 Fed. Reg. at 29,923. Plaintiffs have alleged that the CMS Rule, effective since July 2014, imposes new “obligations” on Medicare Advantage insurers. *See* Compl. ¶ 9. The active obligation currently imposed by the CMS Rule on the Medicare Advantage insurers to engage in “proactive compliance activities” by “qualified individuals” falls squarely into the kind of regulation contemplated by *Lujan* and *Big Spring* to establish standing.

The government responds that Plaintiffs argue for *per se* standing. *See* Reply at 5-8. That phrase never appears in Plaintiffs’ briefs nor in any case Plaintiffs cite. While the government cites multiple cases involving, *inter alia*, gun owners, passport holders, and Sierra Club members, none of these cases is inconsistent with, or otherwise challenges, the general framework relating to regulated entities, as articulated in *Lujan* and *Big Spring*. *See* Reply at 5-7 (citing *Parker v. District of Columbia*, 478 F.3d 370 (D.C. Cir. 2007)(gun owners); *Zivotofsky v.*

standing but dismissing for lack of ripeness). While the Court understands the parties to be contesting Plaintiffs’ Article III standing, it finds that the matter is ripe for review. “The Supreme Court’s landmark decision in *Abbott Laboratories* largely resolved the ripeness issue for many challenges to agency action. There, the Supreme Court ruled that affected parties could challenge agency regulations in pre-enforcement suits. The Supreme Court explained that regulated parties generally need not violate a law in order to challenge the law.” *Big Spring*, 795 F.3d at 53-54 (citing *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-53 (1967)). Such is the case here.

Sec'y of State, 444 F.3d 614 (D.C. Cir. 2006)(passport holders); *Sierra Club v. EPA*, 292 F.3d 895 (D.C. Cir. 2002)(Sierra Club members)). The Court therefore construes the government's argument as challenging the sufficiency of Plaintiffs' allegations of harm. *See* Reply at 7 (“[Plaintiffs have not even offered factual allegations that could be backed up with evidentiary submissions”). “At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we ‘presume that general allegations embrace those specific facts that are necessary to support the claim.’” *Lujan* 504 U.S. at 561 (1992) (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 883-889 (1990)). It is only at the summary judgment stage that “the plaintiff can no longer rest on such ‘mere allegations,’ but must ‘set forth’ by affidavit or other evidence ‘specific facts,’” *Lujan*, 504 U.S. at 561. Plaintiffs have alleged that they are Medicare Advantage insurers and that the CMS Rule is actively in effect. Compl. ¶¶ 1, 9. The agency's own interpretation of the CMS Rule requires Medicare Advantage insurers to engage in “proactive compliance activities” sufficient to validate medical care with diagnostic codes. 79 Fed. Reg. at 29,923. *Lujan* does not require the Court to demand an in-depth accounting of the cost of compliance activities when the CMS Rule itself requires affirmative compliance efforts on its face. Plaintiffs have adequately pled injury-in-fact.

Because the CMS Rule's affirmative obligations establishes an injury-in-fact upon Plaintiffs, the Court now must consider the remaining two components of Article III standing. The Court concludes that Plaintiffs have met their burden. The Court has found injury through the compliance obligations imposed on the Plaintiffs by the CMS Rule. While the parties veer repeatedly into territory that might be better understood as addressing the merits of the Complaint or whether Plaintiffs have been injured at all, their arguments about traceability and redressability essentially collapse into one question: Did the CMS Rule impose a novel legal

obligation on Plaintiffs or simply restate pre-existing obligations? If it is the latter, then Plaintiffs' injury is not fairly traceable to the CMS Rule. Similarly, any injury could not be redressed because the preexisting obligations would still require Plaintiffs to carry out the same activities.

The government asserts that Medicare Advantage insurers are otherwise obligated to exercise "due diligence" and undertake "good faith efforts" to certify that the information they submit to CMS is accurate. Mot. to Dismiss at 15-16 (citing 42 C.F.R. § 422.504(l)(2)). The government also argues that 42 C.F.R. § 422.503(b)(4)(vi) requires Medicare Advantage insurers to adopt and implement effective compliance programs to ensure fraud detection and reporting accuracy. *Id.* It scorns Plaintiffs' argument as an attempt to get paid for erroneous entries. *See, e.g.,* Mot. to Dismiss at 1.

Parties also dedicate part of a reply, a sur-reply and a sur-sur-reply to the Ninth Circuit decision *United States ex rel Swoben v. United Healthcare Ins. Co.*, No. 13-56746 (9th Cir. Aug. 8, 2016). *Swoben*, a non-controlling case in this Circuit, is of limited use because it does not involve any Rule 12(b)(1) standing issue, does not concern the CMS Rule, and involved a defendant Medicare Advantage insurer that allegedly concealed coding information. *See Swoben*, slip op. at 15. *Swoben* held that a *qui tam* plaintiff could state a cognizable claim under Rule 12(b)(6) that a Medicare Advantage insurer who concealed and otherwise failed to report faulty diagnostic codes failed to exercise due diligence as required by 42 C.F.R. § 422.504(l)(2). The government points to *Swoben* as evidence that the Plaintiffs have a pre-existing obligation to exercise due diligence and therefore cannot show redressability. *See* Reply at 15. *Swoben* is not the droid the Secretary is looking for.

The CMS Rule requires Medicare Advantage organizations to undertake “reasonable diligence” which the agency explains requires “at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments.” 79 Fed. Reg. at 29,923. While the Secretary points to other requirements that Plaintiffs must exercise “due diligence,” CMS has pointed to no other regulation where the statute has been interpreted to apply such a standard, either to CMS or to Medicare Advantage insurers. In essence, the Secretary would have the Court find that the CMS Rule’s insistence on “proactive compliance activities,” under pain of a False Claims Act suit provable by negligence alone, is meaningless. It is not; it imposes (for good reason or not) new obligations. Plaintiffs have established Article III standing.

B. Statutory Standing

A federal court must assure itself of both constitutional and statutory subject matter jurisdiction. Typically, when a plaintiff seeks redress for an issue involving a federal law, 28 U.S.C. § 1331 confers subject matter jurisdiction on district courts to hear that case. *See* 28 U.S.C. § 1331 (2012) (conferring jurisdiction over “all civil actions arising under the Constitution, laws, or treaties of the United States”). However, Congress has from time to time restricted this general grant of jurisdiction. One such instance is the Medicare Act, which incorporates certain jurisdictional restrictions originating in the Social Security Act, to which Medicare was an addition.

The mechanisms providing for administrative review are complicated. Certain provisions of the Social Security Act provide for administrative review of proceedings. *See* 42 U.S.C. § 405 (2012). In particular, § 405(b) allows an aggrieved party with a dispute under the Social Security Act to bring such grievances in an administrative hearing before an SSA Administrative Law Judge and then to the Commissioner of Social Security. Section 405(g)

provides for judicial review of a § 405(b) hearing. Finally, § 405(h) states that it provides the exclusive path to bring any complaints under the Social Security Act: “No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.” 42 U.S.C. § 405(h).

Section 405 does not apply “on its own terms” to Medicare, *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 680 (1986), but Congress has extended these provisions to claims arising under the Medicare Act. At 42 U.S.C. § 1395ii, Medicare incorporates most provisions of § 405 *mutatis mutandis* into the Medicare Act, although not §§ 405(b) and 405(g). *See* 42 U.S.C. § 1395ii (“[S]ubsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter . . .”). The Medicare statute does provide that certain categories of disputes must be channeled through the procedures set forth in §§ 405(b) and 405(g); for example, § 1395ff(b)(1) allows beneficiaries dissatisfied with a benefit determination to challenge that determination through a hearing as provided in § 405(b). *See* § 1395ff(b)(1). Where a § 405(b) hearing is available, or an administrative procedure is otherwise provided, § 405(h) makes that procedure the exclusive avenue for aggrieved parties to challenge a CMS decision. Accordingly, “§ 405(h)[] channels most, if not all, Medicare claims through” administrative procedures before they may be brought into a federal court. *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 8 (2000).

However, not all claims that can conceivably arise under the Medicare Act are necessarily afforded an administrative hearing. *Illinois Council* recognized that direct judicial

review is not foreclosed to plaintiffs where it would mean “no review at all.” 529 U.S. at 20-21. “No review at all” means one of two things: Firstly, when there is literally no avenue for judicial review, because no prior administrative route for reviewing a claim exists; and, secondly, where a claim is foreclosed as a practical matter because the likelihood of severe sanctions for noncompliance is so great that it serves to “deny review in practice.” *Id.* at 20-22. For sanctions to be so great as to deny review in practice, they must go beyond the typical burdens associated with administrative review, such as “occasional individual delay related hardship.” *Id.* at 13, 22-23 (“[W]e do not hold that an individual party could circumvent [the Medicare Act’s] channeling requirement simply because that party shows that postponement would mean added inconvenience or cost in an isolated, particular case.”). Further, the fact that a particular plaintiff may not have an avenue to challenge a particular regulation is not sufficient to escape § 405(h) where other, similarly-motivated plaintiffs may have an avenue of appeal. *See Am. Chiropractic Ass’n v. Leavitt*, 431 F.3d 812, 817 (D.C. Cir. 2005) (finding no standing where theoretical plaintiffs could obtain administrative review even though that option was not available to plaintiffs before the court).

There is no direct appeal process that allows these Plaintiffs to challenge the promulgated CMS Rule on their own initiative, under § 405(b) or otherwise. Further, CMS does not bring enforcement actions; if it determines that Plaintiffs have received an overpayment, Plaintiffs have no opportunity to challenge that determination directly.³ If an overpayment is discovered, Plaintiffs have two options: (1) repay the overpayment, at which point there is no further review; or (2) withhold the overpayment, which, per the CMS Rule, violates the

³ The same, of course, applies in situations where the Plaintiffs discover an overpayment themselves.

regulation and triggers liability under the False Claims Act after 60 days. Either the Office of the Inspector General (OIG) for Health and Human Services could bring an enforcement action against Plaintiffs under its own authority found in 42 U.S.C. § 1320a-7a, or a *qui tam* action could be brought by a private plaintiff.⁴

Plaintiffs raise several theories as to why such a situation does not preclude judicial review now. They assert that (1) an OIG enforcement action brought under § 1320a-7a is not a proceeding under the Medicare Act, and therefore § 405(h) would not apply; (2) an OIG enforcement action would not provide an avenue for administrative review of the CMS Rule; and (3) the penalty for the Plaintiffs is so great that it is the “practical equivalent of a total denial of judicial review” under *Illinois Council*. See Opp. at 35-45; *Illinois Council*, 529 U.S. at 20.

As to the first point, Plaintiffs assert that an OIG enforcement action, brought under its own governing procedures found in § 1320a-7a, is not a proceeding under § 405(b) and therefore not subject to § 405(h). *Id.* at 37. In their view, § 405(h) applies only in conjunction with §§ 405(b) and 405(g), citing as support the D.C. Circuit’s statement in *Council for Urological Interests* that “section 405(h) is inapplicable where the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims.” *Council for Urological Interests v. Sebelius*, 668 F.3d. 704, 708 (D.C. Cir. 2011).

However, the Court reads *Illinois Council* to apply to proceedings under § 1320a-7a for two reasons. First, *Illinois Council* explicitly identifies § 1320a-7a as part of the “special review system” through which “§ 405(h) channels most, if not all, Medicare claims.” 529 U.S.

⁴ This issue has not been discussed by the parties, but to the extent Plaintiffs are publicly-traded companies, they would also presumably face possible SEC scrutiny, which has previously brought enforcement actions predicated on behavior that potentially violated the False Claims Act. See, e.g., *SEC v. RPM Int’l, Inc.*, No. CV 16-1803 (ABJ), 2016 WL 7388284, at *1 (D.D.C. Dec. 20, 2016).

at 8. Second, *Illinois Council* states that § 405(h) would not apply where “application of § 405(h) would not simply channel review through the agency, but would mean no review *at all.*” *Id.* at 19 (emphasis added). OIG enforcement procedures would ultimately end in judicial review of some kind, suggesting that, under the reasoning of *Illinois Council*, § 405(h) would still apply.

While the Court is satisfied that an OIG enforcement action could constitute a review pathway, the more difficult question is whether it would constitute a review pathway *for the CMS Rule at issue*, which is the crux of Plaintiffs’ second argument. OIG has in fact promulgated its own, separate rule concerning overpayments, titled “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules,” 81 Fed. Reg. 88,334 (Dec. 7, 2016) (OIG Rule).⁵ The OIG Rule defines OIG’s procedures for enforcing the reporting and return requirements of overpayments. The OIG Rule refers to the similar CMS Rule, stating “[i]n the context of Parts C and D, CMS has interpreted the meaning of ‘overpayment,’ and we are required to apply the same meaning in an enforcement action against a Part C plan or Part D plan sponsor.” 81 Fed. Reg. at 88,344. Despite this language, in many instances OIG otherwise disclaimed responsibility for interpreting the CMS Rule. For example, OIG has refused to state that good faith compliance with the CMS Rule would necessarily mean a Medicare Advantage insurer is complying with the OIG Rule. *Id.* OIG also states that its own rulemaking “did not propose to interpret the CMS final rule concerning Part C plans,” and that commenters’ concerns with CMS’s definitions are “outside the scope of [OIG’s] rulemaking.” *Id.* While the government has asserted in brief that OIG has

⁵ This rule was in the process of notice-and-comment when the parties submitted their briefs; the government submitted a Notice of Supplemental Authority [Dkt. 23], to which the Plaintiffs responded [Dkt. 24], when the final OIG Rule was promulgated.

applied CMS regulations in the past, *see* Reply at 22 n.12, the text of the OIG Rule and OIG's statements on the OIG Rule indicate that CMS's definitions and the appropriateness thereof would be beyond the scope of any OIG enforcement proceeding.

Accordingly, it cannot be said that an independent enforcement proceeding brought by OIG would serve as a vehicle for Plaintiffs to challenge the CMS Rule. Given the differences between the CMS Rule and the OIG Rule, and the fact that they were promulgated by different agencies within HHS, it is difficult to discern how judicial review of an OIG enforcement action would encompass an APA-like review of the CMS Rule. OIG warns explicitly that the OIG Rule is not intended to interpret the CMS Rule; thus, it is exceedingly doubtful that any judicial review of the OIG Rule would provide an occasion to review the CMS Rule under the APA. The Court concludes that an OIG enforcement action could provide for judicial review of *a* rule, that is, the OIG Rule, but it would not provide judicial review of the CMS Rule at issue here.

As a result, an OIG enforcement action would not serve as an administrative mechanism resulting in judicial review under *Illinois Council*. Neither party suggests a different path for review. Accordingly, as a legal matter, § 405(h) cannot be applied to the CMS Rule, as to do so would leave Plaintiffs with no judicial review of the CMS Rule at all.

Even if there were a legal avenue that would result in judicial review of the CMS Rule, the associated penalties would render such a path practicably foreclosed. Plaintiffs are facing a much different set of circumstances than hardship caused by the typical delays associated with administrative review. *See Illinois Council*, 529 U.S. at 13. If Plaintiffs fail to remit timely an overpayment, they face exposure to an OIG enforcement action and False Claims Act liability. In other words, to challenge the CMS Rule administratively, Plaintiffs first would

have to facially commit “fraud” without correction because correction to avoid possible civil penalties and disbarment from Medicare could moot any challenge to the CMS Rule. Further, this conundrum presents a systematic risk for all Medicare Advantage insurers that might want to challenge the CMS Rule. The costs associated with such action would be inherently more burdensome than the costs associated with a typical delay in resolving a Medicare payment dispute.

The stated purpose of requiring administrative review is not served by such a procedural quagmire. Channeling claims through CMS “assures the agency greater opportunity to apply, interpret or revise policies, regulations or statutes without possibly premature interference by different individual courts applying ‘ripeness’ and ‘exhaustion’ exceptions case by case.” *Id.* Both CMS and the OIG have engaged in rulemaking without addressing the issue posed by Plaintiffs’ suit.

Because the Court sees no viable path for administrative review of the CMS Rule, and because the CMS Rule systematically places such heavy burdens that any review would be practicably foreclosed, the Court finds that § 405(h) does not preclude judicial review at this time.

CONCLUSION

Plaintiffs have established both Article III and statutory standing to bring their suit challenging the CMS Rule. The Court therefore will deny Defendants’ Motion to Dismiss for Lack of Subject Matter Jurisdiction Under 12(b)(1). A memorializing Order accompanies this Memorandum Opinion.

Date: March 31, 2017

/s/
ROSEMARY M. COLLYER
United States District Court

EXHIBIT 58

February 15, 2013

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2014. The following information is also included: preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2014, changes in payment methodology for CY 2014 for Part D benefits, and annual adjustments for CY 2014 to the Medicare Part D benefit parameters for the defined standard benefit. For 2014, CMS will announce the MA capitation rates on the first Monday in April 2013, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Attachment I shows the preliminary estimates of the national per capita MA growth percentage and the national Medicare fee-for-service growth percentage, which are key factors in determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2014 governing payment for original Medicare benefits and rebates. Attachment III sets forth the changes in payment methodology for CY 2014 for Part D benefits. Attachment IV presents the annual adjustments for CY 2014 to the Medicare Part D benefit parameters for the defined standard benefit. Attachment V presents the preliminary risk adjustment factors.

Attachment VI provides the draft CY 2014 Call Letter for Medicare Advantage (MA) organizations; section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including both employer/union-only group health plans (EGWPs) and direct contract plans. The Call Letter contains information these plan sponsor organizations will find useful as they prepare their bids for the new contract year.

Comments or questions may be submitted electronically to the following address:
AdvanceNotice2014@cms.hhs.gov.

Comments may be made public, so submitters should not include any confidential or personal information. In order to receive consideration prior to the April 1, 2013, release of the final Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern Standard Time on Friday, March 1, 2013.

Table 5. Comparison of Current and Revised CMS-HCC Risk Adjustment Model HCCs

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		Category Short Name
HCC	Description	HCC	Description	HCC	Description	
HCC1	HIV/AIDS	HCC1	HIV/AIDS	HCC1	HIV/AIDS	Infection
HCC2	Septicemia/Shock	HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	
HCC5	Opportunistic Infections	HCC6	Opportunistic Infections	HCC6	Opportunistic Infections	Neoplasm
HCC7	Metastatic Cancer and Acute Leukemia	HCC8	Metastatic Cancer and Acute Leukemia	HCC8	Metastatic Cancer and Acute Leukemia	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	HCC9	Lung and Other Severe Cancers	HCC9	Lung and Other Severe Cancers	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	HCC10	Lymphoma and Other Cancers	HCC10	Lymphoma and Other Cancers	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	HCC11	Colorectal, Bladder, and Other Cancers	HCC11	Colorectal, Bladder, and Other Cancers	
		HCC12	Breast, Prostate, and Other Cancers and Tumors	HCC12	Breast, Prostate, and Other Cancers and Tumors	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	HCC17	Diabetes with Acute Complications	HCC17	Diabetes with Acute Complications	Diabetes
HCC16	Diabetes with Neurologic or Other Specified Manifestation	HCC18	Diabetes with Chronic Complications	HCC18	Diabetes with Chronic Complications	
HCC17	Diabetes with Acute Complications	HCC19	Diabetes without Complication	HCC19	Diabetes without Complication	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation					
HCC19	Diabetes without Complication					Metabolic
HCC21	Protein-Calorie Malnutrition	HCC21	Protein-Calorie Malnutrition	HCC21	Protein-Calorie Malnutrition	
		HCC22	Morbid Obesity	HCC22	Morbid Obesity	
		HCC23	Other Significant Endocrine and Metabolic Disorders	HCC23	Other Significant Endocrine and Metabolic Disorders	Liver
HCC25	End-Stage Liver Disease	HCC27	End-Stage Liver Disease	HCC27	End-Stage Liver Disease	
HCC26	Cirrhosis of Liver	HCC28	Cirrhosis of Liver	HCC28	Cirrhosis of Liver	
HCC27	Chronic Hepatitis	HCC29	Chronic Hepatitis	HCC29	Chronic Hepatitis	
HCC31	Intestinal Obstruction/Perforation	HCC33	Intestinal Obstruction/Perforation	HCC33	Intestinal Obstruction/Perforation	Gastrointestinal
HCC32	Pancreatic Disease	HCC34	Chronic Pancreatitis	HCC34	Chronic Pancreatitis	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
HCC33	Inflammatory Bowel Disease	HCC35	Inflammatory Bowel Disease	HCC35	Inflammatory Bowel Disease	Musculoskeletal
HCC37	Bone/Joint/Muscle Infections/Necrosis	HCC39	Bone/Joint/Muscle Infections/Necrosis	HCC39	Bone/Joint/Muscle Infections/Necrosis	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	
HCC44	Severe Hematological Disorders	HCC46	Severe Hematological Disorders	HCC46	Severe Hematological Disorders	Blood
HCC45	Disorders of Immunity	HCC47	Disorders of Immunity	HCC47	Disorders of Immunity	
		HCC48	Coagulation Defects and Other Specified Hematological Disorders	HCC48	Coagulation Defects and Other Specified Hematological Disorders	
HCC51	Drug/Alcohol Psychosis	HCC54	Drug/Alcohol Psychosis	HCC54	Drug/Alcohol Psychosis	Substance Abuse
HCC52	Drug/Alcohol Dependence	HCC55	Drug/Alcohol Dependence	HCC55	Drug/Alcohol Dependence	
HCC54	Schizophrenia	HCC57	Schizophrenia	HCC57	Schizophrenia	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	HCC58	Major Depressive, Bipolar, and Paranoid Disorders	HCC58	Major Depressive, Bipolar, and Paranoid Disorders	Psychiatric
HCC67	Quadriplegia, Other Extensive Paralysis	HCC70	Quadriplegia	HCC70	Quadriplegia	
HCC68	Paraplegia	HCC71	Paraplegia	HCC71	Paraplegia	
HCC69	Spinal Cord Disorders/Injuries	HCC72	Spinal Cord Disorders/Injuries	HCC72	Spinal Cord Disorders/Injuries	Spinal
HCC70	Muscular Dystrophy	HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	
HCC71	Polyneuropathy	HCC74	Cerebral Palsy	HCC74	Cerebral Palsy	
HCC72	Multiple Sclerosis	HCC75	Polyneuropathy	HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	Neurological
HCC73	Parkinson's and Huntington's Diseases	HCC76	Muscular Dystrophy	HCC76	Muscular Dystrophy	
HCC74	Seizure Disorders and Convulsions	HCC77	Multiple Sclerosis	HCC77	Multiple Sclerosis	
HCC75	Coma, Brain Compression/Anoxic Damage	HCC78	Parkinson's and Huntington's Diseases	HCC78	Parkinson's and Huntington's Diseases	
		HCC79	Seizure Disorders and Convulsions	HCC79	Seizure Disorders and Convulsions	
		HCC80	Coma, Brain Compression/Anoxic Damage	HCC80	Coma, Brain Compression/Anoxic Damage	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
HCC77	Respirator Dependence/Tracheostomy Status	HCC82	Respirator Dependence/Tracheostomy Status	HCC82	Respirator Dependence/Tracheostomy Status	Arrest
HCC78	Respiratory Arrest	HCC83	Respiratory Arrest	HCC83	Respiratory Arrest	
HCC79	Cardio-Respiratory Failure and Shock	HCC84	Cardio-Respiratory Failure and Shock	HCC84	Cardio-Respiratory Failure and Shock	
HCC80	Congestive Heart Failure	HCC85	Congestive Heart Failure	HCC85	Congestive Heart Failure	Heart
HCC81	Acute Myocardial Infarction	HCC86	Acute Myocardial Infarction	HCC86	Acute Myocardial Infarction	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	
HCC83	Angina Pectoris/Old Myocardial Infraction	HCC88	Angina Pectoris	HCC88	Angina Pectoris	Cerebrovascular Disease
HCC92	Specified Heart Arrhythmias	HCC96	Specified Heart Arrhythmias	HCC96	Specified Heart Arrhythmias	
HCC95	Cerebral Hemorrhage	HCC99	Cerebral Hemorrhage	HCC99	Cerebral Hemorrhage	
HCC96	Ischemic or Unspecified Stroke	HCC100	Ischemic or Unspecified Stroke	HCC100	Ischemic or Unspecified Stroke	Vascular
HCC100	Hemiplegia/Hemiparesis	HCC103	Hemiplegia/Hemiparesis	HCC103	Hemiplegia/Hemiparesis	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	HCC104	Monoplegia, Other Paralytic Syndromes	HCC104	Monoplegia, Other Paralytic Syndromes	
HCC104	Vascular Disease with Complications	HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	Lung
HCC105	Vascular Disease	HCC107	Vascular Disease with Complications	HCC107	Vascular Disease with Complications	
		HCC108	Vascular Disease	HCC108	Vascular Disease	
HCC107	Cystic Fibrosis	HCC110	Cystic Fibrosis	HCC110	Cystic Fibrosis	Eye
HCC108	Chronic Obstructive Pulmonary Disease	HCC111	Chronic Obstructive Pulmonary Disease	HCC111	Chronic Obstructive Pulmonary Disease	
HCC111	Aspiration and Specified Bacterial Pneumonias	HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	HCC114	Aspiration and Specified Bacterial Pneumonias	HCC114	Aspiration and Specified Bacterial Pneumonias	Kidney
		HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	
		HCC124	Exudative Macular Degeneration	HCC124	Exudative Macular Degeneration	
HCC130	Dialysis Status	HCC134	Dialysis Status	HCC134	Dialysis Status	
HCC131	Renal Failure	HCC135	Acute Renal Failure	HCC135	Acute Renal Failure	
HCC132	Nephritis	HCC136	Chronic Kidney Disease (Stage 5)	HCC136	Chronic Kidney Disease (Stage 5)	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)	
		HCC137	Chronic Kidney Disease, Severe (Stage 4)	HCC137	Chronic Kidney Disease, Severe (Stage 4)
		HCC138	Chronic Kidney Disease, Moderate (Stage 3)		
		HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)		
		HCC140	Unspecified Renal Failure		
		HCC141	Nephritis		
HCC148	Decubitus Ulcer of Skin	HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone
HCC149	Chronic Ulcer of Skin, Except Decubitus	HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss
HCC150	Extensive Third-Degree Burns	HCC161	Chronic Ulcer of Skin, Except Pressure	HCC161	Chronic Ulcer of Skin, Except Pressure
		HCC162	Severe Skin Burn or Condition	HCC162	Severe Skin Burn or Condition
HCC154	Severe Head Injury	HCC166	Severe Head Injury	HCC166	Severe Head Injury
HCC155	Major Head Injury	HCC167	Major Head Injury	HCC167	Major Head Injury
HCC157	Vertebral Fractures w/o Spinal Cord Injury	HCC169	Vertebral Fractures without Spinal Cord Injury	HCC169	Vertebral Fractures without Spinal Cord Injury
HCC158	Hip Fracture/Dislocation	HCC170	Hip Fracture/Dislocation	HCC170	Hip Fracture/Dislocation
HCC161	Traumatic Amputation	HCC173	Traumatic Amputations and Complications	HCC173	Traumatic Amputations and Complications
HCC164	Major Complications of Medical Care and Trauma	HCC176	Complications of Specified Implanted Device or Graft	HCC176	Complications of Specified Implanted Device or Graft
HCC174	Major Organ Transplant Status	HCC186	Major Organ Transplant or Replacement Status	HCC186	Major Organ Transplant or Replacement Status
HCC176	Artificial Openings for Feeding or Elimination	HCC188	Artificial Openings for Feeding or Elimination	HCC188	Artificial Openings for Feeding or Elimination
HCC177	Amputation Status, Lower Limb/Amputation Complications	HCC189	Amputation Status, Lower Limb/Amputation Complications	HCC189	Amputation Status, Lower Limb/Amputation Complications
Community Model Interactions					
D_HCC5	Disabled_Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections
D_HCC44	Disabled_Severe Hematological Disorders	D_HCC34	Disabled, Chronic Pancreatitis	D_HCC34	Disabled, Chronic Pancreatitis
					Disabled/ Disease Interactions

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
D_HCC51	Disabled_Drug/Alcohol Psychosis	D_HCC46	Disabled, Severe Hematological Disorders	D_HCC46	Disabled, Severe Hematological Disorders	
D_HCC52	Disabled_Drug/Alcohol Dependence	D_HCC54	Disabled, Drug/Alcohol Psychosis	D_HCC54	Disabled, Drug/Alcohol Psychosis	
D_HCC107	Disabled_Cystic Fibrosis	D_HCC55	Disabled, Drug/Alcohol Dependence	D_HCC55	Disabled, Drug/Alcohol Dependence	
		D_HCC110	Disabled, Cystic Fibrosis	D_HCC110	Disabled, Cystic Fibrosis	
		D_HCC176	Disabled, Complications of Specified Implanted Device or Graft	D_HCC176	Disabled, Complications of Specified Implanted Device or Graft	
INT1	DM_CHF	SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	Disease Interactions
INT2	DM_CVD	CANCER_IMMUNE	Cancer*Immune Disorders	CANCER_IMMUNE	Cancer*Immune Disorders	
INT3	CHF_COPD	DIABETES_CHF	Diabetes*Congestive Heart Failure	DIABETES_CHF	Diabetes*Congestive Heart Failure	
INT4	COPD_CVD_CAD	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	
INT5	RF_CHF	CHF_RENAL	Congestive Heart Failure*Renal Disease	CHF_RENAL	Congestive Heart Failure*Renal Disease	
INT6	RF_CHF_DM	COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	
Institutional Model Interactions						
D_HCC5	Disabled_Opportunistic Infections	D_HCC85	Disabled, Congestive Heart Failure	D_HCC85	Disabled, Congestive Heart Failure	Disabled/ Disease Interactions
D_HCC44	Disabled_Severe Hematological Disorders	D_PRESSURE_ULCER	Disabled, Pressure Ulcer	D_PRESSURE_ULCER	Disabled, Pressure Ulcer	
D_HCC51	Disabled_Drug/Alcohol Psychosis	D_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	D_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	
D_HCC52	Disabled_Drug/Alcohol Dependence	D_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	D_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	
D_HCC107	Disabled_Cystic Fibrosis	D_HCC77	Disabled, Multiple Sclerosis	D_HCC77	Disabled, Multiple Sclerosis	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		Disease Interactions
		D_HCC6	Disabled, Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections	
DM_CHF1	Diabetes_Congestive Heart Failure	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	
DM_CVD_	Diabetes_Cerebrovascular Disease	COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease *Cardiorespiratory Failure	COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease *Cardiorespiratory Failure	
CHF_COPD	Congestive Heart Failure_Chronic Obstructive Pulmonary Disease	SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	
COPD_CVD_CAD_	Chronic Obstructive Pulmonary Disease_Cerebrovascular Disease_Coronary Artery Disease	SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	
RF_CHF1	Renal Failure_Congestive Heart Failure	ART_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	ART_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	
RF_CHF_DM	Renal Failure_Congestive Heart Failure_Diabetes	DIABETES_CHF	Diabetes*Congestive Heart Failure	DIABETES_CHF	Diabetes*Congestive Heart Failure	
		COPD_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	COPD_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	
		ASP_SPEC_BACT_PNEUM_PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	ASP_SPEC_BACT_PNEUM_PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	
		SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	
		SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	
		SCHIZOPHRENIA_CHF	Schizophrenia* Congestive Heart Failure	SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	

V12 Model (with 70 HCC's)	V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)	
	SCHIZOPHRENIA_ SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	SCHIZOPHRENIA_ SEIZURES	Schizophrenia*Seizure Disorders and Convulsions

Source: RTI International.