CHAD A. READLER
Acting Assistant Attorney General, Civil Division
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
JOHN E. LEE (CBN 128696)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; Fax: (716) 551-3052
Email: 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.* BENJAMIN POEHLING, Plaintiffs, v. UNITEDHEALTH GROUP, INC., *et al.*, Defendants.	No. CV 16-08697 MWF (SSx) UNITED STATES' AND RELATOR POEHLING'S JOINT NOTICE OF MOTION AND MOTION FOR PARTIAL SUMMARY JUDGMENT Date: July 30, 2018 Time: 10:00 a.m. Court: 5A. Hon. Michael W. Fitzgerald

Additional Attorneys (continued from previous page):

ERIC R. HAVIAN (CBN 102295)
ehavian@constantinecannon.com
HARRY LITMAN (CBN 127202)
hlitman@constantinecannon.com
JESSICA T. MOORE (CBN 183431)
jmoore@constantinecannon.com
HENRY C. SU (CBN 211202)
hsu@constantinecannon.com
Constantine Cannon LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Facsimile: (415) 639-4002

STEPHEN HASEGAWA (CBN 198472)
shasegawa@phillipsandcohen.com
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Facsimile: (415) 836-9001

WILLIAM CHRISTOPHER CARMODY (*pro hac vice*)
wcarmody@susmangodfrey.com
ARUN SUBRAMANIAN (*pro hac vice*)
asubramanian@susmangodfrey.com
GENG CHEN (*pro hac vice*)
gchen@susmangodfrey.com
Susman Godfrey L.L.P.
1301 Avenue of the Americas, 32nd Floor
New York, New York 10019-6023
Tel: (212) 336-8330
Facsimile: (212) 336-8340

MENG XI (CBN 280099)
mxi@susmangodfrey.com
CATRIONA LAVERY (CBN 310546)
clavery@susmangodfrey.com
Susman Godfrey L.L.P.
1900 Avenue of the Stars, Suite 1400
Los Angeles, California 90067
Tel: (310) 789-3100
Facsimile: (310) 789-3100

Attorneys for Relator Benjamin Poehling

PLEASE TAKE NOTICE that, on July 30, 2018, at 10:00 a.m., or as soon thereafter as the matter may be heard, in the courtroom of the Honorable Michael W. Fitzgerald, United States District Judge, Courtroom 5A, United States Courthouse, 350 West First Street, Los Angeles, California 90012, the United States of America and relator Benjamin Poehling will and hereby do move for an order granting partial summary judgment in favor of the United States and relator Poehling on the legal issue of whether the United Defendants were required to delete diagnosis codes that they knew (as that term is used in the False Claims Act) were unsupported by their beneficiaries' medical records.

This motion is and will be made pursuant to Rule 56(a), Fed. R. Civ. P., and L.R. 56-1 on the grounds that there is no genuine dispute as to any fact material to this issue and that the United States and relator Poehling are therefore entitled to partial judgment as a matter of law.

This motion is based upon the accompanying Memorandum of Points and Authorities, Declaration of Cheri Rice, Request for Judicial Notice, Exhibits, [proposed] Statement of Uncontroverted Facts and Conclusions of Law, [proposed] Order, the pleadings and other papers on file herein, and such evidence and argument as may be presented in connection with the hearing of this motion.

This motion is made following the conference of counsel pursuant to L.R. 7-3 which took place on December 14, 2017 and May 9, 2018.

Respectfully submitted,

Dated: May 22, 2018

CHAD A. READLER
Acting Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
Assistant United States Attorneys

MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Civil Division, Department of Justice

JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney
Attorneys for the United States of America

Dated: May 22, 2018

ERIC R. HAVIAN
HARRY LITMAN
JESSICA MOORE
Constantine Cannon LLP

STEVE HASEGAWA
Phillips & Cohen LLP

WILLIAM CHRISTOPHER CARMODY
ARUN SUBRAMANIAN
MATTHEW R. BERRY
JOHN P. LAHAD
MENG XI
Susman Godfrey LLP

/S/ Henry C. Su

HENRY C. SU
Attorneys for Relator Beniamin Poehling

Attestation

I hereby attest that the other signatory listed, on whose behalf the filing is submitted, concurs in the filing's content and has authorized the filing.

Dated: May 22, 2018

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney

CHAD A. READLER
Acting Assistant Attorney General, Civil Division
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
JOHN E. LEE (CBN 128696)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; Fax: (716) 551-3052
Email: kathleen.lynch@usdoj.gov
Attorneys for the United States of America

UNITED STATES DISTRICT COURT

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UNITED STATES OF AMERICA *ex rel*. BENJAMIN POEHLING, Plaintiffs, v. UNITEDHEALTH GROUP, INC., *et al*., Defendants.	No. CV 16-08697 MWF (SSx) PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT Date: July 30, 2018 Time: 10:00 a.m. Court: 5A. Hon. Michael W. Fitzgerald

Additional Attorneys (continued from previous page):

ERIC R. HAVIAN (CBN 102295)
ehavian@constantinecannon.com
HARRY LITMAN (CBN 127202)
hlitman@constantinecannon.com
JESSICA T. MOORE (CBN 183431)
jmoore@constantinecannon.com
HENRY C. SU (CBN 211202)
hsu@constantinecannon.com
Constantine Cannon LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Facsimile: (415) 639-4002

STEPHEN HASEGAWA (CBN 198472)
shasegawa@phillipsandcohen.com
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Facsimile: (415) 836-9001

WILLIAM CHRISTOPHER CARMODY (*pro hac vice*)
wcarmody@susmangodfrey.com
ARUN SUBRAMANIAN (*pro hac vice*)
asubramanian@susmangodfrey.com
GENG CHEN (*pro hac vice*)
gchen@susmangodfrey.com
Susman Godfrey L.L.P.
1301 Avenue of the Americas, 32nd Floor
New York, New York 10019-6023
Tel: (212) 336-8330
Facsimile: (212) 336-8340

MENG XI (CBN 280099)
mxi@susmangodfrey.com
CATRIONA LAVERY (CBN 310546)
clavery@susmangodfrey.com
Susman Godfrey L.L.P.
1900 Avenue of the Stars, Suite 1400
Los Angeles, California 90067
Tel: (310) 789-3100
Facsimile: (310) 789-3100

Attorneys for Relator Benjamin Poehling

MEMORANDUM OF POINTS AND AUTHORITIES

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I. INTRODUCTION

A fundamental requirement of the Medicare Advantage (MA) program is that diagnosis codes submitted by Medicare Advantage Organizations (MAOs) for risk adjusted payments must be supported by their beneficiaries' medical records. The Ninth Circuit – and United[1] itself – have recognized this long-standing requirement. *See United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1176 (9th Cir. 2016) ("CMS requires medical diagnosis codes to be supported by a medical record"); Joint Answering Brief of Defendants-Appellees, *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746, Dkt. 39, at 36 (9th Cir. filed June 2, 2014) (Exhibit 9) ("CMS regulations deem a diagnosis code proper if it is supported by a . . . medical record").[2] A corollary to the medical record requirement is that MAOs are obligated to withdraw diagnosis codes if they know that their beneficiaries' medical records do not support the diagnoses for which they have claimed payment. Again, the Ninth Circuit has already held that an MAO has an obligation to correct unsupported diagnoses submitted for risk adjusted payments. *Swoben*, 848 F.3d at 1174-75 (citing MA compliance obligations at 42 C.F.R. § 422.503(b)(4)(vi)). The United States requests that the Court enter partial summary judgment in this case on the legal issue of whether defendants were required to delete diagnosis codes they knew (as that term is used in the False Claims Act) were unsupported by their beneficiaries' medical records.

United is seeking to justify its fraudulent conduct by contending that it was legally permitted to ignore the medical record requirement and its obligation to withdraw unsupported diagnoses. Over the course of this case and the *Swoben* action, United has offered a series of arguments in pursuit of this position. For example, in conferrals with

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[1] "United" is being used in this brief to refer to all Defendants in this action.

[2] Exhibits 1-8 are attached to the Declaration of Cheri Rice, filed herewith, which authenticates the exhibits pursuant to Fed. R. Evid. 901(b)(7)(A), (B) and shows their admissibility pursuant to Fed. R. Evid. 803(6) and 803(8)(A)(i). *See Orr v. Bank of America, NT & SA*, 285 F.3d 764, 773, 778 (9th Cir. 2002) (requiring summary judgment evidence to be authenticated and admissible). Exhibits 9-15 are attached to the Joint Request for Judicial Notice, also filed herewith.

the government, United has asserted a tortured interpretation of the Medicare statute's reference to "actuarial equivalence" to justify its failure to delete unsupported diagnosis codes. According to United, because claims submitted by healthcare providers under Parts A and B of the Medicare Program (the fee-for-service or FFS programs) likely contain diagnosis coding errors, United is allowed to knowingly submit erroneous diagnoses codes to Medicare (or refrain from withdrawing such codes) for payments under the MA program.

The Counterclaim recently filed by United against the United States contains a slight variant of United's argument that it may refrain from correcting even those coding errors revealed by its own chart reviews. According to the Counterclaim, if "CMS also required MA plans to delete all codes that are not supported in provider-submitted codes, such that they received payments only for supported codes even as CMS continued calculating payment amounts using both its supported and unsupported FFS codes, CMS would receive a windfall . . . ." UnitedHealth's Answer to United States' Amended Complaint-in-Partial-Intervention and Counterclaim ¶ 11 (Dkt. 223). Although the Counterclaim does not use the term "actuarial equivalence," United's objective of nullifying an explicit legal requirement of accurate, chart-based coding has been consistent across Defendants' cases, briefs and pleadings. The Court should resolve that there is no merit to Defendants' legal contention in whatever form they may elect to frame it – an issue, as noted, that United has already litigated in the Ninth Circuit and lost. *See Swoben*, 848 F.3d at 1178-79.

Nevertheless, United is pressing the argument in this case and using it to justify irrelevant and burdensome discovery from the United States. United flatly told the government that it was seeking "documents . . . directly relevant to UnitedHealth's defense that the data verification requirements imposed on MAOs versus fee-for-service providers violate the governing statute's actuarial equivalence language." Letter from Abid R. Qureshi, at 4 (Nov. 7, 2017) (Exhibit 15). So that the parties and the Court do not waste substantial time and resources on discovery issues that are not pertinent to this

case, the United States requests that this Court resolve the legal issue by ruling, as the Ninth Circuit already has done, that United was required by regulation and contract to correct diagnostic codes which its own chart reviews had revealed were not supported by its beneficiaries' medical records. There are no factual issues subject to any legitimate dispute that preclude the Court from resolving the issue at this time. The data integrity requirements that control United's entitlement to payments present pure questions of law.

For at least four reasons, summary judgment on this issue is appropriate. First, United was required by regulation and contract to comply with its legal obligations to submit valid diagnosis data and delete diagnoses that it knew were invalid. United was not permitted to unilaterally retain payments based on invalid diagnoses because of any purported disagreement with the manner in which CMS calculates the amounts of risk adjusted payments it makes to MAOs. Just as a physician who believes she should be paid more for a particular medical procedure cannot bill for additional procedures she did not perform, United cannot knowingly fail to delete invalid diagnoses because it claims to be underpaid for valid diagnoses. If United was unwilling to comply with its obligation to correct invalid diagnoses, it should not have executed the contracts under which it agreed to be bound by the CMS payment rules.

Second, United made the same essential argument in *Swoben*, relying on a regulation similar to the statutory language it now invokes. The Ninth Circuit summarily rejected the argument, and United's attempt at a second bite at the apple similarly should be rejected. *See Swoben*, 848 F.3d at 1179.

Third, United's argument that diagnosis code data may be submitted by United with invalid codes just as data submitted by treating physicians to CMS may contain invalid codes is inconsistent with United's own conduct. United has admitted that it modified provider-reported diagnosis data for years by performing millions of its own reviews of its beneficiaries' medical records in order to submit hundreds of thousands of diagnosis codes that the providers did not report. With this history, United cannot now

legitimately contend that provider-reported diagnosis data cannot be modified without violating actuarial equivalency or conflicting with the manner in which payment amounts were set by the agency. United's position that the principle works in only one direction, and permits United to submit additional codes (purportedly because they are supported by the beneficiaries' medical records based on its medical record reviews) but does not permit the government to require the deletion of unsupported diagnoses (based on the results of the same medical record reviews), is transparently self-serving and logically untenable.

Fourth, United's interpretation of the statutory term "actuarial equivalence" is unreasonable and unsupported. This reference in the Medicare Statute was intended to give CMS broad discretion to determine how to make risk adjusted payments to MAOs in the MA Program; it was not intended to entitle individual MAOs to payments based on erroneous diagnosis data. For these reasons, the Court should grant this motion.

II. BACKGROUND

A. Medicare Parts A, B, and C

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, administered by CMS. Medicare Part A "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). 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. *Id.* at 2 (citing 42 U.S.C. §§ 1395j to 1395w-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 MAOs. *See* 42 U.S.C. §§ 1395w-21 to 1395w-29. MAOs "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 (HHS), *see* 42 U.S.C. § 1395w-22(a)(3)." *Matthews v. Leavitt*, 452 F.3d 145, 146 n.1 (2d Cir. 2006). 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. *See, e.g.* Medicare Advantage Contract between United Healthcare of California and CMS ("MA Contract"), 2011, Article IV, CMS Payment to MA Organization (Exhibit 1).[3]

Under Parts A and B, CMS pays providers directly for medical services rendered to beneficiaries under a "fee-for-service" regime. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994). 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 based on that beneficiary's risk score. 42 U.S.C. § 1395w-23(a)(1)(A). 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." *Id.* § 1395w-23(a)(1)(C)(i). 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). MAOs thus receive more for providing benefits to older and sicker people, and less for younger and healthier ones. Adjusting the monthly payments based on risk

[3] Exhibit 1 is the Part C and D MA Contract for calendar year 2011 between United's California MAO and CMS. *See* Rice Decl., ¶ 2. It consists of the following parts: the Part C contract; the Part D Addendum; the Attestation of Benefit Plan, identifying the Plan Benefit Packages; and the Signature Attestation page, *Id.* Thomas Paul executed all parts of this agreement for the California MAO in his capacity as Chief Executive Officer of UnitedHealthcare Medicare & Retirement, which is a group within Defendant UnitedHealthcare, Inc. *Id.* The terms of the contract referenced in this brief for calendar year 2011 and included in Exhibit 1 are the same as those in the contracts for the other calendar years at issue in this case, 2009 to 2010 and 2012 to 2017, and for the other Defendant MAOs. *Id.* The contract terms did not change because the regulations governing the terms and conditions of the contracts did not change. *See* 42 C.F.R. § 422.504 (Part C); 42 C.F.R. §§ 423.504, 423.505 (Part D).

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. *Id.*

B. The Risk Adjustment Payment System

When Congress established Part C, it 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." *Id.* § 1395w-23(a)(3)(C)(i).[4] 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. Since 2004, the Secretary has used the Hierarchical Condition Category (HCC) model to determine these amounts under Part C. The Secretary has used a similar model (the RxHCC model) to risk adjust for health status under Part D. *See* 42 C.F.R. § 423.329(b)(1), (2). 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. The model includes a set of multipliers – that is, "coefficients" – used to determine "the marginal (additional) cost" of each medical "condition or demographic factor (*e.g.*, age/sex group, Medicaid status, disability status)." Medicare Managed Care Manual, Pub. 100-16, Chapter 7, § 70.1 (June 7, 2013) (Exhibit 5). 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. *See* 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). For each Part C beneficiary, the multipliers are added to form a "risk score" and then computed against

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

the negotiated base (fixed) monthly rate to determine how much CMS will pay an MAO for insuring that beneficiary.[5]

MAOs submit diagnosis codes to CMS so the agency can apply the multipliers for each beneficiary's health status. Since 2004, they have submitted the codes through CMS's Risk Adjustment Processing System ("RAPS"). In the last several years, they submit the codes through RAPS and CMS' Encounter Data System ("EDS"). 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. *See, e.g.*, 2013 Medicare Managed Care Manual, Pub. 100-16, chapter 7 at § 120.2.3 (Exhibit 5). 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. *Id*. A diagnosis that has been deleted in RAPS will, of course, not cause an increase in the risk score or risk adjusted payment that otherwise would have been based on the deleted diagnosis code. 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 its payments as part of a routine process. EDS works

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[5] 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 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 40,268 (explaining that the diagnosis data is a claim for payment); *see generally* Defendants' Memorandum in Support of Their Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment in APA case, Dkt. 57-1, at 14-16 (Exhibit 13).

much the same way with respect to the deletion of invalid diagnosis codes. *See* CMS 2012 Regional Technical Assistance Participant Guide, Encounter Data, at 3-32 to 3-33 (Exhibit 8).

C. Part C and D Payment Data Integrity Requirements and Obligations

MAOs have a financial incentive to submit as many risk-adjusting diagnoses as possible to generate as much payment as possible. 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. 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. *See* 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"); *see also* 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). One of the most fundamental data integrity requirements is that diagnoses must be substantiated by the beneficiaries' medical records to be valid and one of the most important payment integrity obligations is that MAOs and their related entities and contractors withdraw diagnoses that they know are invalid based on information available to them.

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. § 422.504 (Part C); 42 C.F.R. §§ 423.504, 423.505 (Part D). 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. *See, e.g.*, Signature Attestation page at the end of Exhibit 1.

During the payment years at issue in this case,[6] 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. *See, e.g.*, Section A of Article II and Section A(1) of Article IX of the Part C contract, which is part of Exhibit 1.[7] The contracts also required defendants to implement an effective compliance program in accordance with the Part C and D compliance regulations. *See, e.g.*, Section F of Art. III of the MA Contract and Section J of Art. II of the Part D Addendum, also part of Exhibit 1. 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. *Swoben*, 848 F.3d at 1174 (citing 42 C.F.R. § 422.503(b)(4)(vi), (vi)(F), (vi)(G) (2005)); *see also* 42 C.F.R., § 423.504(b)(4)(vi), (vi)(F), (vi)(G) (2007) (Part D compliance regulation setting forth same requirements). 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); s*ee also* 42 C.F.R. § 423.504(b)(4)(vi)(G)(2) (Part D) (same). 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. *See, e.g.*, 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

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[6] This action seeks damages for payment years 2009-17. Defendants, however, continue to refrain from correcting invalid diagnoses revealed by their chart reviews. The United States reserves its rights to recover damages for payment years after 2017.

[7] 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.

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").

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. *See* Section D.2 of Article IV of the MA Contract (Exhibit 1).[8] 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). *Id.* Importantly, this contractual and regulatory attestation requirement imposed affirmative duties on the MAOs and their related entities and contractors. 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. *Swoben*, 848 F.3d at 1174 (citing 65 Fed. Reg. at 40,268); *see also* 2004 Manual (Exhibit 4), § 111.7 (discussing this requirement). Thus, MAOs and their related 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 take because of the attestation requirement is to correct or withdraw erroneous data. *Id.* at 1174.

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

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[8] 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).

every version of the Manual since at least 2001. *See, e.g.*, 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"). The Manual, in accordance with federal regulation, also has long specified that diagnoses be coded according to *International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting* and the ICD Guidelines have long specified that the medical record must substantiate the diagnosis coding. *See, e.g.*, 2013 Manual § 40 (Exhibit 5); *see also* 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). 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," ICD-9-CM Preface at 1, 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, at 5 (Exhibit 10) (explaining "[t]he importance of consistent, complete documentation in the medical record," without which accurate diagnosis coding "is a difficult, if not impossible, task"). The Tenth Edition of the ICD Guidelines does the same. ICD-10-CM Official Guidelines for Coding and Reporting FY 2018, at 1 (Exhibit 11) ("importance of consistent, complete documentation in the medical record cannot be overemphasized").

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)." *See* Section B.7 of Art. VI and Section B.1(a)(vii) of Article VIII of the MA Contract.[9] One of the requirements of § 422.310 (a Part C regulation) pertains to the "[v]alidation of risk adjustment data." It also establishes the medical record as the source for determining the validity of risk adjustment data: "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. There may be penalties for submission of false data." 42 C.F.R. § 422.310(e).[10] 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). 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]." *See, e.g.*, Section A.2(b), (d) of Article VI of the MA Contract (Exhibit 1).

During the relevant time period, the United Defendants were also bound by the terms and conditions of Electronic Data Interchange ("EDI") agreements. 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, including diagnoses, to CMS' RAPS and EDS and to receive payments. *See, e.g.*, Electronic Data Interchange Agreement between

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[9] 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).

[10] 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.

United and CMS (Exhibit 2),[11] *see also* 2004 Manual (Exhibit 4), § 111.6.1 (discussing this requirement). Pursuant to the EDI agreements, the defendant MAOs and Optum (and its predecessor, Ingenix) agreed that they were responsible for all risk adjustment data submitted by themselves, their employees, and agents and that "[b]ased on best knowledge, information, and belief, [they would] submit risk adjustment data that are accurate, complete, and truthful." *Id*. at Sections A.1 and 5. Moreover, they agreed to "correct risk adjustment data discrepancies." *Id*. at Section A.11. Of equal significance, pursuant to the EDI agreements, they also agreed that the government had the 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. *Id*. at Section A.4. Thus, the EDI Agreements also established the medical records as the "source of truth" for validating diagnosis data and Defendants' entitlement to payments.

III. ARGUMENT

In this action under the False Claims Act, 31 U.S.C. §§3729-3733 ("FCA"), the United States seeks to recover Medicare funds improperly retained by United. The United States alleges first that, over the past decade, United reviewed millions of its beneficiaries' medical records looking for diagnoses that its providers had not reported so that it could submit additional codes to CMS and thereby obtain increased payments from Medicare. Second, the United States alleges that during the course of its reviews seeking additional diagnosis codes to submit, United identified diagnoses that had improperly been submitted because they were not supported by its beneficiaries' medical records. Third, the government contends that United was obligated to delete these unsubstantiated codes from its previous RAPS and EDS submissions to CMS, and that by failing to delete those codes, United improperly retained the increased payments

[11] Exhibit 2 is a United EDI Agreement dated May 10, 2011, but is substantially similar to other EDI agreements with CMS during 2004 to 2017. *See* Rice Decl., ¶ 3.

based on the invalid diagnoses. This third contention, which involves strictly a legal question, is the subject of this motion and its resolution at this stage will help streamline the case, including the scope of discovery.

A. Partial Summary Judgment on Defendants' Obligation to Correct Known Coding Errors Will Facilitate the Just and Efficient Resolution of This Action

Rule 1 of the Federal Rules of Civil Procedure provides that the federal rules should be construed to secure a "just, speedy, and inexpensive determination of every action." Contentions or defenses lacking either merit or relevance should not be the basis for unnecessary discovery nor allowed to consume the time and resources of the Court or parties. A party may file a motion for summary judgment "at any time until 30 days after the close of all discovery." Fed. R. Civ. P. 56(b). While, in some cases, a summary judgment motion may properly await some amount of discovery, where, as here, the legal issues are clear, partial summary judgment can and should be granted, even before discovery has been completed. *See, e.g.*, *Parra v. Wright*, 2013 WL 6669235, at *7 (W.D.N.Y. Dec. 18, 2013) (granting pre-discovery summary judgment motion where "the legal principles are clear").

Partial summary judgment is appropriate to resolve purely legal questions. *See In Re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 284, 288 (D. Mass. 2006) (granting partial summary judgment on meaning of statutory phrase "average wholesale price" under "plain language canon of statutory construction"); *see also* 10A C. Wright, A. Miller, & M. Kane, Fed. Practice and Procedure § 2725 at 416 (4d ed. 2016) ("when the only issues to be decided in the case are issues of law, summary judgment may be granted"); *id*. at 422-23 ("fact that difficult questions of law exist or that the parties differ on the legal conclusions to be drawn from the facts is not in and of itself a ground for denying summary judgment in as much as refusing to grant the motion does not obviate the court's obligation to make a difficult decision") (footnotes omitted).

The Court should enter partial summary judgment here and hold that United was and is legally obligated to delete those diagnosis codes revealed by its own medical record reviews to be unsubstantiated. This issue should be laid to rest now so that it is not used to divert and waste the resources of the parties or the Court, which will otherwise be called upon to decide discovery disputes and other motions related to this issue. Indeed, United has made this issue the centerpiece of a Counterclaim against the United States as well as serving extensive written discovery and demanding the production of countless documents that it contends relate to its purported "actuarial equivalence" argument. Letter from Abid R. Qureshi, at 4 (Nov. 7, 2017) (Exhibit 15).

B. An MAO's Obligation to Delete Errors it Identified in Its Coding is Determined as a Matter of Law

Having been caught improperly pocketing Medicare funds based on invalid diagnoses, United now contends that it was legally entitled to ignore requirements in its contracts and regulations that "medical diagnosis codes … be supported by a medical record." *Swoben*, 848 F.3d at 1176. Among the various arguments alluded to by United in support of this position, United has most consistently relied on the notion that the express requirement of accurate diagnosis coding is purportedly in tension with the governing statute's reference to "actuarial equivalence." *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).[12] United contends that "actuarial equivalence" trumps the longstanding contractual and regulatory requirement that diagnosis codes be substantiated by its beneficiaries' medical records, and therefore, United could disregard the medical record requirement even when its own chart reviews revealed that diagnosis codes were unsupported. *See, e.g.*, Amended Joint Rule 26(f) Report at (Dkt. 224) at 12 ("United's

[12] This subsection reads follows: "Subject to subparagraph (I), the Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Position: . . . Congress has required CMS to use the "same methodology" to determine payment amounts in the MA program . . . and has directed CMS to "ensure actuarial equivalence" between the two programs . . . . In light of those statutory requirements, UnitedHealth believes that CMS cannot require MA plans to use a different approach to the diagnosis codes they submit than the one CMS itself uses, such as by requiring MA plans to delete all unsupported codes, unless CMS also provides a means of adjusting for the different methodologies." (Citations omitted).[13]

United's actuarial and data equivalence arguments fail as a matter of law and are not a defense to liability in this FCA action. First, these arguments violate not just regulatory, but also contractual provisions with which Defendants expressly promised compliance. United, when submitting claims for Medicare funds, cannot agree to comply with applicable payment requirements and then unilaterally declare those same requirements void. Second, the Ninth Circuit already rejected essentially the same arguments in *Swoben*. Third, the data equivalency argument cannot be applied where United reviewed medical records to add additional diagnosis codes not reported by providers. United contends that an actuarial principle mandates that provider-reported health status information, *i.e.*, diagnosis codes, should not be subject to further medical record review or verification – yet United did precisely that when it added codes based on its own chart reviews. Fourth, as the government has explained at length in briefs filed in the APA case brought by United challenging a MA overpayment regulation, *United Healthcare Ins. Co. v. Hargan*, No. CV 16-00157-RMC (D.D.C. filed Jan. 29, 2016) ("APA case"), United's construction of "actuarial equivalence" in 42 U.S.C. § 1395w-23(a)(1)(C)(i) lacks merit. The agency's interpretation of this term is reasonable and consistent with the language and intent of the statute.

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[13] United incorrectly states that the contractual and regulatory dispute in this FCA case is about an obligation to "attempt to delete *all* unsupported diagnostic codes submitted to them by providers . . . ." Amended Joint Rule 26(f) Report at 11 (emphasis added). That statement mischaracterizes Defendants' obligation and the theory of this FCA case. *See Swoben*, 848 F.3d at 1173 -74. This FCA case is about those diagnosis codes that United identified as unsupported yet nonetheless failed to delete.

1. United's Post Hoc Arguments Do Not Excuse Its Violation of Express Contract Terms

United's MA Contracts (including the Managed Care Manual and MA regulations expressly incorporated into the contracts) and the EDI agreements all establish the medical record as the "source of truth" for determining entitlement to risk adjustment payments. *See* discussion at pp. 8-13, *supra*. United acknowledged the requirement that diagnoses must be validated by the medical records in its brief to the Ninth Circuit in *Swoben*. *See* Joint Answering Brief, *United States ex rel. Swoben v. United Healthcare Ins. Co.*, No. 13-56746, Dkt. 39, at 36 (9th Cir. filed June 2, 2014) (Exhibit 9) ("CMS regulations deem a diagnosis code proper if it is supported by a . . . medical record"). The compliance and attestation requirements and the EDI agreements also established the obligation to delete invalid diagnoses. The 2013 Manual reiterated this obligation. *See* 2013 Manual (Exhibit 5), § 40.

If United disagreed with its regulatory and contractual obligation to delete codes known to be unsupported by its beneficiaries' medical records or if United thought it would be underpaid if it complied with the longstanding medical record requirement, it was free to forego participation in a program governed by terms it found objectionable. But United cannot agree to these regulatory and contractual requirements and then simply ignore them. Acceptance of United's contention – that it may violate contract and regulatory requirements it agreed to honor and then litigate its program-level grievance only when its misconduct is exposed in an FCA matter – would create a perverse incentive for a range of entities participating in the Program. Such entities would claim payment from the federal government by promising compliance with contractual and regulatory obligations and then violate those obligations in order to enhance profits with the intention that the violation either goes unnoticed or, if it is exposed, they can then assert a legal challenge to the requirements to which they had expressly agreed. *Accord City and County of San Francisco v. Tutor-Saliba Corp.*, 2005 WL 645389, at *8 (N.D. Cal. 2005) (rejecting argument in state FCA case that

"allegedly fraudulent conduct should be excused because part of the contract [in which fraud occurred] is invalid" and that "invalid portion of the contract is no excuse for fraudulent behavior"); *see also Bryson v. United States*, 396 U.S. 64, 68 (1969) ("One who elects [fraud] as a means of self-help may not escape the consequences by urging that his conduct be excused because the statute which he sought to evade is [invalid].") (quoting *Dennis v. United States*, 384 U.S. 855, 867 (1966)); *Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 769 (9th Cir. 1997) (purported "invalidity" of payment rule held "no defense" to submission of false claims in violation of challenged rule) (citing *Bryson*); *United States v. Weiss*, 914 F.2d 1514, 1522-23 (2d Cir.1990) (holding that the fact that a Medicare Manual provision requiring filing of statements had not undergone statutorily-required approval procedures was no defense to charge of false statements).

United executed part C and D contracts year after year agreeing to comply with express requirements that diagnoses be supported by the enrollees' medical records. United scoured medical records for additional diagnoses to submit for increased payments by CMS, but refrained from deleting diagnosis codes that it knew were unsupported based on those same record reviews. Having knowingly violated the medical record requirements with which it contractually agreed to comply, United cannot now raise grievances about the contract terms in this FCA case.

2. The Ninth Circuit Has Already Rejected United's Data Equivalency Argument

United previously challenged the medical record requirement in *Swoben*. 848 F.3d at 1179. In that case, instead of relying on the statutory term "actuarial equivalence," United pointed to a regulation which requires that MAOs "must submit data that conform to CMS' requirements for *data equivalent* to Medicare fee-for-service data." *Id.* (citing 42 C.F.R. § 422.310(d)) (emphasis supplied). United argued that this data equivalency requirement was somehow inconsistent with the requirement that diagnoses be supported by the medical record and therefore excused its knowing submission of erroneous diagnosis codes. The Ninth Circuit not only rejected this

argument on the merits, but concluded that it did not provide a defense to the defendants' FCA liability in light of their bad faith in conducting chart reviews.

The Ninth Circuit's reasoning applies with equal force to United's similar actuarial equivalence argument here. In *Swoben*, the Ninth Circuit rejected United's data equivalence argument, holding that "because nothing in § 422.310(d) speaks to [an MAO's] obligations to ensure the accuracy of risk adjustment data, it does not modify [an MAO's] obligations under §§ 422.503(b)(4)(vi) and 422.504(l)." *Id*. at 1179. The appellate court explained that under these sections and others, CMS had made "clear" that MAOs "have always had 'an obligation to undertake steps to ensure the accuracy, completeness and truthfulness of encounter data'" submitted to CMS. *Id*. at 1174.

There is no significant difference between United's current legal argument based on the term "actuarial equivalence" and its previous one based on "data equivalence." Neither the statute nor the regulation alters United's obligation to delete invalid diagnosis codes. The provision United relies on here, 42 U.S.C. § 1395w-23(a)(1)(C)(i), merely directs the Secretary to "adjust the . . . amount" of the Part C payments 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." *Id*. Just like section 422.310(d), as the Ninth Circuit held, does not modify United's other regulatory obligations requiring the submission of valid data and deletion of invalid data, the statute does not give United any right to submit invalid diagnosis codes or to refrain from deleting them.

The Ninth Circuit also found United's data equivalency argument inapposite in light of the conduct alleged by Swoben concerning United's chart reviews. In *Swoben*, United had noted that diagnostic codes are, in the first instance, determined by the healthcare providers who treat the beneficiaries, and argued that there was no "authority indicat[ing] that a [MAO] was obligated to undertake affirmative steps to unearth potentially unsupported codes . . . ." *Swoben*, 848 F.3d at 1173. The Ninth Circuit

found that this argument entirely missed the mark: "Defendants' attempts to portray themselves as the passive victims of their providers' errors wholly misstates Swoben's legal theory, which focuses on the defendant's own conduct in allegedly conceiving, directing and conducting retrospective reviews designed to identify only favorable coding errors." *Id*. at 1174. After considering, first, whether Part C regulations on their face, supported United's defense, the appellate court added that, "[s]econd, this is not a case about whether [MAOs] have to *take* affirmative steps to verify risk adjustment data. [United] indisputably took such steps by conducting retrospect chart reviews." *Id.* at 1179 (emphasis in original). Importantly, it then added that, when an MAO adopts "affirmative verification procedures, [they] have to conduct them in good faith." *Id.*

The Ninth Circuit's unequivocal rejection of United's data equivalence argument does not leave room for United's argument that actuarial equivalence, as it relates to risk adjusted payments, entitles it to payment for unsupported diagnoses or would allow United to disregard its obligation to correct diagnostic data it knows to be invalid. United's attempt to resurrect and rename its "data equivalence" argument, which is plainly at odds with the Ninth Circuit's decision, should be similarly rejected.

3. United's Data Equivalency Argument Cannot be Applied in a Case in Which United Reviewed and Edited Provider Data

As in *Swoben*, in this case, United's role with respect to diagnosis codes was *not* that of a passive conduit of data supplied by healthcare providers. Like *Swoben*, this action focuses on "defendant's own conduct in allegedly conceiving, directing and conducting retrospective reviews designed to identify only favorable coding errors." *Id*. at 1174. By conducting its own chart reviews and using them to add diagnosis codes, United deprived itself of any plausible actuarial equivalence argument in this case.

In the APA case, United has described its actuarial equivalence argument as follows: because CMS uses unaudited claims data from healthcare providers under Medicare Parts A and B to establish the coefficients for the condition categories assigned to beneficiaries enrolled in Part C, CMS may use only unverified RAPs data when

determining the risk score for each Part C beneficiary and the amount of the monthly risk-adjusted payment for that beneficiary. *See* Memorandum in Support of United's Motion for Summary Judgment in APA case (Dkt. 47-1), at 1-2, 21-22 (Exhibit 12). In other words, United contends that because diagnostic information in the Part A and B claims data is *not verified* by CMS when used to establish the coefficients for determining risk scores, invalid diagnoses reported by providers to MAOs for Part C and D beneficiaries can be submitted for payment *and* cannot be deleted even when the MAOs own chart reviews show that the diagnoses are invalid. *Id.* at 21-22. According to United, correcting erroneous Parts C and D diagnosis data based on the results of medical record reviews contravenes "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." *See* United's Opp. To Govt. Motion for Summary Judgment in APA case (Dkt. 60), at 18 (Exhibit 14).

United, however, violated the very principle it relies upon. United's role with respect to diagnosis codes was *not* that of a passive conduit of data supplied by healthcare providers. Even assuming United's actuarial equivalence argument had any merit – which it does not – United's own conduct makes application of that principle impossible with respect to the diagnostic data that is the subject of this case. By conducting chart reviews and *adding* diagnosis data (which increased its beneficiaries' risk scores) based on those reviews, United tampered with – *i.e.*, *verified* – the provider-reported diagnosis data and created the very data inconsistencies that it contends are illegitimate and preclude it from being required to delete unsubstantiated diagnoses.

In reality, what defendants propose is that United may review and edit data submitted by providers in order *to add* unreported diagnoses that are purportedly supported by their beneficiaries medical records, but United cannot be required *to delete* invalid diagnoses codes reported to CMS – even when it is United's own chart reviews that reveal that those codes are unsubstantiated and, thus, invalid. Such a one-sided view of actuarial equivalence defies reason and common sense and should be rejected by this

court as a matter of law.

4. Well-Established Principles of Statutory Construction Preclude United's Tortured Interpretation of 42 U.S.C. § 1395w-23(a)(1)(C)(i)

For any of the preceding reasons, the Court should reject United's actuarial equivalence argument without having to construe the term as it applies to risk adjustment under Part C. However, United's wholly unreasonable construction of the statute can also be summarily rejected. In construing a statute, courts "first evaluate whether the meaning of the statute is plain and unambiguous and, therefore controlling." *Arizona State Bd. For Charter Schs. v. U.S. Dept. of Educ.*, 464 F.3d 1003, 1007 (9th Cir. 2006). The starting point is to "engage in a textual analysis of the relevant statutory provisions and to read the words of a statute in their context and with a view to their place in the overall statutory scheme." *Id.* "Statutory interpretations which would produce absurd results are to be avoided." *Id.* at 1008 (quoting *Ma v. Ashcroft*, 361 F.3d 553, 558 (9th Cir. 2004)). "When a natural reading of the statutes leads to a rational, common-sense result, an alteration of meaning is not only unnecessary, but also extrajudicial." *Id*.

The Medicare statute directs that the Secretary of HHS "adjust the . . . amount" of the monthly payments to MAOs 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 phrase that is used 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) (construing a Federal Energy Regulatory Commission rule). The language of 42 U.S.C. § 1395w-23(a)(1)(C)(i) is discretionary because it allows the Secretary to take into account "such other [risk] factors as the Secretary determines to be appropriate" and says that he "may add to, modify, or substitute for such adjustment factors if such changes will improve the

determination of actuarial equivalence." Similar language has also been understood to be discretionary. *See United Food and Commercial Workers Union, Local 1036 v. NLRB*, 307 F.3d 760, 770-72 (9th Cir. 1986) (rejecting that "statutory equivalence" means "identical" and stating, "[t]he practical effect of the nonmembers' argument would be to deprive the NLRB of its jurisdiction to make factual determinations").[14]

The MA risk adjustment model (*i.e.*, the HCC model) is designed to satisfy the actuarial equivalence provision by paying MAOs a sum commensurate with the expected cost of providing traditional Medicare benefits to a given beneficiary. And 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. This construction leaves no room for United's argument that it was free to disregard the medical record requirements of CMS's risk adjustment system – the implementation of which, by statute, falls within the Secretary's discretion – and reconfigure it in a way that permits United to ignore the medical record requirement and knowingly retain payment for unsupported diagnoses.

United's APA case contends that the per-beneficiary payments calculated by the Secretary systematically underestimate the costs associated with any given disease. United claims that the system can nonetheless function properly, because insurers regularly claim payments for diagnoses that are not substantiated by the beneficiaries' medical records, 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

[14] Such language has also been held to be procedural only and not a basis for creating substantive rights. *See Rhoades, McKee & Boer v. United States*, 43 F.3d 1071, 1075 (6th Cir. 1995) (26 U.S.C. § 412(c)(3)'s "best estimate" requirement is "procedural only," does not place a "substantive" requirement on actuarial assumptions); *Wachtell, Lipton, Rosen & Katz v. Comm'r*, 26 F.3d 291, 296 (2d Cir. 1994) (§ 412(c)(3)'s "best estimate" requirement is procedural only and "factoring in a discount for conservatism after an actuary has [already] arrived at his or her best estimate of anticipated experience would be contrary to the statutory mandate"); *Vinson & Elkins v. Comm'r*, 7 F.3d 1235, 1238 (5th Cir. 1993) (stating that Congress "intended to give actuaries some leeway and freedom from second-guessing" and that it was inappropriate for anyone to "substitute his judgment . . . for that of a qualified actuary").

question. United argues that it is therefore unlawful for the Secretary to limit insurers to claiming payment for the medical conditions that are actually substantiated by their beneficiaries' medical records. If MAOs are not allowed to submit diagnoses not reflected in any medical record, the argument goes, they may 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.

United's interpretation of "actuarial equivalence" would lead to absurd results. Its argument – that it is legally entitled to retain payments for conditions it knows are not substantiated by its beneficiaries' medical records – is utterly at odds with the regulatory and contractual regime that has been in place in the MA Program for the last two decades and is untenable given the Ninth Circuit's unequivocal holding that MAOs "have an obligation to undertake 'due diligence' to ensure the accuracy . . . and truthfulness" of the risk adjustment data "submitted to [CMS]" for Medicare payments. *Swoben*, 848 F.3d at 1169 (quoting 2000 Rule, 65 Fed. Reg. at 40,268). Nothing exempts United from compliance with this obligation. Congress has never embraced the notion of Medicare payments based on invalid data. This Court should not imply such an absurd notion from the term "actuarial equivalence."

In sum, there is nothing in the statute or its legislative history that supports the notion that United could engage in an *ad hoc* restructuring of the legal obligations established by the Secretary and set out in Part C and D contracts and regulations. Nor does the statute or legislative history support the notion that United was entitled to ignore the longstanding medical documentation requirement and submit a certain percentage – of its own choosing – of invalid diagnoses as compensation for purported imperfections in the multipliers for the HCC model and the amount of the risk- adjusted payments. The Court should, as a matter of law, reject United's actuarial equivalence argument as an after-the-fact attempt to justify its fraudulent conduct based on a tortured reading of a statutory phrase.

IV. CONCLUSION

For the foregoing reasons, the United States and Relator respectfully request that the Court grant this motion.

Respectfully submitted,

Dated: May 22, 2018

CHAD A. READLER
Acting Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
Assistant United States Attorneys

MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Civil Division, Department of Justice

JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney

/S/ John E. Lee

JOHN E. LEE, AUSA
Attorneys for the United States of America

Dated: May 22, 2018

ERIC R. HAVIAN
HARRY LITMAN
JESSICA MOORE
Constantine Cannon LLP

STEVE HASEGAWA
Phillips & Cohen LLP

WILLIAM CHRISTOPHER CARMODY
ARUN SUBRAMANIAN
MATTHEW R. BERRY
JOHN P. LAHAD
MENG XI
Susman Godfrey LLP

/S/ Henry C. Su

HENRY C. SU
Attorneys for Relator Beniamin Poehling

Attestation

I hereby attest that the other signatory listed, on whose behalf the filing is submitted, concurs in the filing's content and has authorized the filing.

Dated: May 22, 2018

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney

CHAD A. READLER
Acting Assistant Attorney General, Civil Division
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
JOHN E. LEE (CBN 128696)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; (Fax: (716) 551-3052
Email: 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.* BENJAMIN POEHLING, Plaintiffs, v. UNITEDHEALTH GROUP, INC., *et al.*, Defendants.	No. CV 16-08697 MWF (SSx) DECLARATION OF CHERI RICE IN SUPPORT OF UNITED STATES' AND RELATOR POEHLING'S JOINT MOTION FOR PARTIAL SUMMARY JUDGMENT; EXHIBITS Date: July 30, 2018 Time: 10:00 a.m. Court: 5A. Hon. Michael W. Fitzgerald

Additional Attorneys (continued from previous page):

ERIC R. HAVIAN (CBN 102295)
ehavian@constantinecannon.com
HARRY LITMAN (CBN 127202)
hlitman@constantinecannon.com
JESSICA T. MOORE (CBN 183431)
jmoore@constantinecannon.com
HENRY C. SU (CBN 211202)
hsu@constantinecannon.com
Constantine Cannon LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Facsimile: (415) 639-4002

STEPHEN HASEGAWA (CBN 198472)
shasegawa@phillipsandcohen.com
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Facsimile: (415) 836-9001

WILLIAM CHRISTOPHER CARMODY (*pro hac vice*)
wcarmody@susmangodfrey.com
ARUN SUBRAMANIAN (*pro hac vice*)
asubramanian@susmangodfrey.com
GENG CHEN (*pro hac vice*)
gchen@susmangodfrey.com
Susman Godfrey L.L.P.
1301 Avenue of the Americas, 32nd Floor
New York, New York 10019-6023
Tel: (212) 336-8330
Facsimile: (212) 336-8340

MENG XI (CBN 280099)
mxi@susmangodfrey.com
CATRIONA LAVERY (CBN 310546)
clavery@susmangodfrey.com
Susman Godfrey L.L.P.
1900 Avenue of the Stars, Suite 1400
Los Angeles, California 90067
Tel: (310) 789-3100
Facsimile: (310) 789-3100

Attorneys for Relator Benjamin Poehling

DECLARATION OF CHERI RICE

I, Cheri Rice, declare:

1. I am the Acting Deputy Director, Parts C and D, of the Centers for Medicare and Medicaid Services ("CMS"), an agency of the United States Department of Health and Human Services. As Acting Deputy, I have responsibility for the Medicare Advantage ("MA") and Medicare Prescription Drug ("PD") Programs. This includes oversight responsibility, operations, and policy development for the MA and PD plans that provide coverage to over 40 million Medicare beneficiaries. I have been employed with CMS for approximately 14 years and am familiar with CMS's records relating to Parts C and D of the Medicare Program. I have personal knowledge of the matters set forth herein and, if called to testify, could and would testify competently thereto.

2. Attached hereto as Exhibit 1 is a true and correct copy of the Part C and D contract between CMS and UnitedHealthcare of California, a MA Organization, for calendar year 2011. Exhibit 1 consists of the following parts: the Part C contract; the Part D Addendum; the Attestation of Benefit Plan, identifying the Plan Benefit Packages; and the Signature Attestation page. Thomas Paul executed all parts of this contract for UnitedHealthcare of California in his capacity as Chief Executive Officer of UnitedHealthcare Medicare & Retirement, which is a group within Defendant UnitedHealthcare, Inc. The terms of the contract referenced in Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Partial Summary Judgment for calendar year 2011 and included in Exhibit 1 are the same as those in UnitedHealthcare of California's contracts for the other calendar years at issue in this case, 2009 to 2010 and 2012 to 2017. These contract terms did not change because the regulations governing these terms of the contracts did not change. *See* 42 C.F.R. §§ 422.503, 422.504 (Part C); 42 C.F.R. §§ 423.504, 423.505 (Part D).

3. The terms of the contact referenced in Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Partial Summary Judgment for calendar year

2011 and included in Exhibit 1 are the same as those in the contracts between all other Defendant MA Organizations and CMS for calendar years 2009 to 2017. These contract terms did not differ for individual MA Organizations because they were governed by the Part C and D regulations. *See* 42 C.F.R. §§ 422.503, 422.504 (Part C); 42 C.F.R. §§ 423.504, 423.505 (Part D).

3. Attached hereto as Exhibit 2 is a true and correct copy of the Electronic Data Interchange (EDI) Agreement Form between CMS and OptumInsight and its related entities, dated May 10, 2011. During the time period relevant to this matter, MA Organizations and entities that submit risk adjustment data on their behalf have been required to execute EDI agreements in order to submit risk adjustment data to CMS' Risk Adjustment Payment System ("RAPS") and Encounter Data System ("EDS"). The terms of the EDI agreement referenced in Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Partial Summary Judgment and included in Exhibit 2 are the same to those in all other EDI agreements during the time period relevant to this matter, 2009 to 2017. These terms have not changed during this time period.

4. Attached hereto as Exhibit 3 is a true and correct copy of the Medicare Managed Care Manual, Chapter 7, §§ 110.3 and 110.4 (July 2, 2001).

5. Attached hereto as Exhibit 4 is a true and correct copy of the Medicare Managed Care Manual, Chapter 7, § 111 and Exhibit 30 (Aug. 13, 2004).

6. Attached hereto as Exhibit 5 is a true and correct copy of the Medicare Managed Care Manual, Pub. 100-16, Chapter 7, §§ 40, 70.1, and 120.2.3 (June 7, 2013).

7. Attached hereto as Exhibit 6 is a true and correct copy of the 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).

8. Attached hereto as Exhibit 7 is a true and correct copy of the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and

Medicare Advantage and Part D Payment Policies and Final Call Letter, Table 1, at 67-70.

9. Attached hereto ax Exhibit 8 is a true and correct copy of the CMS 2012 Regional Technical Assistance Participant Guide, Encounter Data, at 3-32 to 3-33.

10. Exhibits 1-8, inclusive, are documents that are recorded or filed within CMS offices as authorized by law. They are also public records or statements from CMS, where items of this kind are kept.

11. Exhibits 1-8, inclusive, are records of CMS's regularly conducted activities that were made at or near the time by, or from information transmitted by, someone with knowledge; the records were kept in the course of a regularly conducted activity of CMS; and the making of this record was a regular practice of that activity.

12. Exhibits 1-8, inclusive, are also records or statements of CMS that set out the office's activities as authorized by law.

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

Executed on May 21, 2018 at Baltimore, Maryland.

Cheri Rice

CHERI RICE

CONTRACT WITH ELIGIBLE MEDICARE ADVANTAGE (MA) ORGANIZATION PURSUANT TO SECTIONS 1851 THROUGH 1859 OF THE SOCIAL SECURITY ACT FOR THE OPERATION OF A MEDICARE ADVANTAGE COORDINATED CARE PLAN(S)

CONTRACT (H0543)

Between

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

and

UNITEDHEALTHCARE OF CALIFORNIA
(hereinafter referred to as the MA Organization)

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

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

Article I
Term of Contract

The term of this contract shall be from the date of signature by CMS authorized representative through December 31, 2011, after which this contract may be renewed for successive one-year periods in accordance with 42 CFR 422.505(c) and as discussed in Paragraph A in Article VII below. **[422.505]**

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

Article II
Coordinated Care Plan

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

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

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

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

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

Article III
Functions To Be Performed By Medicare Advantage Organization

A. PROVISION OF BENEFITS

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

2. The MA Organization agrees to provide post-hospital extended care services, should an MA enrollee elect such coverage, through a skilled nursing home facility according to the requirements of section 1852(l) of the Act and §422.133. A skilled nursing home facility is a facility in which an MA enrollee resided at the time of admission to the hospital, a facility that provides services through a continuing care retirement community, a facility in which the spouse of the enrollee is residing at the time of the enrollees discharge from the hospital, or hospital, or wherever the enrollee resides immediately before admission for extended care services. **[422. 133; 422.504(a)(3)]**

B. ENROLLMENT REQUIREMENTS

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

2. The MA Organization shall comply with the provisions of §422.110 concerning prohibitions against discrimination in beneficiary enrollment, other than in enrolling eligible beneficiaries in a CMA-approved special needs plan that exclusively enrolls special needs individuals as consistent with §§422.2, 422.4(a)(1)(iv) and 422.52. **[422.504(a)(2)]**

C. BENEFICIARY PROTECTIONS

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

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

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

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

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

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

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

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

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

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

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

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

D. PROVIDER PROTECTIONS

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

2. Prompt Payment.

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

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

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

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

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

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

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

E. QUALITY IMPROVEMENT PROGRAM

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

2. Chronic Care Improvement Program

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

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

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

4. Utilization Review:

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

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

5. Information Systems:

(a) The MA Organization must:

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

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

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

6. External Review

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

F. COMPLIANCE PLAN

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

A. COMPLIANCE DEEMED ON THE BASIS OF ACCREDITATION

CMS may deem the MA Organization to have met the quality improvement requirements of §1852(e) of the Act and §422.152, the confidentiality and accuracy of enrollee records requirements of §1852(h) of the Act and §422.118, the anti-discrimination requirements of §1852(b) of the Act and §422.110, the access to services requirements of §1852(d) of the Act and §422.112, and the advance directives requirements of §1852(i) of the Act and §422.128, the provider participation requirements of §1852(j) of the Act and 42 CFR Part 422, Subpart E, and the applicable requirements described in §423.165, if the MA Organization is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by CMS and the accreditation organization used the standards approved by CMS for the purposes of assessing the MA Organization's compliance with Medicare requirements. The provisions of §422.156 shall govern the MA Organization's use of deemed status to meet MA program requirements.

B. PROGRAM INTEGRITY

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

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

C. MARKETING

1. The MA Organization may not distribute any marketing materials, as defined in 42 CFR 422.2260 and in the Marketing Materials Guidelines for Medicare Advantage-Prescription Drug Plans and Prescription Drug Plans (Medicare Marketing Guidelines), unless they have been filed with and not disapproved by CMS in accordance with §422.80. The file and use process set out at §422.2262 must be used, unless the MA organization notifies CMS that it will not use this process.

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

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

4. The MA Organization must comply with the Medicare Marketing Guidelines, as well as all applicable statutes and regulations, including and without limitation Section 1851(h) of the Act and 42 CFR § 422.111, 42 CFR Part 422 Subpart V and 42 CFR Part 423 Subpart V. Failure to comply may result in sanctions as provided in 42 CFR Part 422 Subpart O.

Article IV
CMS Payment to MA Organization

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

B. Methodology. CMS agrees to pay the MA Organization under this contract in accordance with the provisions of section 1853 of the Act and 42 CFR Part 422 Subpart G. **[422.504(a)(9)]**

C. The MA Organization agrees to abide by the requirements in 42 CFR 495.200 et seq. and §1853(l) and (m) of the Act, including the fact that payment may be made directly to MA-affiliated hospitals that are certified Medicare hospitals through the Medicare FFS hospital incentive payment program.

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

As a condition for receiving a monthly payment under paragraph B of this article, and 42 CFR Part 422 Subpart G, the MA 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 request payment under the contract on the forms attached hereto as Attachment A (enrollment attestation) and Attachment B (risk adjustment data) which attest to *(based on best knowledge, information and belief, as of the date specified on the attestation form)* the accuracy, completeness, and truthfulness of the data identified on these attachments. The Medicare Advantage Plan Attestation of Benefit Plan and Price must be signed and attached to the executed version of this contract.

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

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

3. The Medicare Advantage Plan Attestation of Benefit Plan and Price (an example of which is attached hereto as Attachment C) requires that the CEO, 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 attest *(based on best knowledge, information and belief, as of the date specified on the attestation form)* 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 proposed bid submission agree with the benefit package the MA Organization will offer during the period covered by the proposed bid submission. This document is being sent separately to the MA Organization and must be signed and attached to the executed version of this contract, and is incorporated herein by reference. **[422.504(l)]**

Article V
MA Organization Relationship with Related Entities, Contractors, and Subcontractors

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

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

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

2. HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent information for any particular contract period for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later. **[422.504(i)(2)]**

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

1. Enrollee protection provisions that provide

(a) Consistent with Article III(C), arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the legal obligation of the MA Organization; and

(b) Consistent with Article III(C), provision for the continuation of benefits.

2. Accountability provisions that indicate that the MA Organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph D of this article.

3. A provision requiring that any services or other activity performed by a related entity, contractor or subcontractor in accordance with a contract or written agreement between the related entity, contractor, or subcontractor and the MA Organization will be consistent and comply with the MA Organization's contractual obligations to CMS. **[422.504(i)(3)]**

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

1. Written arrangements must specify delegated activities and reporting responsibilities.

2. Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA Organization determine that such parties have not performed satisfactorily.

3. Written arrangements must specify that the performance of the parties is monitored by the MA Organization on an ongoing basis.

4. Written arrangements must specify that either-

(a) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA Organization; or

(b) The credentialing process will be reviewed and approved by the MA Organization and the MA Organization must audit the credentialing process on an ongoing basis.

5. All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions. **[422.504(i)(4)]**

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

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

1. Agrees that any physician incentive plan it operates meets the requirements of §422.208, and

2. Has assured that all physicians and physician groups that the MA Organizations physician incentive plan places at substantial financial risk have adequate stop-loss protection in accordance with §422.208(f). **[422.208]**

Article VI
Records Requirements

A. MAINTENANCE OF RECORDS

1. The MA Organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that-

(a) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the benefit and price bid) of the MA Organization.

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the MA Organization.

(iii) Enable CMS to audit and inspect any books and records of the MA Organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the benefit and price bid proposal.

(v) Establish component rates of the benefit and price bid for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(b) Include at least records of the following:

(i) Ownership and operation of the MA Organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and six prior periods.

(iii) Federal income tax or informational returns for the current contract period and six prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts (including, but not limited to, with related or unrelated prescription drug benefit managers) and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the MA Organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received, by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.**[422.504(d)]**

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

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

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

(ii) The facilities of the MA Organization; and

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

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

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

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

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

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

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

B. REPORTING REQUIREMENTS

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

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

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

(i) The cost of its operations;

(ii) A description, submitted to CMS annually and within 120 days of the end of the fiscal year, of significant business transactions (as defined in §422.500) between the MA Organization and a party in interest showing that the costs of the transactions listed in paragraph (2)(a)(v) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(iii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(iv) A combined financial statement for the MA Organization and a party in interest if either of the following conditions is met:

(aa) thirty-five percent or more of the costs of operation of the MA Organization go to a party in interest.

(bb) thirty-five percent or more of the revenue of a party in interest is from the MA Organization. **[422.516(b)]**

(v) Requirements for combined financial statements.

(aa) The combined financial statements required by paragraph (2)(a)(iv) must display in separate columns the financial information for the MA Organization and each of the parties in interest.

(bb) Inter-entity transactions must be eliminated in the consolidated column.

(cc) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(dd) Upon written request from the MA Organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in paragraph (2)(a)(v) with respect to a particular entity. **[422.516(c)]**

(vi) A description of any loans or other special financial arrangements the MA Organization makes with contractors, subcontractors, and related entities. **[422.516(e)]**

(b) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA Organization. **[422.504(f)]**

(c) Patterns of utilization of the MA Organization's services. **[422.516(a)(2)]**

3. The MA Organization agrees to participate in surveys required by CMS and to submit to CMS all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under the MA plan;

(ii) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including --

(i) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(ii) Information on Medicare enrollee satisfaction;

(iii) The patterns of utilization of plan services;

(iv) The availability, accessibility, and acceptability of the plan's services;

(v) Information on health outcomes and other performance measures required by CMS;

(vi) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

(vii) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) Any other information deemed necessary by CMS for the administration or evaluation of the Medicare program. **[422.504(f)(2)]**

4. The MA Organization agrees to provide to its enrollees and upon request, to any individual eligible to elect an MA plan, all informational requirements under §422.64 and, upon an enrollee's, request, the financial disclosure information required under §422.516. **[422.504(f)(3)]**

5. Reporting and disclosure under ERISA.

(a) For any employees' health benefits plan that includes an MA Organization in its offerings, the MA Organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the MA Organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(b) The MA Organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA. **[422.516(d)]**

6. Electronic communication. The MA Organization must have the capacity to communicate with CMS electronically. **[422.504(b)]**

7. Risk Adjustment data. The MA Organization agrees to comply with the requirements in §422.310 for submitting risk adjustment data to CMS. **[422.504(a)(8)]**

Article VII
Renewal of the MA Contract

A. Renewal of contract: In accordance with §422.505, following the initial contract period, this contract is renewable annually only if-

1. The MA Organization has not provided CMS with a notice of intention not to renew; **[422.506(a)]**

2. CMS and the MA Organization reach agreement on the bid under 42 CFR Part 422, Subpart F; and **[422.505(d)]**

3. CMS informs the MA Organization that it authorizes a renewal.

B. Nonrenewal of contract

1. Nonrenewal by the Organization.

(a) In accordance with §422.506, the MA Organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason, provided it meets the time frames for doing so set forth in subparagraphs (b) and (c) of this paragraph.

(b) If the MA Organization does not intend to renew its contract, it must notify--

(i) CMS, in writing, by the first Monday in June of the year in which the contract would end, pursuant to §422.506

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

(c) CMS may accept a nonrenewal notice submitted after the applicable annual non-renewal notice deadline if -

(i) The MA Organization notifies its Medicare enrollees and the public in accordance with subparagraph (1)(b)(ii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(d) If the MA Organization does not renew a contract under subparagraph (1), CMS will not enter into a contract with the Organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. **[422.506(a)]**

2. CMS decision not to renew.

(a) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) For any of the reasons listed in §422.510(a) [Article VIII, section (B)(1)(a) of this contract], which would also permit CMS to terminate the contract.

(ii) The MA Organization has committed any of the acts in §422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under 42 CFR Part 422 Subpart O.

(iii) The MA Organization did not submit a benefit and price bid or the benefit and price bid was not acceptable **[422.505(d)]**

(b) Notice. CMS shall provide notice of its decision whether to authorize renewal of the contract as follows:

(i) To the MA Organization by August 1 of the contract year, except in the event of (2)(a)(iv) above, for which notice will be sent by September 1.

(ii) To the MA Organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(c) Notice of appeal rights. CMS shall give the MA Organization written notice of its right to reconsideration of the decision not to renew in accordance with § 422.644.**[422.506(b)]**

Article VIII
Modification or Termination of the Contract

A. Modification or Termination of Contract by Mutual Consent

1. This contract may be modified or terminated at any time by written mutual consent.

(a) If the contract is modified by written mutual consent, the MA Organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within time frames specified by CMS. **[422.508(a)(2)]**

(b) If the contract is terminated by written mutual consent, except as provided in section (A)(2) of this Article, the MA Organization must provide notice to its Medicare enrollees and the general public as provided in section B(2)(b)(ii) and B(2)(b)(iii) of this Article. **[422.508(a)(1)]**

2. If this contract is terminated by written mutual consent and replaced the day following such termination by a new MA contract, the MA Organization is not required to provide the notice specified in section B of this article. **[422.508(b)]**

B. Termination of the Contract by CMS or the MA Organization

1. Termination by CMS.

(a) CMS may at any time terminate a contract if CMS determines that the MA Organization meets any of the following:

(i) has failed substantially to carry out the terms of its contract with CMS.

(ii) is carrying out its contract in a manner that is inconsistent with the efficient and effective implementation of 42 CFR Part 422.

(iii) no longer substantially meets the applicable conditions of 42CFR Part 422.

(iv) based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care program, including submission of false or fraudulent data.

(v) experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists.

(vi) substantially fails to comply with the requirements in 42 CFR Part 422 Subpart M relating to grievances and appeals.

(vii) fails to provide CMS with valid risk adjustment data as required under §422.310 and 423.329(b)(3).

(viii) fails to implement an acceptable quality improvement program as required under 42 CFR Part 422 Subpart D.

(ix) substantially fails to comply with the prompt payment requirements in §422.520.

(x) substantially fails to comply with the service access requirements in §422.112.

(xi) fails to comply with the requirements of §422.208 regarding physician incentive plans.

(xii) substantially fails to comply with the marketing requirements in 42 CFR Part 422 Subpart V.

(b) Notice. If CMS decides to terminate a contract for reasons other than the grounds specified in section (B)(1)(a) above, it will give notice of the termination as follows:

(i) CMS will notify the MA Organization in writing 90 days before the intended date of the termination.

(ii) The MA Organization will notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The MA Organization will notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(c) Expedited termination of contract by CMS.

(i) For terminations based on violations prescribed in paragraph (B)(1)(a)(iv) or (B)(1)(a)(v) of this article, CMS will notify the MA Organization in writing that its contract has been terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA Organization covering the period of the month following the contract termination.

(ii) CMS will notify the MA Organization's Medicare enrollees in writing of CMS' decision to terminate the MA Organization's contract. This notice will occur no later than 30 days after CMS notifies the plan of its decision to terminate this contract. CMS will simultaneously inform the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA Organizations in a similar geographic area and original Medicare.

(iii) CMS will notify the general public of the termination no later than 30 days after notifying the MA Organization of CMS' decision to terminate this contract. This notice will be published in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(d) Corrective action plan

(i) General. Before providing a notice of intent to terminate a contract for reasons other than the grounds specified in section (B)(1)(a)(iv) or (B)(1)(a)(v) of this article, CMS will provide the MA Organization with notice specifying the MA Organizations deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(ii) Exceptions. If a contract is terminated under section (B)(1)(a)(iv) or (B)(1)(a)(v) of this article, the MA Organization will not be provided with the opportunity to develop and implement a corrective action plan.

(e) Appeal rights. If CMS decides to terminate this contract, it will send written notice to the MA Organization informing it of its termination appeal rights in accordance with 42 CFR Part 422 Subpart N. **[422.510(d)]**

2. Termination by the MA Organization

(a) Cause for termination. The MA Organization may terminate this contract if CMS fails to substantially carry out the terms of the contract.

(b) Notice. The MA Organization must give advance notice as follows:

(i) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA Organization is requesting contract termination.

(ii) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA and MA-PD plans, PDP plans, Medigap options, and original Medicare and must receive CMS approval.

(iii) To the general public at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA Organization's geographic area.

(c) Effective date of termination. The effective date of the termination will be determined by CMS and will be at least 90 days after the date CMS receives the MA Organization's notice of intent to terminate.

(d) CMS' liability. CMS' liability for payment to the MA Organization ends as of the first day of the month after the last month for which the contract is in effect, but CMS shall make payments for amounts owed prior to termination but not yet paid.

(e) Effect of termination by the organization. CMS will not enter into an agreement with the MA Organization for a period of two years from the date the Organization has terminated this contract, unless there are circumstances that warrant special consideration, as determined by CMS. **[422.512]**

Article IX
Requirements of Other Laws and Regulations

A. The MA Organization agrees to comply with--

1. Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 USC 3729 et seq.) , and the anti -kickback statute (section 1128B(b) of the Act): and

2. HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164. **[422.504(h)]**

B. Pursuant to section 13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), the MA Organization agrees that as it implements, acquires, or upgrades its health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as amended by section 13101 of the ARRA.

C. The MA Organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS, notwithstanding any relationship(s) that the MA organization may have with related entities, contractors, or subcontractors. **[422.504(i)]**

D. In the event that any provision of this contract conflicts with the provisions of any statute or regulation applicable to an MA Organization, the provisions of the statute or regulation shall have full force and effect.

Article X
Severability

The MA Organization agrees that, upon CMS' request, this contract will be amended to exclude any MA plan or State-licensed entity specified by CMS, and a separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made. **[422.504(k)]**

Article XI
Miscellaneous

A. Definitions. Terms not otherwise defined in this contract shall have the meaning given to such terms in 42 CFR Part 422.

B. Alteration to Original Contract Terms. The MA Organization agrees that it has not altered in any way the terms of this contract presented for signature by CMS. The MA Organization agrees that any alterations to the original text the MA Organization may make to this contract shall not be binding on the parties.

C. Approval to Begin Marketing and Enrollment. The MA Organization agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part C marketing and enrollment activities. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on the MA Organizations Sponsors behalf) and successfully demonstrating capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, the MA Organization must, 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS, and 4) check and receive transaction status information.

**ATTESTATION OF ENROLLMENT INFORMATION
RELATING TO CMS PAYMENT
TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This attestation shall not be considered a waiver of the MA Organization's right to seek payment adjustments from CMS based on information or data which does not become available until after the date the MA Organization submits this attestation.

1. The MA Organization has reported to CMS for the month of (INDICATE MONTH AND YEAR) all new enrollments, disenrollments, and appropriate changes in enrollees status with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The MA Organization has reviewed the CMS monthly membership report and reply listing for the month of (INDICATE MONTH AND YEAR) for the above-stated MA plans and has reported to CMS any discrepancies between the report and the MA Organization's records. For those portions of the monthly membership report and the reply listing to which the MA Organization raises no objection, the MA Organization, through the certifying CEO/CFO, will be deemed to have attested, based on best knowledge, information, and belief as of the date indicated below, to its accuracy, completeness, and truthfulness.

ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS during the period of (INDICATE DATES) all (INDICATE TYPE - DIAGNOSIS/ENCOUNTER) risk adjustment data available to the MA Organization with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

ATTACHMENT C - Medicare Advantage Plan Attestation of Benefit Plan and Price

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR THE MA ORGANIZATION

THOMAS PAUL

_____

Contracting Official Name

9/7/2010 2:24:51 PM

_____

Date

UNITEDHEALTHCARE OF CALIFORNIA

_____

Organization

5995 PLAZA DRIVE
CYPRESS, CA 90630

_____

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

10/4/2010 3:03:20 PM

_____

Danielle R. Moon, J.D., M.P.A
Director
Medicare Drug and Health
Plan Contract Administration Group,
Center for Medicare

_____

Date

ADDENDUM TO MEDICARE MANAGED CARE CONTRACT PURSUANT TO SECTIONS 1860D-1 THROUGH 1860D-42 OF THE SOCIAL SECURITY ACT FOR THE OPERATION OF A VOLUNTARY MEDICARE PRESCRIPTION DRUG PLAN

The Centers for Medicare & Medicaid Services (hereinafter referred to as "CMS") and UNITEDHEALTHCARE OF CALIFORNIA , a Medicare managed care organization (hereinafter referred to as the MA-PD Sponsor) agree to amend the contract H0543 governing the MA-PD Sponsors operation of a Part C plan described in Section 1851(a)(2)(A) of the Social Security Act (hereinafter referred to as "the Act") or a Medicare cost plan to include this addendum under which the MA-PD Sponsor shall operate a Voluntary Medicare Prescription Drug Plan pursuant to sections 1860D-1 through 1860D-42 (with the exception of section 1860D-22 and 1860D-31) of the Act.

This addendum is made pursuant to Subpart L of 42 CFR Part 417 (in the case of cost plan sponsors offering a Part D benefit) and Subpart K of 42 CFR Part 422 (in the case of an MA-PD Sponsor offering a Part C plan).

NOTE: For purposes of this addendum, unless otherwise noted, reference to an "MA-PD Sponsor" or "MA-PD Plan" is deemed to include a cost plan sponsor or a MA private fee-for-service contractor offering a Part D benefit.

Article I
Medicare Voluntary Prescription Drug Benefit

A. The MA-PD Sponsor agrees to operate one or more Medicare Voluntary Prescription Drug Plans as described in its application and related materials, including but not limited to all the attestations contained therein and all supplemental guidance, for Medicare approval and in compliance with the provisions of this addendum, which incorporates in its entirety the Solicitation For Applications for New Medicare Advantage Prescription Drug Plan (MA-PD) Sponsors, released on January 5, 2010 [applicable to Medicare Part C contractors] or the Solicitation for Applications for New Cost Plan Sponsors, released on January 5, 2010 [applicable to Medicare cost plan contractors] (hereinafter collectively referred to as "the addendum"). The MA-PD Sponsor also agrees to operate in accordance with the regulations at 42 CFR Part 423 (with the exception of Subparts Q, R, and S), sections 1860D-1 through 1860D-43 (with the exception of sections 1860D-22(a) and 1860D-31) of the Social Security Act, and the applicable solicitation identified above, as well as all other applicable Federal statutes, regulations, and policies. This addendum is deemed to incorporate any changes that are required by statute to be implemented during the term of this addendum and any regulations or policies implementing or interpreting such statutory provisions.

B. CMS agrees to perform its obligations to the MA-PD Sponsor consistent with the regulations at 42 CFR Part423 (with the exception of Subparts Q, R, and S), sections 1860D-1 through 1860D-43 (with the exception of sections 1860D-22(a) and 1860D-31) of the Social Security Act, and the applicable solicitation, as well as all other applicable Federal statutes, regulations, and policies.

C. CMS agrees that it will not implement, other than at the beginning of a calendar year, regulations under 42 CFR Part 423 that impose new, significant regulatory requirements on the MA-PD Sponsor. This provision does not apply to new requirements mandated by statute.

D. This addendum is in no way intended to supersede or modify 42 CFR, Parts 417, 422 or 423. Failure to reference a regulatory requirement in this addendum does not affect the applicability of such requirements to the MA-PD Sponsor and CMS.

Article II
Functions to be Performed by the MA-PD Sponsor

A. ENROLLMENT

1. MA-PD Sponsor agrees to enroll in its MA-PD plan only Part D-eligible beneficiaries as they are defined in 42 CFR §423.30(a) and who have elected to enroll in MA-PD Sponsors Part C or Section 1876 benefit.

2. If the MA-PD Sponsor is a cost plan sponsor, the MA-PD Sponsor acknowledges that its Section 1876 plan enrollees are not required to elect enrollment in its Part D plan.

B. PRESCRIPTION DRUG BENEFIT

1. MA-PD Sponsor agrees to provide the required prescription drug coverage as defined under 42 CFR §423.100 and, to the extent applicable, supplemental benefits as defined in 42 CFR §423.100 and in accordance with Subpart C of 42 CFR Part 423. MA-PD Sponsor also agrees to provide Part D benefits as described in the MA-PD Sponsors Part D bid(s) approved each year by CMS (and in the Attestation of Benefit Plan and Price, attached hereto).

2. MA-PD Sponsor agrees to calculate and collect beneficiary Part D premiums in accordance with 42 CFR §§423.286 and 423.293.

3. If the MA-PD Sponsor is a cost plan sponsor, it acknowledges that its Part D benefit is offered as an optional supplemental service in accordance with 42 CFR §417.440(b)(2)(ii).

4. MA-PD Sponsor agrees to administer for its prescription drug plan members at point-of-sale the Medicare Coverage Gap Discount authorized by section 1860D-14A of the Social Security Act ("the Act").

C. DISSEMINATION OF PLAN INFORMATION

1. MA-PD Sponsor agrees to provide the information required in 42 CFR §423.48.

2. MA-PD Sponsor agrees to disclose information related to Part D benefits to beneficiaries in the manner and the form specified by CMS under 42 CFR §§423.128 and 423 Subpart V and in the "Marketing Materials Guidelines for Medicare Advantage-Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs)," and agrees to comply with requirements in 42 CFR 423 Subpart V requiring approval of certain marketing materials prior to distribution.

3. MA-PD Sponsor certifies that all materials it submits to CMS under the File and Use Certification authority described in the Marketing Materials Guidelines are accurate, truthful, not misleading, and consistent with CMS marketing guidelines.

D. QUALITY ASSURANCE/UTILIZATION MANAGEMENT

MA-PD Sponsor agrees to operate quality assurance, cost, and utilization management, medication therapy management programs, and support electronic prescribing in accordance with Subpart D of 42 CFR Part 423.

E. APPEALS AND GRIEVANCES

MA-PD Sponsor agrees to comply with all requirements in Subpart M of 42 CFR Part 423 governing coverage determinations, grievances and appeals, and formulary exceptions. MA-PD Sponsor acknowledges that these requirements are separate and distinct from the appeals and grievances requirements applicable to the MA-PD Sponsor through the operation of its Part C or cost plan benefits.

F. PAYMENT TO MA-PD SPONSOR

MA-PD Sponsor and CMS agree that payment paid for Part D services under the addendum will be governed by the rules in Subpart G of 42 CFR Part 423.

G. BID SUBMISSION AND REVIEW

If the MA-PD Sponsor intends to participate in the Part D program for the future year, MA-PD Sponsor agrees to submit a future years Part D bid, including all required information on premiums, benefits, and cost-sharing, by the applicable due date, as provided in Subpart F of 42 CFR Part 423 so that CMS and the MA-PD Sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal. MA-PD Sponsor acknowledges that failure to submit a timely bid under this section may affect the sponsors ability to offer a Part C plan, pursuant to the provisions of 42 CFR §422.4(c).

H. COORDINATION WITH OTHER PRESCRIPTION DRUG COVERAGE

1. MA-PD Sponsor agrees to comply with the coordination requirements with State Pharmacy Assistance Programs (SPAPs) and plans that provide other prescription drug coverage as described in Subpart J of 42 CFR Part 423.

2. MA-PD Sponsor agrees to comply with Medicare Secondary Payer procedures as stated in 42 CFR §423.462.

I. SERVICE AREA AND PHARMACY ACCESS

1. The MA-PD Sponsor agrees to provide Part D benefits in the service area for which it has been approved by CMS to offer Part C or cost plan benefits utilizing a pharmacy network and formulary approved by CMS that meet the requirements of 42 CFR §423.120.

2. The MA-PD Sponsor agrees to ensure adequate access to Part D-covered drugs at out-of-network pharmacies according to 42 CFR §423.124.

3. MA-PD Sponsor agrees to provide benefits by means of point-of-service systems to adjudicate prescription drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in 42 CFR §423.100), and long-term care pharmacies (as defined in 42 CFR §423.100).

4. MA-PD Sponsor agrees to contract with any pharmacy that meets the MA-PD Sponsors reasonable and relevant standard terms and conditions. If MA-PD Sponsor has demonstrated that it historically fills 98% or more of its enrollees prescriptions at pharmacies owned and operated by the MA-PD Sponsor (or presents compelling circumstances that prevent the sponsor from meeting the 98% standard or demonstrates that its Part D plan design will enable the sponsor to meet the 98% standard during the contract year), this provision does not apply to MA-PD Sponsors plan.

5. The provisions of 42 CFR §423.120(a) concerning the TRICARE retail pharmacy access standard do not apply to MA-PD Sponsor if the Sponsor has demonstrated to CMS that it historically fills more than 50% of its enrollees prescriptions at pharmacies owned and operated by the MA-PD Sponsor. MA-PD Sponsors excused from meeting the TRICARE standard are required to demonstrate retail pharmacy access that meets the requirements of 42 CFR §422.112 for a Part C contractor and 42 CFR §417.416(e) for a cost plan contractor.

J. COMPLIANCE PROGRAM/PROGRAM INTEGRITY

MA-PD Sponsor agrees that it will develop and implement a compliance program that applies to its Part D-related operations, consistent with 42 CFR §423.504(b)(4)(vi).

K. LOW-INCOME SUBSIDY

MA-PD Sponsor agrees that it will participate in the administration of subsidies for low-income individuals according to Subpart P of 42 CFR Part 423.

L. BENEFICIARY FINANCIAL PROTECTIONS

The MA-PD Sponsor agrees to afford its enrollees protection from liability for payment of fees that are the obligation of the MA-PD Sponsor in accordance with 42 CFR §423.505(g).

M. RELATIONSHIP WITH FIRST TIER, DOWNSTREAM, AND RELATED ENTITIES

1. The MA-PD Sponsor agrees that it maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of this addendum.

2. The MA-PD Sponsor shall ensure that any contracts or agreements with first tier, downstream, and related entities performing functions on the MA-PD Sponsors behalf related to the operation of the Part D benefit are in compliance with 42 CFR §423.505(i).

N. CERTIFICATION OF DATA THAT DETERMINE PAYMENT

MA-PD Sponsor must provide certifications in accordance with 42 CFR §423.505(k).

O. MA-PD SPONSOR REIMBURSEMENT TO PHARMACIES

1. If an MA-PD Sponsor uses a standard for reimbursement of pharmacies based on the cost of a drug, MA-PD Sponsor will update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of the drug.

2. MA-PD Sponsor will issue, mail, or otherwise transmit payment with respect to all claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only, or are located in, or contract with, a long-term care facility) within 14 days of receipt of an electronically submitted claim or within 30 days of receipt of a claim submitted otherwise.

3. MA-PD Sponsor must ensure that a pharmacy located in, or having a contract with, a long-term care facility will have not less than 30 days (but not more than 90 days) to submit claims to MA-PD Sponsor for reimbursement.

Article III
Record Retention and Reporting Requirements

A. MAINTENANCE OF RECORDS

MA-PD Sponsor agrees to maintain records and provide access in accordance with 42 CFR §§ 423.505 (b)(10) and 423.505(i)(2).

B. GENERAL REPORTING REQUIREMENTS

The MA-PD Sponsor agrees to submit to information to CMS according to 42 CFR §§423.505(f), 423.514, and the "Final Medicare Part D Reporting Requirements," a document issued by CMS and subject to modification each program year.

C. CMS LICENSE FOR USE OF PLAN FORMULARY

MA-PD Sponsor agrees to submit to CMS each plan's formulary information, including any changes to its formularies, and hereby grants to the Government, and any person or entity who might receive the formulary from the Government, a non-exclusive license to use all or any portion of the formulary for any purpose related to the administration of the Part D program, including without limitation publicly distributing, displaying, publishing or reconfiguration of the information in any medium, including www.medicare.gov, and by any electronic, print or other means of distribution.

Article IV
HIPAA Transactions/Privacy/Security

A. MA-PD Sponsor agrees to comply with the confidentiality and enrollee record accuracy requirements specified in 42 CFR §423.136.

B. MA-PD Sponsor agrees to enter into a business associate agreement with the entity with which CMS has contracted to track Medicare beneficiaries true out-of-pocket costs.

Article V
Addendum Term and Renewal

A. TERM OF ADDENDUM

This addendum is effective from the date of CMS authorized representatives signature through December 31, 2011. This addendum shall be renewable for successive one-year periods thereafter according to 42 CFR §423.506.

B. QUALIFICATION TO RENEW ADDENDUM

1. In accordance with 42 CFR §423.507, the MA-PD Sponsor will be determined qualified to renew this addendum annually only if

(a) The MA-PD Sponsor has not provided CMS with a notice of intention not to renew in accordance with Article VII of this addendum, and

(b) CMS has not provided the MA-PD Sponsor with a notice of intention not to renew.

2. Although MA-PD Sponsor may be determined qualified to renew its addendum under this Article, if the MA-PD Sponsor and CMS cannot reach agreement on the Part D bid under Subpart F of 42 CFR Part 423, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in Subpart N of 42 CFR Parts 422 or 423. (Refer to Article X for consequences of non-renewal on the Part C contract and the ability to enter into a Part C contract.)

Article VI
Nonrenewal of Addendum

A. NONRENEWAL BY THE MA-PD SPONSOR

1. MA-PD Sponsor may non-renew this addendum in accordance with 42 CFR 423.507(a).

2. If the MA-PD Sponsor non-renews this addendum under this Article, CMS cannot enter into a Part D addendum with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

B. NONRENEWAL BY CMS

CMS may non-renew this addendum under the rules of 42 CFR 423.507(b). (Refer to Article X for consequences of non-renewal on the Part C contract and the ability to enter into a Part C contract.)

Article VII
Modification or Termination of Addendum by Mutual Consent

This addendum may be modified or terminated at any time by written mutual consent in accordance with 42 CFR 423.508. (Refer to Article X for consequences of non-renewal on the Part C contract and the ability to enter into a Part C contract.)

Article VIII
Termination of Addendum by CMS

CMS may terminate this addendum in accordance with 42 CFR 423.509. (Refer to Article X for consequences of non-renewal on the Part C contract and the ability to enter into a Part C contract.)

Article IX
Termination of Addendum by the MA-PD Sponsor

A. The MA-PD Sponsor may terminate this addendum only in accordance with 42 CFR 423.510.

B. CMS will not enter into a Part D addendum with an organization that has terminated its addendum within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

C. If the addendum is terminated under section A of this Article, the MA-PD Sponsor must ensure the timely transfer of any data or files. (Refer to Article X for consequences of non-renewal on the Part C contract and the ability to enter into a Part C contract.)

D. If the addendum is terminated under section A of this Article, CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

Article X
Relationship between Addendum and Part C Contract or 1876 Cost Contract

A. MA-PD Sponsor acknowledges that, if it is a Medicare Part C contractor, the termination or nonrenewal of this addendum by either party may require CMS to terminate or non-renew the Sponsors Part C contract in the event that such non-renewal or termination prevents the MA-PD Sponsor from meeting the requirements of 42 CFR §422.4(c), in which case the Sponsor must provide the notices specified in this contract, as well as the notices specified under Subpart K of 42 CFR Part 422. MA-PD Sponsor also acknowledges that Article IX.B. of this addendum may prevent the sponsor from entering into a Part C contract for two years following an addendum termination or non-renewal where such non-renewal or termination prevents the MA-PD Sponsor from meeting the requirements of 42 CFR §422.4(c).

B. The termination of this addendum by either party shall not, by itself, relieve the parties from their obligations under the Part C or cost plan contracts to which this document is an addendum.

C. In the event that the MA-PD Sponsors Part C or cost plan contract (as applicable) is terminated or nonrenewed by either party, the provisions of this addendum shall also terminate. In such an event, the MA-PD Sponsor and CMS shall provide notice to enrollees and the public as described in this contract as well as 42 CFR Part 422, Subpart K or 42 CFR Part 417, Subpart K, as applicable.

Article XI
Intermediate Sanctions

The MA-PD Sponsor shall be subject to sanctions and civil monetary penalties, consistent with Subpart O of 42 CFR Part 423.

Article XII
Severability

Severability of the addendum shall be in accordance with 42 CFR §423.504(e).

Article XIII
Miscellaneous

A. DEFINITIONS: Terms not otherwise defined in this addendum shall have the meaning given such terms at 42 CFR Part 423 or, as applicable, 42 CFR Part 422 or Part 417.

B. ALTERATION TO ORIGINAL ADDENDUM TERMS: The MA-PD Sponsor agrees that it has not altered in any way the terms of the MA-PD addendum presented for signature by CMS. MA-PD Sponsor agrees that any alterations to the original text the MA-PD Sponsor may make to this addendum shall not be binding on the parties.

C. ADDITIONAL CONTRACT TERMS: The MA-PD Sponsor agree to include in this addendum other terms and conditions in accordance with 42 CFR §423.505(j).

D. CMS APPROVAL TO BEGIN MARKETING AND ENROLLMENT ACTIVITIES: The MA-PD Sponsor agrees that it must complete CMS operational requirements related to its Part D benefit prior to receiving CMS approval to begin MA-PD plan marketing activities relating to its Part D benefit. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on MA-PD Sponsors behalf) and successfully demonstrating the capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, the MA-PD Sponsor must, 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS, and 4) check and receive transaction status information.

E. Pursuant to section 13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), the MA-PD Sponsor agrees that as it implements, acquires, or upgrades its health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as amended by section 13101 of the ARRA.

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR THE MA ORGANIZATION

THOMAS PAUL

_____

Contracting Official Name

9/7/2010 2:24:51 PM

_____

Date

UNITEDHEALTHCARE OF CALIFORNIA

_____

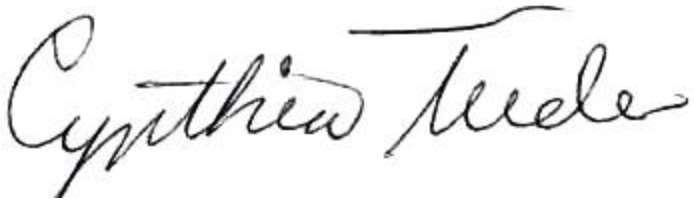
Organization

5995 PLAZA DRIVE
CYPRESS, CA 90630

_____

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES



_____

Cynthia Tudor, PhD
Director
Medicare Drug Benefit
and C & D Data Group,
Center for Medicare

10/4/2010 3:03:20 PM

_____

Date

Medicare Advantage Attestation of Benefit Plan

UNITEDHEALTHCARE OF CALIFORNIA

H0543

I attest that I have examined the Plan Benefit Packages (PBPs) identified below and that the benefits identified in the PBPs are those that the above-stated organization will make available to eligible beneficiaries in the approved service area during program year 2011. I further attest that we have reviewed the bid pricing tools (BPTs) with the certifying actuary and have determined them to be consistent with the PBPs being attested to here.

I attest that I have examined the employer/union-only group waiver ("800 series") PBPs identified below and that these PBPs are those that the above-stated organization will make available only to eligible employer/union-sponsored group plan beneficiaries in the approved service area during program year 2011. I further attest we have reviewed any MA bid pricing tools (BPTs) associated with these PBPs (no Part D bids are required for 2011 "800 series" PBPs) with the certifying actuary and have determined them to be consistent with any MA PBPs being attested to here.

I further attest that these benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations and program guidance that CMS has issued to date and will issue during the remainder of 2010 and 2011, including but not limited to, the 2011 Call Letter, the 2011 Solicitations for New Contract Applicants, the Medicare Prescription Drug Benefit Manual, the Medicare Managed Care Manual, and the CMS memoranda issued through the Health Plan Management System (HPMS).

Plan ID	Segment ID	Version	Plan Name	Plan Type	Transaction Type	MA Premium	Part D Premium	CMS Approval Date	Effective Date
001	0	6	AARP MedicareComplete (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
004	0	6	AARP MedicareComplete Premier (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
007	0	7	AARP MedicareComplete Plan 1 (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
013	0	7	AARP MedicareComplete Value (HMO)	HMO	Renewal	18.30	6.70	09/07/2010	01/01/2011
019	0	6	AARP MedicareComplete (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
022	0	6	AARP MedicareComplete (HMO)	HMO	Renewal	49.50	15.50	09/07/2010	01/01/2011
028	0	6	AARP MedicareComplete (HMO)	HMO	Renewal	81.70	17.30	09/07/2010	01/01/2011
029	0	6	AARP MedicareComplete (HMO)	HMO	Renewal	87.40	17.60	09/07/2010	01/01/2011
032	0	7	AARP MedicareComplete (HMO)	HMO	Renewal	51.70	17.30	09/07/2010	01/01/2011
035	0	5	AARP MedicareComplete Plan 1 (HMO)	HMO	Renewal	58.40	10.60	09/07/2010	01/01/2011
036	0	5		HMO	Renewal	76.60	12.40	09/07/2010	01/01/2011

Plan ID	Segment ID	Version	Plan Name	Plan Type	Transaction Type	MA Premium	Part D Premium	CMS Approval Date	Effective Date
			AARP MedicareComplete (HMO)						
060	0	5	AARP MedicareComplete Premier (HMO)	HMO	Renewal	52.60	16.40	09/07/2010	01/01/2011
070	0	5	AARP MedicareComplete (HMO)	HMO	Renewal	65.60	13.40	09/07/2010	01/01/2011
078	0	6	Evercare Plan DH (HMO SNP)	HMO	Renewal	0.00	22.80	09/07/2010	01/01/2011
079	0	6	Evercare Plan DH (HMO SNP)	HMO	Renewal	0.00	24.90	09/07/2010	01/01/2011
081	0	6	Evercare Plan DH (HMO SNP)	HMO	Renewal	0.00	21.30	09/07/2010	01/01/2011
085	0	5	AARP MedicareComplete (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
086	0	5	AARP MedicareComplete (HMO)	HMO	Renewal	67.10	10.90	09/07/2010	01/01/2011
089	0	5	AARP MedicareComplete (HMO)	HMO	Renewal	82.50	16.50	09/07/2010	01/01/2011
121	0	2	AARP MedicareComplete Essential (HMO)	HMO	Renewal	0.00	N/A	09/07/2010	01/01/2011
125	0	5	AARP MedicareComplete Plan 3 (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
138	0	6	AARP MedicareComplete Plan 2 (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
140	0	5	AARP MedicareComplete (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
141	0	6	Evercare Plan DH (HMO SNP)	HMO	Renewal	0.00	22.00	09/07/2010	01/01/2011
142	0	5	AARP MedicareComplete (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
144	0	5	AARP MedicareComplete Plan 2 (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
145	0	6	AARP MedicareComplete Plan 2 (HMO)	HMO	Renewal	0.00	0.00	09/07/2010	01/01/2011
802	0	1	MedicareComplete Retiree Plan (HMO)	HMO	Renewal	0.00	N/A	09/07/2010	01/01/2011
805	0	1	MedicareComplete Retiree Plan (HMO)	HMO	Renewal	0.00	N/A	09/07/2010	01/01/2011
806	0	1	MedicareComplete Retiree Plan (HMO)	HMO	Renewal	0.00	N/A	09/07/2010	01/01/2011

THOMAS PAUL	9/7/2010 2:24:51 PM
Contracting Official Name	Date
UNITEDHEALTHCARE OF CALIFORNIA	5995 PLAZA DRIVE CYPRESS, CA 90630
Organization	Address

SIGNATURE ATTESTATION

Contract ID: H0543
Contract Name: UNITEDHEALTHCARE OF CALIFORNIA

I understand that by signing and dating this form, I am acknowledging that I am an authorized representative of the above named organization and that I am the contracting official associated with the user ID used to log on to the Health Plan Management System (HPMS) to sign the 2011 Medicare contracting documents. I also acknowledge that in accordance with the HPMS Rules of Behavior, sharing user IDs is strictly prohibited.

This document has been electronically signed by:

THOMAS PAUL

_____

Contracting Official Name

9/7/2010 2:24:51 PM

_____

Date

UNITEDHEALTHCARE OF CALIFORNIA

_____

Organization

5995 PLAZA DRIVE
CYPRESS, CA 90630

_____

Address

EXHIBIT 12

UnitedHealthcare®
MEDICARE & RETIREMENT

UnitedHealthcare Medicare & Retirement
9701 Data Park
Minnetonka MN 55343

April 27, 2011

Medicare Advantage EDI Enrollment
CSSC Operations AG-570
2300 Springdale Drive, Bldg. One
Camden, SC 29020-1728

RE: Letter of Authorization
Encounter Data Front-End System

Effective May 1, 2011, Ingenix is authorized to begin transmitting encounter data for the following Medicare Advantage Health Plans and contract numbers:

Contract Number	Legal Entity Name
H0151	UNITEDHEALTHCARE OF ALABAMA, INC.
H0251	UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.
H0303	PACIFICARE OF ARIZONA, INC
H0316	UNITEDHEALTHCARE OF ARIZONA, INC.
H0319	UNITEDHEALTHCARE INSURANCE COMPANY
H0321	ARIZONA PHYSICIANS IPA, INC.
H0401	UNITEDHEALTHCARE OF ARKANSAS, INC.
H0408	UNITEDHEALTHCARE INSURANCE COMPANY
H0543	PACIFICARE OF CALIFORNIA
H0609	PACIFICARE OF COLORADO, INC
H0620	UNITEDHEALTHCARE INSURANCE COMPANY

ENC0022
INGENIX

H0624	UNITEDHEALTHCARE INSURANCE COMPANY
H0710	UNITEDHEALTHCARE INSURANCE COMPANY
H0752	OXFORD HEALTH PLANS (CT), INC.
H0755	HEALTH NET OF CONNECTICUT.
H1080	UNITEDHEALTHCARE OF FLORIDA, INC.
H1108	UNITEDHEALTHCARE INSURANCE COMPANY
H1111	UNITEDHEALTHCARE OF GEORGIA, INC.
H1286	UNITEDHEALTHCARE INSURANCE COMPANY
H1303	UNITEDHEALTHCARE INSURANCE COMPANY
H1509	UNITEDHEALTHCARE INSURANCE COMPANY
H1717	UNITEDHEALTHCARE INSURANCE COMPANY
H1944	UNITEDHEALTHCARE INSURANCE COMPANY
H2001	UNITEDHEALTHCARE INSURANCE COMPANY
H2111	UNITEDHEALTHCARE INSURANCE COMPANY
H2182	UNITEDHEALTHCARE INSURANCE COMPANY
H2226	UNITEDHEALTHCARE INSURANCE COMPANY
H2228	UNITEDHEALTHCARE INSURANCE COMPANY
H2406	UNITEDHEALTHCARE INSURANCE COMPANY
H2654	UNITEDHEALTHCARE OF THE MIDWEST, INC.
H2802	UNITEDHEALTHCARE OF THE MIDLANDS, INC.
H2803	UNITEDHEALTHCARE INSURANCE COMPANY

H2905	SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC,
H2931	HEALTH PLAN OF NEVADA, INC.
H3107	OXFORD HEALTH PLANS (NJ), INC.
H3113	OXFORD HEALTH PLANS (NJ), INC.
H3164	AMERICHOICE OF NEW JERSEY, INC
H3209	UNITEDHEALTHCARE INSURANCE COMPANY
H3307	OXFORD HEALTH PLANS (NY), INC.
H3379	UNITEDHEALTHCARE OF NEW YORK, INC.
H3387	UNITEDHEALTHCARE OF NEW YORK, INC.
H3456	UNITEDHEALTHCARE OF NORTH CAROLINA, INC.
H3659	UNITEDHEALTHCARE OF OHIO, INC.
H3749	PACIFICARE OF OKLAHOMA, INC.
H3805	PACIFICARE OF OREGON, INC.
H3812	UNITEDHEALTHCARE INSURANCE COMPANY
H3887	UNITEDHEALTHCARE INSURANCE COMPANY
H3912	UNITEDHEALTHCARE INSURANCE COMPANY
H3920	UNITEDHEALTHCARE OF PENNSYLVANIA, INC.
H3921	UNITEDHEALTHCARE INSURANCE COMPANY
H4102	UNITEDHEALTHCARE OF NEW ENGLAND, INC.
H4406	UNITEDHEALTHCARE OF TENNESSEE, INC.
H4456	UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.

H4514	EVERCARE OF TEXAS, LLC
H4522	UNITEDHEALTHCARE INSURANCE COMPANY
H4590	PACIFICARE OF TEXAS, INC.
H4604	UNITEDHEALTHCARE OF UTAH, INC.
H4837	UNITEDHEALTHCARE OF WISCONSIN
H4971	UNITEDHEALTHCARE INSURANCE COMPANY
H5005	PACIFICARE OF WASHINGTON, INC.
H5008	UNITEDHEALTHCARE INSURANCE COMPANY
H5253	UNITEDHEALTHCARE OF WISCONSIN, INC
H5417	UNITEDHEALTHCARE INSURANCE COMPANY
H5424	UNITEDHEALTHCARE INSURANCE COMPANY
H5435	UNITEDHEALTHCARE INSURANCE COMPANY
H5440	UNITEDHEALTHCARE INSURANCE COMPANY
H5507	UNITEDHEALTHCARE INSURANCE COMPANY
H5516	UNITEDHEALTHCARE INSURANCE COMPANY
H5532	UNITEDHEALTHCARE INSURANCE COMPANY
H5652	UNITEDHEALTHCARE INSURANCE COMPANY
H5749	UNITEDHEALTHCARE INSURANCE COMPANY
H5998	UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.
H6952	UNITEDHEALTHCARE OF THE GREAT LAKES HLTH PLAN, INC

H7187	UNITEDHEALTHCARE INSURANCE COMPANY
H7949	PACIFICARE OF NEVADA, INC.
H8748	UNITEDHEALTHCARE INSURANCE COMPANY
H9011	UNITEDHEALTHCARE OF FLORIDA, INC.
R3175	UNITEDHEALTHCARE INSURANCE COMPANY
R5287	UNITEDHEALTHCARE INSURANCE COMPANY
R5342	UNITEDHEALTHCARE INSURANCE COMPANY OF NEW YORK
R5674	SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC,
R7444	UNITEDHEALTHCARE INSURANCE COMPANY

Sincerely,

Scott Theisen
Chief Financial Officer

ENC00022

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare Advantage Organization

Electronic Data Interchange Agreement Form

MANAGED CARE ELECTRONIC DATA INTERCHANGE (EDI) AGREEMENT FORM

ONLY for the Collection of Encounter Data and/or

With Medicare Advantage Eligible Organizations

The eligible organization agrees to the following provisions for submitting Medicare encounter data electronically to The Centers for Medicare & Medicaid Services (CMS) or to CMS contractors.

A. **The Eligible Organization Agrees:**

1. That it will be responsible for all Medicare encounter data submitted to CMS by itself, its employees, or its agents.
2. That it will not disclose any information concerning a Medicare beneficiary to any other person or organization, except CMS and/or its contractors, without the express written permission of the Medicare beneficiary or his/her parent or legal guardian, or where required for the care and treatment of a beneficiary who is unable to provide written consent, or to bill insurance primary or supplementary to Medicare, or as required by State or Federal law.
3. That it will ensure that every electronic entry can be readily associated and identified with an original source document.
4. That the Secretary of Health and Human Services or his/her designee and/or the contractor has the right to audit and confirm information submitted by the eligible organization and shall have access to all original source documents and medical records related to the eligible organization's submissions, including the beneficiary's authorization and signature.
5. Based on best knowledge, information, and belief, that it will submit encounter data that are accurate, complete, and truthful.
6. That it will retain all original source documentation and medical records pertaining to any such particular Medicare encounter data for a period of at least 6 years, 3 months after the encounter data is received and processed.
7. That it will affix the CMS-assigned unique identifier number of the eligible organization on each encounter data electronically transmitted to the contractor.
8. That the CMS-assigned unique identifier number constitutes the eligible organization's legal electronic signature.
9. That it will use sufficient security procedures to ensure that all transmissions of documents are authorized and protect all beneficiary-specific data from improper access.
10. That it will establish and maintain procedures and controls so that information concerning Medicare beneficiaries, or any information obtained from CMS or its contractor, shall not be used by agents, officers, or employees of the billing service except as provided by the contractor (in accordance with §1106(a) of the Act).
11. That it will research and correct encounter data discrepancies.
12. That it will notify CMS or its contractor within 2 business days if any transmitted data are received in an unintelligible or garbled form.

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BY:

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JUL - 1 2011
BY:

RECEIVED
JUN 30 2011
MEDICARE DC
CAMDEN

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

B. **The Centers for Medicare & Medicaid Services Agrees To:**

1. Transmit to the eligible organization an acknowledgment of encounter data receipt.
2. Affix the intermediary/carrier number, as its electronic signature, on each response/report sent to the eligible organization.
3. Ensure that no CMS contractor may require the eligible organization to purchase any or all electronic services from the CMS contractor or from any subsidiary of the CMS contractor or from any company for which the CMS contractor has an interest.
4. The contractor will make alternative means available to any electronic biller to obtain such services.
5. Ensure that all Medicare electronic transmitters have equal access to any services that CMS requires Medicare contractors to make available to eligible organizations or their billing services, regardless of the electronic billing technique or service they choose. Equal access will be granted to any services the contractor sells directly, indirectly, or by arrangement.
6. Notify the provider within 2 business days if any transmitted data are received in an unintelligible or garbled form.

NOTICE:
Federal law shall govern both the interpretation of this document and the appropriate jurisdiction and venue for appealing any final decision made by CMS under this document.

This document shall become effective when signed by the eligible organization. The responsibilities and obligations contained in this document will remain in effect as long as Medicare encounter data are submitted to CMS or the contractor. Either party may terminate this arrangement by giving the other party (30) days written notice of its intent to terminate. In the event that the notice is mailed, the written notice of termination shall be deemed to have been given upon the date of mailing, as established by the postmark or other appropriate evidence of transmittal.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

C. **Signature:**

I am authorized to sign this document on behalf of the indicated party and I have read and agree to the foregoing provisions and acknowledge same by signing below.

Contract Number:	n/a - Third Party Submitter
Eligible Organization's Name:	OPTUMInsight (Formerly Ingenix)
Address:	12125 Technology Drive
City/State/ZIP:	Eden Prairie, MN 55344
Phone:	(952) 833-7223
Email:	jeff.dumcum@ingenix.com
Signature:	Jeff Dumcum
Printed Name:	Jeff Dumcum
Title:	Sr. Vice President
Date:	May 10, 2011

cc: Regional Offices

Please retain a copy of all forms submitted for your records.

Complete and mail this form with original signature to:

Medicare Advantage EDI Agreement
CSSC Operations AG-570
2300 Springdale Drive Bldg. One
Camden, SC 29020-1728

Phone (877) 534-2772
www.csscoperations.com

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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.**

CMS-Pub. 86

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

(i.e., diagnosis code, procedure code, admission date or discharge date), the organization must make sure that its database matches and supports the provider's database for these fields. Thus, it is recommended that the M+C organization return the record to the provider for correction and resubmission. For other items on the record, the M+C organization may use its own databases to fill in or correct these items.

Secondary Diagnoses - If an M+C organization does not report secondary diagnoses, it may not receive the payment to which it is entitled. Generally, the PIP-DCG model uses only the principal diagnosis to assign a beneficiary to a PIP-DCG category. However, there are two exceptions (see §90.2.2). For beneficiaries with a principal diagnosis related to chemotherapy (ICD-9 codes V58.1 and V66.2), the PIP-DCG category is assigned based on the type of cancer, using a secondary diagnosis. Also, all beneficiaries with a secondary diagnosis of AIDS will be placed in the same PIP-DCG category as those with a principal diagnosis of AIDS. M+C organizations should assure that they obtain all diagnostic information from their providers and submit all diagnoses to their Fiscal Intermediaries (FIs).

110.5 - Data Formats and Processing

(Rev. 1, 07-02-01)

A record of each enrollee discharge should be submitted, from contracted as well as non-contracted hospitals. Encounter data will be priced only for discharges on or after July 1, 1998. M+C organizations may submit to CMS electronic records using either a complete or abbreviated UB-92 format. M+C organizations may also submit using a Medicare Part A ANSI ASC X12 837 format, also called the "ANSI 837.

Abbreviated UB-92 Version 6.0 format - To indicate that the format being submitted is abbreviated, the "Z" code must be included in the third digit of "Type of bill." The abbreviated UB-92 will not be discontinued. Version 6.0 has been approved by CMS for submission of inpatient encounter data. M+C organizations could begin using Version 6.0 effective August 1, 2000 to submit data to their current FI. All M+C organizations are required to transition from Version 5.0 to Version 6.0 for submissions after December 31, 2000.

Teaching Hospitals - M+C organizations should be aware that teaching hospitals submit UB-92/ANSI837 records for the computation and payment of indirect and direct Graduate Medical Education (GME) costs for inpatients who are plan enrollees. Teaching hospitals will submit these records to the hospital's FI. These records will resemble those submitted by the M+C organization or the hospital as encounter data except that the GME transactions will contain the condition code "69" – indicating request by teaching hospital for indirect and direct GME payment. Note that the "69" code cannot be used in M+C encounter data submissions.

110.6 - Deadlines for Submission of Encounter Data

(Rev. 1, 07-02-01)

NOTE: On May 25, 2001, the Secretary announced that CMS has suspended through July 1, 2002, any filing by M+C organizations of physician and hospital outpatient encounter data. For this reason, discussions of policy related to these types of encounter data have been deleted from this release.

Medicare Managed Care Manual

Chapter 7 - Payment to Medicare + Choice (M+C) Organizations

Last Updated - Rev. 57, 08-13-04

NOTE 1: This revision includes information pertaining to the CMS-HCC risk adjustment model effective January 1, 2004. Information pertaining to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will be included in future updates.

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capitation payment will be a blended payment consisting of 90 percent of the current payment (i.e., 2.39 times the demographic rate book amount) plus 10 percent of the frailty adjusted payment. In 2005, the blend will be 70 percent current payment and 30 percent frailty adjustment. The blend will be 50/50 in 2006 and 25/75 in 2007. In 2008, frailty adjustment will be fully phased in for PACE. The phase-in schedule for WPP, MSHO and MnDHO will be consistent with the PACE phase-in schedule. That is, the blend will be 90/10 in 2004 and will continue to lag the M+C phase-in schedule by 1 year through 2008. Payment for the S/HMO demonstration in 2004 will be based on a 90/10 blend, with 90 percent of the payment based on the methodology in prior use during the demonstration, and 10 percent based on the new risk adjustment system with the additional frailty adjustment.

91.7.2 - Application of Frailty Factor to M+C Organizations

(Rev. 47, 02-20-04)

The CMS is working to improve the frailty adjustor to implement for all M+C organizations, while we implement the CMS-HCC model with a frailty adjustor for PACE organizations and certain demonstrations as an initial step. However, our current model needs further validation before implementation could be considered across the M+C program. We also need to develop an appropriate rate book adjustment for frailty.

91.8 - Exclusions From Risk Adjustment Payment

(Rev. 47, 02-20-04)

The M+C organizations with Cost or Health Care Pre-Payment Plan (HCPP) contracts will be excluded from payment under risk adjustment, but risk adjustment rates will be reported to these organizations as "risk equivalent" rates. This will replace the current reporting of the "risk equivalent" demographic-only rates to the Cost and HCPP plans.

The M+C enrollees who are capitated at the hospice rates are excluded from payment under risk adjustment. The M+C organizations will receive the demographic-only rate for these members. The CMS has separate reconciliation processes for hospice (§210).

111 – Data Collection and Submission for Risk Adjustment

(Rev. 47, 02-20-04)

The CMS uses diagnoses to calculate each beneficiary's risk adjustment factor. The risk adjustment factor is then multiplied by the capitation rate assigned to each beneficiary (county of residence) to produce the amount paid the M+C organization for each beneficiary. (See §91.6.4 on M+C payment calculations.)

The M+C organizations may submit diagnoses from certain provider types. Diagnoses received from the provider types defined below may be submitted. The following three

sections discuss provider types. Also see Exhibit 25 for information on facility types and physician specialties, with the ranges of Medicare provider numbers.

111.1 - Hospital Inpatient Data

(Rev. 57, 08-13-04)

Inpatient hospital data should be differentiated based on whether it is received from within or outside of the M+C organization's provider network. Per 42 CFR 422.204(a)3(i) all M+C organization network hospitals must have a Medicare provider agreement; by extension, a network provider should have a Medicare provider billing number for a hospital inpatient facility. If a facility does not have a hospital inpatient Medicare provider number, the M+C organization shall not submit diagnoses from that facility as hospital inpatient data. Please note that it is not necessary for M+C organizations to receive the Medicare provider number from the hospital on incoming transactions, i.e., the M+C organization may utilize its own provider identifications system. Regardless of how M+C organizations identify their facilities, M+C organizations must be able to distinguish diagnoses submitted by facilities that qualify as Medicare hospital inpatient facilities from diagnoses submitted by non-qualifying facilities.

For diagnoses received from non-network facilities, the M+C organization should first check whether the hospital is a Medicare-certified hospital inpatient facility. If the provider is a Medicare-certified hospital inpatient facility, the M+C organization should submit the diagnoses from this facility. If the hospital is not Medicare-certified, but is a Department of Veterans Affairs (VA) or DoD facility, the M+C organization must verify that it is a legitimate inpatient facility by contacting the Customer Service and Support Center (CSSC) prior to submitting data from that facility. If the hospital is not Medicare-certified or VA/DoD, the M+C organization should contact CMS to verify that the facility qualifies as a hospital inpatient facility prior to submitting any diagnoses from that facility.

To aid in determining whether or not a provider is a Medicare-certified hospital inpatient facility, the M+C organization may refer to the Medicare provider number. The Medicare provider number has a two-digit state code followed by four digits that identify the type of provider and the specific provider number. Exhibit 25 outlines the number ranges for all facility types that CMS considers to be Medicare hospital inpatient facilities. If the facility's Medicare provider number is unknown, the M+C organization may verify the provider number with the facility's billing department.

Some hospitals also operate Skilled Nursing Facilities (SNFs) as separate components within the hospital or have components with "swing beds" that can be used for either hospital inpatient or SNF stays. The M+C organizations shall not submit any diagnoses for stays in the SNF component of a hospital or from swing bed stays when the swing beds were utilized as SNF beds. Stays in both of these circumstances qualify as SNF stays and do not qualify as hospital inpatient stays. If the Medicare provider number is

on the incoming transaction from the facility, the M+C organization may distinguish the SNF or SNF swing-bed stays by the presence of a U, W, Y, or Z in the third position of the Medicare provider number (e.g., 11U001).

Principal Hospital Inpatient and Other Hospital Inpatient Diagnoses

The M+C organizations must differentiate between the principal hospital inpatient diagnosis and all other hospital inpatient diagnoses when coding the provider type on the risk adjustment transaction. According to the Official ICD-9 CM Guidelines for Coding and Reporting, the principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." The principal diagnosis as reported by the hospital shall be coded as Provider Type 01, Principal Hospital Inpatient. The CMS strongly recommends that M+C organizations continue to collect electronic encounter data or claims from hospital inpatient stays to ensure the proper identification of the principal diagnosis.

The remaining diagnoses from a hospital inpatient stay shall be coded as Provider Type 02, Other Hospital Inpatient. The guidance for coding other conditions appears in Official ICD-9 CM Guidelines for Coding and Reporting, as well as in *Exhibit 30*.

111.2 - Outpatient Hospital Data

(Rev. 47, 02-20-04)

Hospital outpatient data includes any diagnoses from a hospital outpatient department, excluding diagnoses that are derived only from claims or encounters for laboratory services, ambulance, or durable medical equipment, prosthetics, orthotics, and supplies. Hospital outpatient departments include all provider types listed in Exhibit 25. Also see Exhibit 25 for the valid Medicare provider number ranges.

Because Medicare has multiple number ranges for many provider types, and continuous number ranges feature multiple provider types, Exhibit 25 also includes a simplified list with the continuous valid Medicare provider number ranges for hospital outpatient facilities. The CMS has included Federally Qualified Health Centers, Community Mental Health Centers, and Rural Health clinics in the list of outpatient facilities to ensure M+C organizations are allowed to submit complete physician data. These three facility types utilize a composite bill that covers both the physician and the facility component of the services, and services rendered in these facilities do not result in an independent physician claim.

The M+C organizations should determine which providers qualify as hospital outpatient facilities in a similar manner as they determine which providers qualify as hospital inpatient facilities. As with hospital inpatient data, diagnoses collected from network providers are differentiated from diagnoses collected from non-network providers. Because all M+C organization network hospitals must have a provider agreement, all

network hospital outpatient facilities must have a Medicare provider number within the range of valid hospital outpatient provider numbers (see Exhibit 25). If a facility does not have a hospital outpatient Medicare provider number, the M+C organization shall not submit diagnoses from that facility as hospital outpatient data. It is not necessary that M+C organizations receive the Medicare provider number on incoming risk adjustment transactions, even if the transactions are electronic encounters or claims. However, M+C organizations must be able to distinguish diagnoses submitted by providers that qualify as hospital outpatient facilities from diagnoses submitted by non-qualifying providers.

For diagnoses received from non-network facilities, the M+C organization should first check whether the hospital is a Medicare-certified hospital outpatient facility. If the provider is a Medicare-certified hospital outpatient facility, the M+C organization should submit the diagnoses from this facility. If the hospital is not Medicare certified but is a VA or DoD facility, the M+C organization must verify that it is a legitimate outpatient facility by contacting the Customer Service and Support Center (CSSC) at 1-877-534-2772 prior to submitting data from that facility. If the hospital is not Medicare certified or VA/DoD, the M+C organization should contact CMS to verify that the facility qualifies as a hospital outpatient facility prior to submitting any diagnoses from that facility.

As with hospital inpatient facilities, if the facility's Medicare provider number is unknown, the M+C organization may verify the provider number by contacting the facility's billing department.

111.3 - Physician Data

(Rev. 47, 02-20-04)

For purposes of risk adjustment data, physicians are defined by the specialty list in Exhibit 25. This list includes certain non-physician practitioners, who for purposes of risk adjustment data, will be covered under the broad definition of physicians. This list also includes multi-specialty groups and clinics. This inclusion is solely intended to allow M+C organizations to submit data based on claims received from groups and clinics that bill M+C organizations on behalf of individual practitioners covered on the specialty list.

Physician risk adjustment data is defined as diagnoses that are noted as a result of a face-to-face visit by a patient to a physician (as defined above) for medical services. Pathology and radiology services represent the only allowable exceptions to the face-to-face visit requirement, since pathologists do not routinely see patients and radiologists are not required to see patients to perform their services. Medicare fee-for-service coverage and payment rules do not apply to risk adjustment data; therefore, M+C organizations may submit diagnoses noted by a physician even when the services rendered on the visit are not Medicare-covered services. The diagnoses should be coded in accordance with the diagnosis coding guidelines in these instructions.

111.4 - Alternative Data Sources (ADS)

(Rev. 47, 02-20-04)

Alternative data sources include diagnostic data from sources other than inpatient hospital, outpatient hospital, and physician services. The M+C organizations may use ADS as a check to ensure that all required diagnoses have been submitted to CMS for risk adjustment purposes. Two examples of ADS include pharmacy records and information provided to national or state cancer registries.

Note that M+C organizations may not utilize ADS as an alternative to diagnoses from a provider. If M+C organizations elect to utilize one or more ADS, they must 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.

For example, prescription of an ACE inhibitor, alone, would not be considered as sufficient "clinical evidence" of CHF; instead the medical record would need to document an appropriate clinician's diagnosis of congestive heart failure during the data collection period (e.g., where an "appropriate clinician" is a physician/nurse practitioner/physician assistant). A laboratory test showing one reading of high blood sugar would also not be considered to be sufficient "clinical evidence" of diabetes--the medical record would need to document a clinician's diagnosis of diabetes during the data collection period.

111.5 - Data Collection

(Rev. 47, 02-20-04)

The M+C organizations have several options for collecting data from providers to support the risk adjustment submission. When M+C organizations collect data, they may choose to utilize:(1) the standard claim or encounter formats; (2) a superbill (a common physician office claim form that lists standard ICD-9-CM codes, CPT codes, and beneficiary information); or (3) the minimum data set (HIC, diagnosis, "from date," "through date," and provider type), which is the format used to support CMS' Risk Adjustment Processing System (RAPS).

Standard claim and encounter formats currently include the UB-92, the National Standard Format (NSF), and ANSI X12 837. All M+C organizations that collect electronic fee-for-service claim or no-pay encounters from their provider networks shall utilize the data from these transactions to prepare their risk adjustment data submissions. The M+C organizations with capitated or mixed networks may also choose to use an electronic claim or encounter format to collect risk adjustment data from their capitated providers.

Under mandatory Health Insurance Portability and Accountability Act (HIPAA) transaction standards, all electronic claims or encounters sent from providers (physicians and hospitals) to health plans (M+C organizations) will constitute HIPAA-covered transactions. Any M+C organization that utilizes an electronic claim or encounter format for their risk adjustment data collection will need to convert to ANSI X12N 837 version 4010.

Any M+C organization that utilizes an electronic claim or encounter to collect diagnoses from their providers shall submit the diagnoses collected on those claims and encounters. The M+C organizations shall not utilize a superbill or the minimum risk adjustment data set to obtain diagnoses from providers who submit electronic claims or encounters, except when correcting erroneous diagnoses or supplementing incomplete diagnoses.

Regardless of the method(s) that the M+C organization utilizes to collect data from providers, any M+C organization may utilize any submission method accepted by CMS (UB-92, NSF, ANSI, risk adjustment data format, or direct data entry).

111.6 - Diagnosis Submission

(Rev. 47, 02-20-04)

For each enrolled beneficiary, M+C organizations shall submit each relevant diagnosis at least once during a data collection period. A relevant diagnosis is one that meets three criteria:

1. *The diagnosis is utilized in the model;*

2. *The diagnosis was received from one of the three provider types covered by the risk adjustment requirements (hospital inpatient, hospital outpatient, and physician); and*

3. *The diagnosis was collected according to the risk adjustment data collection instructions*

The M+C organizations may elect to submit a diagnosis more than once during a data collection period for any given beneficiary, as long as that diagnosis was recorded based on a visit to one of the three provider types covered by the risk adjustment data collection requirements. The M+C organizations may submit any qualifying diagnoses received from one of the three provider types, including diagnoses that are not in the CMS-HCC risk adjustment model. Diagnoses that are in the model, but that were not collected from one of the three provider types should not be submitted as risk adjustment data. See Table 3 in §91.4 for risk adjustment data submission deadlines.

The CMS will utilize the "through date" of a particular diagnosis when determining the "date of service" for purposes of risk adjustment; i.e., all diagnoses that have a "through

date" that falls within the data collection year will be utilized in the risk adjustment model.

- *For hospital inpatient diagnoses, the "through date" should be the date of discharge. All hospital inpatient diagnoses shall have a "through date."*
- *For physician and hospital outpatient diagnoses, the "through date" should represent either the exact date of a patient visit or the last visit date for a series of services.*
- *For outpatient and physician diagnoses that correspond to a single date of service, M+C organizations have the option of submitting only the "from date," leaving the "through date" blank.*

When a M+C organization submits a "from date" and no "through date," the Risk Adjustment Processing System (RAPS) will automatically copy the "from date" into the "through date" field. The returned file, provided to the M+C organization, will contain both a "from date" and "through date" for every diagnosis.

Date Span

Date span is the number of days between the "from date" and "through date" on a diagnosis. For inpatient diagnoses, the "from date" and "through date" should always represent the admission and discharge dates respectively. Therefore, the date span should never be greater than the length of the inpatient stay. For physician and hospital outpatient data, the date span shall not exceed 31 days.

111.6.1 - Submission Methods

(Rev. 47, 02-20-04)

Data submission to CMS may be accomplished through any of the following methods:

- *The new RAPS format (all provider types);*
- *Full or abbreviated UB-92 (hospital inpatient and outpatient);*
- *Full or abbreviated National Standard Format (NSF) (physician only);*
- *ANSI X12N 837 Version 30.51 (all provider types, only for those submitters currently utilizing this version);*
- *ANSI X12N 837 Version 40.10 (all provider types); and*
- *Online direct data entry (DDE) available through Palmetto Government Benefits Administrators (all provider types).*

The Risk Adjustment Processing System

RAPS is the data processing system used to edit and store risk adjustment data submitted to CMS through the Front End Risk Adjustment System (FERAS) at Palmetto GBA, South Carolina. The RAPS reports to the submitter the results of each individual transaction at a detail and summary level. The RAPS also provides to all submitters monthly and cumulative summaries of the diagnoses on file.

M+C organizations may elect to utilize more than one submission method. All transactions will be submitted using the same network connectivity that M+C organizations currently utilize for encounter data submission. For assistance in utilizing any of the submission methods, please contact the Computer Service and Support Center (CSSC) at 1-877-534-2772.

Regardless of the method of submission that a M+C organization selects, all transactions will be subject to the same edits. The Front-End Risk Adjustment System (FERAS) will automatically format all DDE transactions in the Risk Adjustment Processing System (RAPS) format. Transactions that are submitted in claim or encounter formats will be converted to the RAPS format prior to going through any editing. The mapping from each claim or encounter transaction to the RAPS format is on the CSSC Web site at http://www.mcoservice.com/.

Electronic Data Interchange (EDI) Agreements

The All M+C organizations should have EDI agreements on file at Palmetto GBA, the front-end recipient of all risk adjustment data. All M+C organizations must complete an EDI agreement prior to submitting to the RAPS system.

Use of Third Party Submitters

The M+C organizations may continue to utilize third-party vendors to submit risk adjustment data. Regardless who submits the data, CMS holds the M+C organization accountable for the content of the submission.

111.6.2 - Submission Frequency

(Rev. 47, 02-20-04)

M+C organizations shall submit risk adjustment data at least once per calendar quarter. Each quarter's submission should represent approximately one quarter of the data that the M+C organization will submit over the course of the year. The amount of records and diagnoses to which this corresponds depends upon the type of submission a M+C organization selects. If a M+C organization elects to use a claim or encounter submission, the ratio of records and diagnoses to enrollees will be much higher than if a M+C organization elects to use a quarterly summary transaction.

The CMS will monitor submissions to ensure that all M+C organizations meet the quarterly submission requirements. For M+C organizations that do not receive a regular submission of superbills, claims, or encounter data from their providers, CMS strongly recommends that these organizations request new diagnoses from all network providers on a quarterly basis at a minimum to ensure accurate, complete and timely data submission.

111.7 - Certification of Data Accuracy, Completeness, and Truthfulness

(Rev. 47, 02-20-04)

As a condition for receiving a monthly payment under the M+C program, the M+C organization agrees that its chief executive officer (CEO), 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 in the M+C contract, based on best knowledge, information, and belief, that the risk adjustment data the M+C organization submits to CMS are accurate, complete, and truthful. (This form is appended to Chapter 11 of the Managed Care Manual.) If risk adjustment 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).)

The CMS expects M+C organizations to design and implement effective systems to monitor the accuracy, completeness, and truthfulness of risk adjustment 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 risk adjustment data requirements.

The M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate data. 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.

111.8 - Data Validation

(Rev. 47, 02-20-04)

A sample of risk adjustment data used for making payments may be validated against hospital inpatient, hospital outpatient, and physician medical records to ensure the accuracy of medical information. Risk adjustment data will be validated to the extent that the diagnostic information justifies appropriate payment under the risk adjustment

model. The M+C organizations will be provided with additional information as the process for these reviews is developed.

The M+C organizations must submit risk adjustment data that are substantiated by the physician or provider's full medical record. M+C organizations must maintain sufficient information to trace the submitted diagnosis back to the hospital or physician that originally reported the diagnosis. Since M+C organizations may submit summary level transactions without a link to a specific encounter or claim, establishing an appropriate audit trail to the original source of the data requires diligent information management on the part of the M+C organization.

120 - Announcement of Annual Capitation Rates and Methodology Changes

(Rev. 47, 02-20-04)

Under the BBA, CMS must notify M+C organizations of any proposed changes to the payment methodology no later than 45 days prior to announcement of the annual capitation rates, which must be published annually. The annual rate announcement must include the final county rates, a description of the risk and other factors, and other information necessary to ensure that M+C organizations can calculate the monthly-adjusted capitation rates for individuals in each of their payment areas.

The Public Health Security and Bioterrorism Response Act of 2002 (Public Law 107-188) changed the deadline for the annual announcement of the M+C capitation rates from no later than March 1 to no later than the second Monday in May for 2004 and 2005 rates. Proposed changes to the payment methodology must still be published no later than 45 days before annual announcement of rates.

130 - Special Rules for Beneficiaries Enrolled in M+C Medical Savings Account (MSA) Plans

(Rev. 1, 07-02-01)

The statute directs CMS to allocate the per capita amount associated with each M+C MSA enrollee in two portions: the deposit CMS makes to the enrollee's MSA and the premium CMS pays to the M+C organization offering the MSA plan.

CMS allocates the capitated amount associated with each M+C MSA enrollee into a plan premium and an MSA deposit as follows:

- First, CMS compares the monthly M+C MSA premium filed by the organization offering the MSA plan to 1/12th of the annual M+C capitation rate for the payment area in which the beneficiary resides.

Exhibit 30 - Diagnostic Coding and Guidelines for Data Collection from Provider Networks

((Rev. 57, 08-13-04)

Medicare utilizes ICD-9-CM as the official diagnosis code set for all lines of business. The "Official ICD-9 CM Guidelines for Coding and Reporting" provides guidance on diagnosis coding. This document provides guidelines for hospital inpatient, hospital outpatient and physician services. In accordance with this policy, CMS will utilize ICD-9 diagnosis codes in the determination of risk adjustment factors. M+C organizations must submit for each beneficiary all relevant ICD-9 codes that are utilized in the risk adjustment model. M+C organizations must submit each relevant diagnosis at least once during a risk adjustment data reporting period, with the first period being July 1, 2002 – June 30, 2003. See http://www.cms.hhs.gov/paymentsystems/icd9/default.asp for information regarding ICD-9-CM codes.

At a minimum, the submitted ICD-9 codes must be sufficiently specific to allow appropriate grouping of the diagnoses in the risk adjustment model. For the complete list of diagnoses used in the risk adjustment model, as well as the list of minimal ICD-9 codes required to group diagnoses for risk adjustment, see http://www.cms.hhs.gov/healthplans/riskadj/. In all cases, coding to the highest degree of specificity provides the most accurate coding and ensures appropriate grouping in the risk adjustment model.

M+C organizations must apply the following guidelines when collecting data from their provider networks. If the M+C organization utilizes an abbreviated method of collecting diagnoses, such as a superbill, the diagnoses may be coded to the highest level of specificity or to the level of specificity necessary to group the diagnosis appropriately for risk adjusted payments. If the M+C organization collects data using an encounter or claim format, the codes should already be at the highest level of specificity. CMS encourages M+C organizations to utilize the full level of specificity in submitting risk adjustment data. Regardless of the level of specificity of submitted diagnoses, a medical record must substantiate all diagnostic information provided to CMS.

Coexisting Conditions

Physicians and providers should use the "Official ICD –9-CM Guidelines for Coding and Reporting" (found at http://www.cms.hhs.gov/paymentsystems/icd9/default.asp) and Medicare fee-for-service rules when submitting risk adjustment data to M+C organizations. The official guidelines that govern those coexisting conditions that may be coded and reported by hospital inpatient, hospital outpatient and physician providers are summarized below. The guidelines for inpatient hospital stays are as follows:

> *"…all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay.*

> *Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded."*

The guidelines for coexisting conditions that should be coded for hospital outpatient and physician services are as follows:

> *"Code all documented conditions that coexist at time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment."*

Physicians and hospital outpatient departments shall not code diagnoses documented as "probable," "suspected," "questionable," "rule out," or "working" diagnosis. Rather, physicians and hospital outpatient departments shall code the condition(s) to the highest degree of certainty for that encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit.

CMS Manual System

Pub. 100-16 Medicare Managed Care

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 114 | **Date: June 7, 2013**

SUBJECT: Chapter 7 – Risk Adjustment

I. SUMMARY OF CHANGES: Chapter 7 was last revised August 13, 2004, when it was titled "Payment to Medicare + Choice (M+C) Organizations." CMS has revised this chapter significantly by focusing it only on Risk Adjustment, retitling it accordingly, and moving the topic of payments to Medicare Advantage Organizations to Chapter 8. It now includes much more information on risk adjustment since the last revision, including background on the statutory and regulatory authority for risk adjustment, the history of risk adjustment, a schedule, and information on the Part D (RxHCC) model.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: June 7, 2013
IMPLEMENTATION DATE: June 7, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	7/Entire Chapter

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

40. Role and Responsibilities of Plan Sponsors

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

MA organizations, PACE organizations, 1876 Cost HMOs/Competitive Medical Plans (CMPs), and starting in 2012, Health Care Prepayment Plans (HCPPs) like the United Mine Workers of America Health and Retirement Funds, must submit risk adjustment data, as required by CMS.

This section provides a high-level checklist of plan requirements. Detailed information about risk adjustment data collection, submission, reporting, and validation are outlined in later sections within this chapter.

Risk Adjustment Data Submission Requirements – Plan Sponsors (Medicare Advantage Organizations (MAOs), PACE organizations, and 1876 Cost HMO/CMPs) must:

- Ensure the accuracy and integrity of risk adjustment data submitted to CMS. All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) Guidelines for Coding and Reporting.*

- Implement procedures to ensure that diagnoses are from acceptable data sources. The only acceptable data sources are hospital inpatient facilities, hospital outpatient facilities, and physicians. Plan sponsors are responsible for determining provider type based on the source of the data.

- Submit the required data elements from acceptable data sources according to the coding guidelines.

- Submit all required ICD-9-CM diagnosis codes for each beneficiary and submit unique diagnoses at least once during the risk adjustment data-reporting period. Submitters must filter diagnosis data to eliminate the submission of duplicate diagnosis clusters.

    - For Part B-only beneficiaries enrolled in a plan, the plan sponsor must submit ICD-9-CM diagnosis codes under the same rules as for a beneficiary with both Parts A and B. The plan should also submit ICD-9-CM codes for Part A services provided under a non-Medicare contract.

  If upon conducting an internal review of submitted diagnosis codes, the plan sponsor determines that any ICD-9-CM diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted ICD-9-CM diagnosis codes as soon as possible.

- Receive and reconcile CMS Risk Adjustment Reports in a timely manner. Plan sponsors must track their submission and deletion of ICD-9-CM diagnosis codes on an ongoing basis.

- Once CMS calculates the final risk scores for a payment year, plan sponsors may request a recalculation of payment upon discovering the submission of inaccurate ICD-9-CM diagnosis codes that CMS used to calculate a final risk score for a previous payment year and that had an impact on the final payment. Plan sponsors must inform CMS immediately upon such a finding.

50. History of Risk Adjustment

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The Balanced Budget Act of 1997 (BBA) mandated that a risk adjustment payment methodology, incorporating information on beneficiaries' health status, be implemented in the Medicare+Choice (M+C) program (now the Medicare Advantage program) no later than January 2000. Under the BBA, risk adjustment of M+C payments was initially to be based only on data from enrollees' inpatient hospital stays, with later implementation of risk adjustment based on data from additional sites of care. CMS selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method to be implemented in 2000. This model recognizes diagnoses for which inpatient care is most frequently appropriate and which are predictive of higher future costs.

To assist managed care organizations, CMS provided for a gradual phase-in of risk adjusted payment, initially adjusting only a portion of the total payment based on the PIP-DCG methodology - and later the CMS Hierarchical Condition Category (HCC) methodology - with the remainder still adjusted under the pre-BBA method based only on demographic information. This phase in was intended to provide more stable payments to M+C organizations.

The phase in schedule was as follows:

<table>
<tr><th>Payment year</th><th>MA plans</th><th>Evercare*</th><th>SHMO*</th><th>PACE and dual demonstrations*</th></tr>
<tr><td>2000-2003</td><td>10% risk/90% demographic</td><td>100% demographic</td><td>100% demographic</td><td>100% demographic</td></tr>
<tr><td>2004</td><td colspan="3">30% risk/70% demographic</td><td>10% risk/90% demographic</td></tr>
<tr><td>2005</td><td colspan="2">50% risk/50% demographic</td><td colspan="2">30% risk/70% demographic</td></tr>
<tr><td>2006</td><td colspan="2">75% risk/25% demographic</td><td colspan="2">50% risk/50% demographic</td></tr>
<tr><td>2007</td><td colspan="2" rowspan="2">100% risk/0% demographic</td><td colspan="2">75% risk/25% demographic</td></tr>
<tr><td>2008 and later</td><td colspan="2">100% risk/0% demographic</td></tr>
</table>

*Note: For MA plans (formerly M+C plans), the demographic-only portion of the payment was adjusted for age, gender, Medicaid eligibility, institutional status, and working aged status. For certain demonstrations, the non-risk portion of the payment may have involved a demonstration-specific payment methodology.

ESRD risk adjustment was implemented at 100% in 2005. Part D risk adjustment was implemented at 100% in 2006.

70.1 Calibration of the CMS-HCC Risk Adjustment Models

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The CMS-HCC risk adjustment model is used to adjust payments for Part C benefits offered by MA plans and PACE organizations to aged/disabled beneficiaries. The CMS-HCC model includes both diseases and demographic factors. There are separate sets of coefficients for beneficiaries in the community, beneficiaries in long term care institutions, and new enrollees. The CMS-HCC model was first used for payment in 2004 and has been recalibrated two times since then (2007 and 2009).

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. When developing the model, CMS consulted with a panel of outside clinicians to review the ICD-9 codes in order to group them with other clinically similar ICD-9 codes. These diagnosis groupings were then mapped to condition categories based on similar clinical characteristics and severity, and cost implications. Both the panel of clinicians and analyses of cost data informed the creation of condition categories.

Coefficients for condition categories were estimated 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. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (e.g., age/sex group, Medicaid status, disability status).

While all ICD-9 codes are mapped to a condition category, not all condition categories are included in the model used in payment. The decision to include a condition category in the model is based on each category's ability to predict costs for Medicare Parts A and B benefits. Condition categories that don't predict costs well – because the coefficient is small, the t-value is low, the number of beneficiaries with a certain condition is small so the coefficient is unstable, or the condition does not have well specified diagnostic coding – are not included in the model.

In a final step, hierarchies were imposed on the condition categories, assuring that more advanced and costly forms of a condition are reflected in the risk score.

In order to use the risk adjustment model to calculate risk scores for payment, CMS creates a relative factor for each demographic factor and HCC in the model. CMS does this by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year (i.e., the "denominator year"). See Table 3 below for a list of data years and denominator years in each version of the risk adjustment model. The relative factors are used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year for the FFS population.

Each time the risk adjustment model is recalibrated, the relative factors can change. Changes in the dollar coefficients resulting from the regression – the marginal cost attributable to an HCC – can change relative to the average cost. For example, the coefficient for diabetes can increase, reflecting higher costs for the disease; but if the average cost for Medicare beneficiaries has

increased even more than for diabetes, then the relative cost of diabetes will decrease. This decrease in relative cost will be reflected in a decrease in the relative factor, even though the costs associated with diabetes have increased.
Although recalibrated models retain an average 1.0 risk score, individual beneficiaries' risk scores may change, as may plan average risk scores, depending on each individual beneficiaries' combination of diagnoses.

Table 3. Data Years and Denominator Years

Payment Years	Diagnoses Year	Costs Year	Denominator Year
2004, 2005, 2006	1999	2000	2000
2007, 2008	2002	2003	2005
2009, 2010, 2011	2004	2005	2007

70.2 CMS-HCC Risk Adjustment Model

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The CMS-HCC risk adjustment model is used to calculate risk scores for aged/disabled beneficiaries and is used in bidding and payment for Part A and B benefits, under the Part C program. In this section, CMS will discuss in detail the specific characteristics of the CMS-HCC risk adjustment model.

70.2.1 Community, Institutional, and New Enrollee Segments

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

MA uses separate models for aged/disabled (non-ESRD) community and long-term institutional residents. CMS created the separate models because there are significant cost differences between the community-based Medicare beneficiaries and the long-term institutionalized beneficiaries with the same disease profile. Adjusting payment for place of residence improves payment accuracy.

Long-term institutionalized MA enrollees are individuals residing in an institution for more than 90 days as identified using 90-day assessments in the Minimum Data Set (MDS). Short term institutionalized MA beneficiaries are included in the community population.

During the payment year, CMS assigns a new enrollee factor to any beneficiary who does not have 12 months of diagnoses to support a risk score. Operationally, CMS identifies new enrollees as those beneficiaries with less than 12 months of Medicare Part B entitlement during the data collection year.

Part A only enrollees are defined as beneficiaries with 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period and are treated as new enrollees, unless the enrolling organization elects to have them treated as a full risk enrollee.

120.2.3 Diagnosis Cluster

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The diagnosis cluster contains the core information regarding each diagnosis submitted by an MA organization. The following components are included in the cluster:

- Provider Type
- From Date
- Through Date
- Delete Indicator
- Diagnosis Code

A maximum of 10 diagnosis clusters are allowed per CCC record. Each cluster must include the items identified above. If any of these attributes are submitted more than once for the same HIC number, a duplicate diagnosis cluster error will occur.

ICD-9-CM Diagnosis Codes - *International Classification of Diseases-9th Edition-Clinical Modification (ICD-9-CM)* codes are 3- to 5-digit codes used to describe the clinical reason for a patient's treatment. ICD-9-CM codes describe the patient's medical condition, not the service performed. Diagnosis codes drive the risk scores, which drive the risk adjusted reimbursement from CMS to MA organizations.

Service From and Through Dates – Defines the start and end dates for a provided service. The correct submission format for the "From" and "Through" dates of service is CCYYMMDD. The "Through Date" defines the data used in the data collection year for risk adjustment purposes. Table 21 describes the "From" and "Through" dates.

Table 21. From and Through Dates

PROVIDER TYPE	FROM DATE	THROUGH DATE
Hospital Inpatient	Admission Date	Must have a through date and must be the discharge date
Hospital Outpatient	Exact date of patient visit or the first date service began for a series of services	Exact date of patient visit or the last date of service for a series of services
Physician		

Hospital Inpatient dates of service must reflect the final bill. Interim bills are not acceptable for risk adjustment data.

MA organizations may submit several occurrences of the same diagnosis in one cluster with a 31-date span. The "From" date will reflect the first occurrence and the "Through" date will reflect the final occurrence within the 31 days.

Delete Indicator – To delete a diagnosis, for correction purposes, that has been stored in the RAPS database, a "D" is entered. If not correcting a diagnosis, then a space is entered.

Provider Type – For risk adjustment purposes, MA organizations are responsible for collecting data from the acceptable data sources (hospital inpatient, hospital outpatient, and physician) and determining the provider type based on the source of data.

Type of Bill (TOB), which is coded on the UB-92 and UB-04 during the collection of hospital data, may be used to assist in translating the correct provider type.

Table 22 lists the acceptable sources of data, provider types, provider type codes, TOB.

Table 22. Provider Type and Code

Source of Data	Provider Type	Provider Type Code	Type of Bill
Hospital Inpatient	Hospital Inpatient Principle Diagnosis	01	111 or 11Z
Hospital Inpatient	Hospital Inpatient Other Diagnosis	02	111 or 11Z
Hospital Outpatient	Hospital Outpatient	10	131, 13Z, 141 or 14Z
Physician	Physician	20	N/A

120.2.4 Valid Diagnosis Codes

(Rev.114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

Valid diagnosis codes are those that are published for the fiscal years pertaining to the CMS-HCC risk adjustment model in use for a particular payment year. Current model diagnosis codes are ICD-9-CM codes that CMS accepts as valid, and are also included in the current version of the CMS-HCC model; only these diagnosis codes affect the risk score in a particular payment year. Future model diagnosis codes are ICD-9-CM codes that are currently valid, but are not included in the current version of the CMS-HCC model and, therefore, do not count toward the risk score.

A current model diagnosis code must meet the following criteria:

1. The diagnosis is included in the CMS-Hierarchical Condition Category (CMS-HCC), Prescription Drug (CMS-RxHCC) or End Stage Renal Disease (CMS-HCC ESRD) risk adjustment models.
2. The diagnosis must be received from one of the three provider types (hospital inpatient, hospital outpatient, and physician) covered by the risk adjustment requirements.
3. The diagnosis must be collected according to the risk adjustment data collection instructions.

A list of current and future ICD-9-CM codes for the CMS-HCC, ESRD, and RxHCC risk adjustment models for any given payment year includes published National Center for Health

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.

CMS recalibrated the CMS-HCC risk adjustment model using 100 percent fee-for-service (FFS) claims for the years 2010 and 2011. Specifically, 2010 diagnoses were used to predict 2011 expenditures.

In addition to using more recent data years in recalibrating the model, the new CMS-HCC model will reflect a clinical update that involved reviewing all ICD-9 diagnoses codes. In consultation with a panel of outside clinicians, CMS reviewed and grouped clinically similar ICD-9 codes into diagnosis groupings, which are used as the building blocks of the condition categories. These diagnosis groupings were then mapped to condition categories based on similar clinical characteristics and cost implications. Both the panel of clinicians and analyses of cost data informed CMS' creation of condition categories.

We estimated coefficients for condition categories and demographic factors by regressing the total expenditure for A/B benefits for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (for example, age/sex group, Medicaid status, disability status) in predicting FFS per capita costs.

Changes to the condition categories, such as additions, deletions, and revisions, are based on each condition category's ability to predict costs for Medicare Parts A and B benefits. Condition categories that do not predict costs well – because the coefficient is small, the t-value is low, a small number of beneficiaries with a certain condition results in an unstable coefficient, or the condition does not have well-specified diagnostic coding – are not included in the model. There were no changes in the demographic factors used in the CMS-HCC model.

In a final step, hierarchies were imposed on the condition categories, assuring that more advanced and costly forms of a condition are reflected in a higher coefficient. Hierarchies also ensure that double credit is not given when a beneficiary develops a more severe form of a condition. For example, if a beneficiary has diagnoses that map to both Chronic Kidney Disease (CKD), Severe (Stage 4) (HCC 137) and CKD, Stage 5 (HCC 136), then this beneficiary's risk score will reflect CKD, Stage 5 and not CKD, Severe (Stage 4).

In order to use the risk adjustment model to calculate risk scores for payment, we create relative factors for each demographic factor and HCC in the model. We do this by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year (that is, the "denominator year"). For 2014, CMS used the predicted per capita costs for 2012, adjusted for model phase in (see Phase in of New Model discussion below). The relative factors are used to calculate risk scores for individual beneficiaries. The denominator, which is used to create relative factors for all segments of the CMS-HCC model, is $9,050.01.

Differences between the current model and the revised model will occur for several reasons. Changes in the marginal cost attributable to an HCC, relative to changes in the average cost, can alter the relative factor associated with that HCC. Similarly, changes in the marginal cost

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

Table 1. 2014 CMS-HCC Model Relative Factors for Community and Institutional Beneficiaries

Variable		Community	Institutional
Female			
0-34 Years		0.197	1.169
35-44 Years		0.205	0.949
45-54 Years		0.263	0.915
55-59 Years		0.326	0.981
60-64 Years		0.392	0.986
65-69 Years		0.288	1.237
70-74 Years		0.348	1.145
75-79 Years		0.437	1.033
80-84 Years		0.539	0.922
85-89 Years		0.677	0.836
90-94 Years		0.815	0.705
95 Years or Over		0.840	0.533
Male			
0-34 Years		0.121	1.162
35-44 Years		0.124	0.894
45-54 Years		0.181	0.910
55-59 Years		0.269	0.951
60-64 Years		0.311	1.081
65-69 Years		0.288	1.388
70-74 Years		0.356	1.431
75-79 Years		0.442	1.391
80-84 Years		0.543	1.327
85-89 Years		0.683	1.252
90-94 Years		0.848	1.076
95 Years or Over		1.028	0.948
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.151	0.067
Medicaid_Female_Disabled		0.085	0.067
Medicaid_Male_Aged		0.177	0.067
Medicaid_Male_Disabled		0.086	0.067
Originally Disabled_Female		0.239	0.013
Originally Disabled_Male		0.163	0.013
Disease Coefficients	**Description Label**		
HCC1	HIV/AIDS	0.470	1.904
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.535	0.575
HCC6	Opportunistic Infections	0.440	0.344
HCC8	Metastatic Cancer and Acute Leukemia	2.484	1.203
HCC9	Lung and Other Severe Cancers	0.973	0.674
HCC10	Lymphoma and Other Cancers	0.672	0.412
HCC11	Colorectal, Bladder, and Other Cancers	0.317	0.296
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.154	0.198
HCC17	Diabetes with Acute Complications	0.368	0.474
HCC18	Diabetes with Chronic Complications	0.368	0.474
HCC19	Diabetes without Complication	0.118	0.182
HCC21	Protein-Calorie Malnutrition	0.713	0.399
HCC22	Morbid Obesity	0.365	0.579

Variable		Community	Institutional
HCC23	Other Significant Endocrine and Metabolic Disorders	0.245	0.282
HCC27	End-Stage Liver Disease	0.923	1.083
HCC28	Cirrhosis of Liver	0.399	0.351
HCC29	Chronic Hepatitis	0.251	0.351
HCC33	Intestinal Obstruction/Perforation	0.310	0.384
HCC34	Chronic Pancreatitis	0.286	0.095
HCC35	Inflammatory Bowel Disease	0.302	0.318
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.498	0.340
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.374	0.351
HCC46	Severe Hematological Disorders	1.136	0.794
HCC47	Disorders of Immunity	0.521	0.519
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.252	0.164
HCC54	Drug/Alcohol Psychosis	0.420	0.053
HCC55	Drug/Alcohol Dependence	0.420	0.053
HCC57	Schizophrenia	0.490	0.311
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.330	0.311
HCC70	Quadriplegia	1.234	0.650
HCC71	Paraplegia	1.052	0.539
HCC72	Spinal Cord Disorders/Injuries	0.509	0.280
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.958	0.367
HCC74	Cerebral Palsy	0.045	-
HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	0.408	0.300
HCC76	Muscular Dystrophy	0.565	0.215
HCC77	Multiple Sclerosis	0.556	-
HCC78	Parkinson's and Huntington's Diseases	0.691	0.173
HCC79	Seizure Disorders and Convulsions	0.284	0.144
HCC80	Coma, Brain Compression/Anoxic Damage	0.570	0.104
HCC82	Respirator Dependence/Tracheostomy Status	1.520	1.769
HCC83	Respiratory Arrest	0.802	1.169
HCC84	Cardio-Respiratory Failure and Shock	0.329	0.442
HCC85	Congestive Heart Failure	0.368	0.229
HCC86	Acute Myocardial Infarction	0.275	0.515
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.258	0.515
HCC88	Angina Pectoris	0.141	0.474
HCC96	Specified Heart Arrhythmias	0.295	0.262
HCC99	Cerebral Hemorrhage	0.339	0.216
HCC100	Ischemic or Unspecified Stroke	0.317	0.216
HCC103	Hemiplegia/Hemiparesis	0.581	0.061
HCC104	Monoplegia, Other Paralytic Syndromes	0.396	0.061
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.413	0.886
HCC107	Vascular Disease with Complications	0.410	0.301
HCC108	Vascular Disease	0.299	0.107
HCC110	Cystic Fibrosis	0.417	0.364
HCC111	Chronic Obstructive Pulmonary Disease	0.346	0.364

Variable		Community	Institutional
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.274	0.260
HCC114	Aspiration and Specified Bacterial Pneumonias	0.672	0.285
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.200	0.285
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.203	0.433
HCC124	Exudative Macular Degeneration	0.335	0.166
HCC134	Dialysis Status	0.476	0.509
HCC135	Acute Renal Failure	0.476	0.509
HCC136	Chronic Kidney Disease (Stage 5)	0.224	0.509
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.224	0.294
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.488	1.050
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.338	0.435
HCC161	Chronic Ulcer of Skin, Except Pressure	0.536	0.311
HCC162	Severe Skin Burn or Condition	0.411	0.327
HCC166	Severe Head Injury	0.570	0.104
HCC167	Major Head Injury	0.163	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.497	0.228
HCC170	Hip Fracture/Dislocation	0.446	-
HCC173	Traumatic Amputations and Complications	0.265	0.122
HCC176	Complications of Specified Implanted Device or Graft	0.566	0.522
HCC186	Major Organ Transplant or Replacement Status	0.891	0.515
HCC188	Artificial Openings for Feeding or Elimination	0.651	0.594
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.779	0.468
Disease Interactions			
CANCER_IMMUNE	Cancer*Immune Disorders	0.947	-
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.259	0.221
CHF_RENAL	Congestive Heart Failure*Renal Disease	0.317	-
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.456	0.506
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.182	0.189
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.214	-
ARTIF_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	-	0.282
ASP_SPEC_BACT_PNEUM_PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	-	0.495
COPD_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	-	0.319
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	-	0.212
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	-	0.389
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	-	0.452

Variable		Community	Institutional
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	-	0.553
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	-	0.339
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	-	0.522
Disabled/Disease Interactions			
DISABLED_HCC6	Disabled, Opportunistic Infections	0.451	-
DISABLED_HCC34	Disabled, Chronic Pancreatitis	0.548	-
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	-	0.383
DISABLED_HCC46	Disabled, Severe Hematological Disorders	1.347	-
DISABLED_HCC54	Disabled, Drug/Alcohol Psychosis	0.331	-
DISABLED_HCC55	Disabled, Drug/Alcohol Dependence	-	-
DISABLED_HCC77	Disabled, Multiple Sclerosis	-	0.407
DISABLED_HCC85	Disabled, Congestive Heart Failure	-	0.441
DISABLED_HCC110	Disabled, Cystic Fibrosis	2.415	-
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	-	0.430
DISABLED_HCC176	Disabled, Complications of Specified Implanted Device or Graft	0.503	-
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer	-	0.270

Notes:

1. The denominator is $9,276.26.
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Opportunistic Infections = HCC 6.
   Cancer = HCCs 8-12.
   Diabetes = HCCs 17, 18, 19.
   Bone/Joint/Muscle Infections/Necrosis = HCC 39.
   Immune Disorders = HCC 47.
   Schizophrenia = HCC 57.
   Multiple Sclerosis = HCC 77.
   Seizure Disorders and Convulsions = HCC 79.
   Cardiorespiratory Failure = HCCs 82-84.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Aspiration and Specified Bacterial Pneumonias = HCC 114.
   Renal Disease = HCCs 134-137.
   Pressure Ulcer = HCCs 157-158. HCCs 159-160 are no longer included in the pressure ulcer interaction terms.
   Chronic Ulcer of Skin, except Pressure = HCC 161.
   Artificial Openings for Feeding or Elimination = HCC 188.

Sources:
RTI International analysis of 2010-2011 Medicare 100% data and RTI International analysis of 2010-2011 Medicare 100% institutional sample.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

2012 Regional Technical Assistance Participant Guide

Monday, August 6 – Tuesday, August 7, 2012

Encounter Data

ARDX
A. Reddix & Associates

- 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.

CHAD A. READLER
Acting Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
JOHN E. LEE (CBN 128696)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; Fax: (716) 551-3052
Email: 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.* BENJAMIN POEHLING, Plaintiffs, v. UNITEDHEALTH GROUP, INC., *et al.*, Defendants.	No. CV 16-08697 MWF (SSx) UNITED STATES' AND RELATOR POEHLING'S JOINT REQUEST FOR JUDICIAL NOTICE; EXHIBITS Date: July 30, 2018 Time: 10:00 a.m. Court: 5A. Hon. Michael W. Fitzgerald

Additional Attorneys (continued from previous page):

ERIC R. HAVIAN (CBN 102295)
ehavian@constantinecannon.com
HARRY LITMAN (CBN 127202)
hlitman@constantinecannon.com
JESSICA T. MOORE (CBN 183431)
jmoore@constantinecannon.com
HENRY C. SU (CBN 211202)
hsu@constantinecannon.com
Constantine Cannon LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Facsimile: (415) 639-4002

STEPHEN HASEGAWA (CBN 198472)
shasegawa@phillipsandcohen.com
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Facsimile: (415) 836-9001

WILLIAM CHRISTOPHER CARMODY (*pro hac vice*)
wcarmody@susmangodfrey.com
ARUN SUBRAMANIAN (*pro hac vice*)
asubramanian@susmangodfrey.com
GENG CHEN (*pro hac vice*)
gchen@susmangodfrey.com
Susman Godfrey L.L.P.
1301 Avenue of the Americas, 32nd Floor
New York, New York 10019-6023
Tel: (212) 336-8330
Facsimile: (212) 336-8340

MENG XI (CBN 280099)
mxi@susmangodfrey.com
CATRIONA LAVERY (CBN 310546)
clavery@susmangodfrey.com
Susman Godfrey L.L.P.
1900 Avenue of the Stars, Suite 1400
Los Angeles, California 90067
Tel: (310) 789-3100
Facsimile: (310) 789-3100

Attorneys for Relator Benjamin Poehling

Pursuant to Rule 201(b)(2), Fed. R. Evid., the United States of America and relator Benjamin Poehling, by their attorneys, respectfully request that, in connection with their Joint Motion for Partial Summary Judgment, the Court take judicial notice of the following documents, true and correct copies of which are submitted herewith:

Exhibit 9: Joint Answering Brief of Defendants-Appellees, *United States v. United Healthcare Ins. Co.*, No. 13-56746, Dkt. 39, at 4 (9th Cir. filed June 2, 2014).

Exhibit 10: Joint Appendix of Rulemaking Record Excerpts, *United Healthcare Ins. Co. v. Hargan*, CV 16-157-RMC, ICD-9 Guidelines, at Preface 1, 5 (AR005952, AR011375) (D.D.C. filed Mar. 1, 2018).

Exhibit 11: ICD-10-CM Official Guidelines for Coding and Reporting, at 1, available at https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2018-ICD-10-CM-Coding-Guidelines.pdf (last accessed May 10, 2018).

Exhibit 12: Mem. in Support of United's Mot. for Summ. J., *United Healthcare Ins. Co. v. Hargan*, CV 16-157-RMC, Dkt. 47-1, at 1-2, 21-22 (D.D.C. filed Oct. 17, 2017).

Exhibit 13: 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).

Exhibit 14: United's Opp'n to Govt's Mot. for Summ. J., *United Healthcare Ins. Co. v. Hargan*, CV 16-157-RMC, Dkt. 60, at 18 (D.D.C. filed Jan. 18, 2018).

Exhibit 15: Letter from Abid R. Qureshi, at 4 (Nov. 7, 2017).

See Reyn's Pasta Bella, LLC v. Visa USA, Inc., 442 F.3d 741, 746 n.6 (9th Cir. 2006) (stating "We may take judicial notice of court filings and other matters of public record" and taking judicial notice of briefs and transcripts from other courts); *United States ex rel. Robinson Rancheria Citizens Council v. Borneo, Inc.*, 971 F.2d 244, 248 (9th Cir. 1992) (court may take judicial notice of "proceedings in other courts . . . if those proceedings have a direct relation to matters at issue); *Daniels–Hall v. Nat'l*

Education Association, 629 F.3d 992, 999 (9th Cir.2010) (taking judicial notice of information on the websites of government entities).

Respectfully submitted,

Dated: May 22, 2018

CHAD A. READLER
Acting Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
Assistant United States Attorneys

MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Civil Division, Department of Justice

JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney
Attorneys for the United States of America

Dated: May 22, 2018

ERIC R. HAVIAN
HARRY LITMAN
JESSICA MOORE
Constantine Cannon LLP

STEVE HASEGAWA
Phillips & Cohen LLP

WILLIAM CHRISTOPHER CARMODY
ARUN SUBRAMANIAN
MATTHEW R. BERRY
JOHN P. LAHAD
Susman Godfrey LLP

/S/ Henry C. Su

HENRY C. SU
Attorneys for Relator Beniamin Poehling

Attestation

I hereby attest that the other signatory listed, on whose behalf the filing is submitted, concurs in the filing's content and has authorized the filing.

Dated: May 22, 2018

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney

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, a Minnesota Corporation; UHIC; UNITEDHEALTH GROUP; UNITED HEALTHCARE; UNITEDHEALTH; PACIFICARE OF CALIFORNIA; 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

JOINT ANSWERING BRIEF OF DEFENDANTS-APPELLEES

LATHAM & WATKINS LLP
David J. Schindler
Michael C. Godino
355 South Grand Avenue
Los Angeles, CA 90071
Telephone: (213) 485-1234
Facsimile: (213) 891-8763

F.3d 40, 48 (1st Cir. 2009) (leave to amend denied in an FCA case based on the "repeated failure to cure the deficiencies in the[] pleadings"); *United States ex rel. Gale v. Raytheon Co.*, No 05cv2264-MMA(LSP), 2009 WL 3378976, at *4 (S.D. Cal. Oct. 19, 2009) (dismissing complaint with prejudice in an FCA case because plaintiff's second amended complaint "demonstrated to the Court that he cannot allege additional facts to satisfy the level of particularity required under Rule 9(b)" and amendment would therefore have been futile).

1. It is Undisputed That the TAC Failed to State an Actionable Claim Under the False Claims Act.

The crux of Swoben's allegations in the TAC is that in the course of engaging in retrospective reviews of medical charts, neither HealthCare Partners nor the "coding companies" retained by the Defendant MA Plans sought to compare codes previously submitted by providers with the codes found by the chart reviewers, and that, as a result, the Defendant MA Plans failed to delete, or insure deletion of, allegedly unsupported diagnosis codes previously submitted to CMS. Notably, the TAC did not allege that any of the reviewers actually knew that any previously-submitted codes were unsupported; on the contrary, it affirmatively alleges that the reviewers were *not* aware of the providers' prior coding decisions.

As the district court correctly held, and as Swoben does not dispute, the TAC did not set forth sufficient specific factual allegations against the Defendants

that support the key elements of a False Claims Act violation. To state a claim under the FCA, the complaint must allege "(1) a false statement or fraudulent course of conduct, (2) made with requisite scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Lee v. Corinthian Coll.*, 655 F.3d 984, 992 (9th Cir. 2011). A complaint must do more than generally allege these elements to survive a motion to dismiss. Even under Rule 8's standards it must, "together with all reasonable inference, state a plausible claim for relief." *Cafasso*, 637 F.3d at 1054 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). In addition, because an FCA claim is an allegation of fraud, FCA claims must be pled with the particularity required by the heightened pleading standard of Rule 9(b). *Cafasso*, 637 F.3d at 1054.

Further, "'[i]t seems to be a fairly obvious notion that a False Claims Act suit ought to require a false claim.'" *Id.* at 1055 (quoting *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 997 (9th Cir. 2002)). "[T]he [FCA] attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.' " *Cafasso*, 637 F.3d at 1055 (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)). Accordingly, to satisfy Rule 9(b), a plaintiff must plead specific facts creating a strong inference that the alleged conduct actually resulted in the submission of false claims for payment. *Ebeid*, 616 F.3d at 998-99.

The allegations in the TAC do not describe *any* specific instances of falsity, let alone any such instances *with particularity* by identifying the time, place, and manner of the alleged falsity, the person making the false representation, or what they obtained thereby. The TAC fails to identify a single instance where previously submitted codes were inconsistent with those identified during the retrospective reviews, or to explain why any such inconsistencies would necessarily lead to false claims.[15]

Nor does the TAC set forth reliable indicia that any false claims were actually submitted. *See Ebeid*, 616 F.3d at 998-99. Swoben, who has not worked for any of the non-SCAN defendants and claims no particular relationship or insider knowledge of the Defendants, offers mainly conclusory statements about

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[15] Swoben cites various statutory and regulatory provisions which he alleges require that MA Plans conducting such retrospective review "must also withdraw previously submitted diagnosis codes that were not supported by properly documented medical charts reviewed in the retrospective review." Opening Br. at 17. However, even a cursory examination of the regulations and statutory provisions reveals that none of the cited provisions set forth any such duty, let alone with the requisite clarity and specificity required to support a False Claims Act theory. *See* 42 U.S.C. §§ 1395*l*(e) (no payment to a provider of services under Medicare unless sufficient information to determine the amounts due), 1395y(a)(1)(A) (no payment under Medicare for items and services unless "reasonable and necessary"); 42 C.F.R. §§ 422, 310(b) (CMS basic data collection rules), 310(d)(1) (CMS data requirements); *see also Safeco Ins. Co. v. Burr*, 551 U.S. 47 (2007) (finding that "reckless disregard" is an objective standard that is not met in circumstances where the statutory text of the disputed provision is ambiguous, where no authoritative guidance has been given on it, and where the defendant's interpretation was reasonable).

their conduct. Moreover, he ignores a whole host of "obvious alternative explanation[s]," *Cafasso*, 637 F.3d at 1057, for why the failure of a coder to code a particular diagnosis code in a given retrospective review of a medical chart does not render the prior submission of that code by a provider on a claim form and the subsequent transmission of the code by the plan to CMS improper.[16] As explained above, CMS regulations deem a diagnosis code proper if it is supported by a single medical record by a single provider. *See supra* at 11.[17] Accordingly, the absence of documentation for a diagnosis code in a single retrospective review of a single provider's charts does not establish that the submission of that code to CMS was improper: the code may simply be located in charts not encompassed by the retrospective review. Swoben does not allege that the coding companies or

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[16] There are many innocuous explanations for why a reviewer may not have identified the same codes as the original coder. For example, the coding company might simply have made a mistake and failed to identify a properly documented diagnosis in its review of the medical chart. The presence of such "alternative explanations" weighs against drawing "an inference that false claims were part of the scheme alleged." *Cafasso*, 637 F.3d at 1056-57.

[17] Swoben asserts that the CMS regulation requiring only a single medical record in support of a submitted diagnosis code is limited to the RADV audit context. Opening Br. 39. But that strained distinction omits that the entire purpose of a RADV audit is to determine whether the diagnosis codes submitted by MA plans are valid. *See CMS Final Payment Error Calculation Methodology*, *supra* note 6, at 1. Indeed, Swoben himself concedes in a footnote that CMS recently began employing RADV audits to determine whether or not a given MA Plan has been overpaid. Opening Br. at 39 n. 23. Tellingly, Swoben does not identify any regulation or legal authority requiring *more* than a single medical record from a single provider in support of a diagnosis code submitted to CMS.

HealthCare Partners reviewed every single chart or every encounter for each of the tens of thousands of patients (nor, plausibly, could he), and a particular member may have multiple charts for any number of reasons (*e.g.*, a beneficiary might visit multiple providers, or might have multiple charts from the same provider based on separate encounters from different office locations or dates of service). Thus, simply alleging that a retrospective review of a single encounter did not identify every diagnosis code previously submitted for that particular member, does not in any way warrant concluding that the unidentified diagnosis codes are erroneous.[18]

The FCA theory set forth in the Third Amended Complaint and the proposed Fourth Amended Complaint amounted to no more than sheer speculation. This Court refuses to allow complaints to proceed upon that basis, particularly where obvious alternative explanations such as those described above exist. *See Cafasso*, 637 F.3d at 1057.

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[18] In addition, because multiple different diagnosis codes can "map to" (i.e. lead to) the same HCC, and because submission of a single valid diagnosis code is sufficient to support an HCC, it may very well be that even if a particular diagnosis is in fact not adequately documented, the patient may have a different diagnosis that "maps to" the same HCC, or a more severe HCC. *See supra* at 9-11. In other words, the same, or an even higher, capitated payment may be warranted for that particular beneficiary based on a completely different diagnosis code that was properly documented. In short, a single review of a single patient encounter (or even multiple, but not all, relevant encounters) does not necessarily yield sufficient data to support any conclusion regarding the "accurate" HCC risk score associated with any beneficiary, let alone demonstrate that a plan falsely represented the risk score to which it was entitled.

Swoben also impermissibly lumps numerous, distinct entities together as "defendant HMOs" throughout the TAC. *Corinthian Coll.*, 655 F.3d at 997-98 ("Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud.") (quotation and citation omitted). Swoben's TAC does not articulate which allegations apply to which defendants and includes no particularized allegations at all with respect to WellPoint, Aetna, or Health Net. Instead, the TAC addresses these entities by name only to identify them as parties, to define the term "defendant HMOs," and to discuss the procedural history of his claims.

Swoben's proposed Fourth Amended Complaint does not cure this deficiency. It fails to set forth any allegations, claims, or even information specific to these defendants, as 9(b) requires. *See Comwest, Inc. v. Am. Operator Servs., Inc.*, 765 F. Supp. 1467, 1471 (C.D. Cal. 1991) ("Each defendant is entitled to know what misrepresentations are attributable to them and what fraudulent conduct they are charged with . . . [and] [i]n order to satisfy Rule 9(b), fraud claims 'must allege the roles of defendants in sufficient detail to permit each to assess and answer the various claims of . . . liability asserted in the complaint.'") (internal quotation and citations omitted).

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 Acting Secretary of the Department of Health and Human Services, *et al.*, Defendants.	No. 1:16-cv-00157-RMC

JOINT APPENDIX OF RULEMAKING RECORD EXCERPTS

VOLUME 1 of 5

AR000001 - AR002830

PREFACE

This sixth edition of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) is being published by the United States Government in recognition of its responsibility to promulgate this classification throughout the United States for morbidity coding. The International Classification of Diseases, 9th Revision, published by the World Health Organization (WHO) is the foundation of the ICD-9-CM and continues to be the classification employed in cause-of-death coding in the United States. The ICD-9-CM is completely comparable with the ICD-9. The WHO Collaborating Center for Classification of Diseases in North America serves as liaison between the international obligations for comparable classifications and the national health data needs of the United States.

The ICD-9-CM is recommended for use in all clinical settings but is required for reporting diagnoses and diseases to all U.S. Public Health Service and Health Care Financing Administration programs. Guidance in the use of this classification can be found in the section "Guidance in the Use of ICD-9-CM."

ICD-9-CM extensions, interpretations, modifications, addenda, or errata other than those approved by the U.S. Public Health Service and the Health Care Financing Administration are not to be considered official and should not be utilized. Continuous maintenance of the ICD-9- CM is the responsibility of the Federal Government. However, because the ICD-9-CM represents the best in contemporary thinking of clinicians, nosologists, epidemiologists, and statisticians from both public and private sectors, no future modifications will be considered without extensive advice from the appropriate representatives of all major users.

All official authorized addenda through October 1, 2000, have been included in this sixth edition.

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Amy L. Blum, M.H.S.A., R.H.I.A.
Data Policy and Standards Staff
National Center for Health Statistics

Lizabeth J. Wing, R.H.I.A.
Data Policy and Standards Staff
National Center for Health Statistics

Linda Washington
Marketing
National Center for Health Statistics

Development InfoStructure
1137 N. Highland St.
Arlington, VA 22201
Contact: David W. Martin

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cerebrovascular disease when no neurologic deficits are present.

1.8 Uncertain Diagnosis

If the diagnosis documented at the time of discharge is qualified as "probable", "suspected", "likely", "questionable", "possible", or "still to be ruled out", code the condition as if it existed or was established. The bases for this guidelines are the diagnostic workup, arrangements for further workup or observation, and initial therapeutic approach that correspond most closely with the established diagnosis.

1.9 Impending or Threatened Condition

Code any condition described at the time of discharge as "impending" or "threatened" as follows:
If it did occur, code as confirmed diagnosis.
If it did not occur, reference the Alphabetic Index to determine if the condition has a subentry term for "impending" or "threatened" and also reference main term entries for Impending and for Threatened.

If the subterms are listed, assign the given code.
If the subterms are not listed, code the existing forerunner condition(s) and not the condition described as impending or threatened.

2. SELECTION OF PRINCIPAL DIAGNOSIS

The circumstances of inpatient admission always govern the selection of principal diagnosis. The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care".

In determining principal diagnosis the coding directives in the ICD-9-CM manuals, Volumes I, II, and III, take precedence over all other guidelines.

The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation the application of all coding guidelines is a difficult, if not impossible, task.

2.1 Codes for symptoms, signs, and ill-defined conditions.

Codes for symptoms, signs, and ill-defined conditions from Chapter 16 are not to be used as principal diagnosis when a related definitive diagnosis has been established.

2.2 Codes in brackets.

Codes in brackets in the Alphabetic Index can never be sequenced as principal diagnosis. Coding directives require that the codes in brackets be sequenced in the order as they appear in the Alphabetic Index.

2.3 Acute and chronic conditions.

If the same condition is described as both acute (subacute) and chronic and separate subentries exist in the Alphabetic Index at the same indentation level, code both and sequence the acute (subacute) code first.

2.4 Two or more interrelated conditions, each potentially meeting the definition for principal diagnosis.

When there are two or more interrelated conditions (such as diseases in the same ICD-9-CM chapter or manifestations characteristically associated with a certain disease) potentially meeting the definition of principal diagnosis, either condition may be sequenced first, unless the circumstances of the admission, the therapy provided, the Tabular List, or the Alphabetic Index indicate otherwise.

2.5 Two or more diagnoses that equally meet the definition for principal diagnosis.

In the unusual instance when two or more diagnoses equally meet the criteria for principal diagnosis as determined by the circumstances of admission, diagnostic workup and/or therapy provided, and the Alphabetic Index, Tabular List, or another coding guidelines does not provide sequencing direction, any one of the diagnoses may be sequenced first.

2.6 Two or more comparative or contrasting conditions.

In those rare instances when two or more contrasting or comparative diagnoses are documented as "either/or" (or similar terminology), they are coded as if the diagnoses were confirmed and the diagnoses are sequenced according to the circumstances of the admission. If no further determination can be made as to which diagnosis should be principal, either diagnosis may be sequenced first.

2.7 A symptom(s) followed by contrasting/comparative diagnoses.

When a symptom(s) is followed by contrasting/comparative diagnoses, the symptom code is sequenced first. All the contrasting/comparative diagnoses should be coded as suspected conditions.

2.8 Codes from the V71.0-V71.9 series, Observation and evaluation for suspected conditions.

Codes from the V71.0-V71.9 series are assigned as principal diagnoses for encounters or admissions to evaluate the patient's condition when there is some evidence to suggest the existence of an abnormal condition or following an accident or other incident that ordinarily results in a health problem, and where no supporting evidence for the suspected condition is found and no treatment is currently required. The fact that the patient may be scheduled for continuing observation in the office/clinic setting following discharge does not limit the use of this category.

2.9 Original treatment plan not carried out.

Sequence as the principal diagnosis the condition which after study occasioned the admission to the hospital, even though treatment may not have been carried out due to unforeseen circumstances.

2.10 Residual condition or nature of late effect.

The residual condition or nature of the late effect is sequenced first, followed by the late effect code for the cause of the residual condition, except in a few instances where the Alphabetic Index or Tabular List directs otherwise.

2.11 Multiple burns.

Sequence first the code that reflects the highest degree of burn when more than one burn is present. (See also Burns guideline 8.3)

2.12 Multiple injuries.

When multiple injuries exist, the code for the most severe injury as determined by the attending physician is sequenced first.

2.13 Neoplasms.

A. If the treatment is directed at the malignancy, designate the malignancy as the principal diagnosis, except when the purpose of the encounter or hospital admission is for radiotherapy session(s), V58.0, or for chemotherapy session(s), V58.1, in which instance the malignancy is coded and sequenced second.

B. When a patient is admitted for the purpose of radiotherapy or chemotherapy and develops complications such as uncontrolled nausea and vomiting or dehydration,

the principal diagnosis is Encounter for radiotherapy, V58.0, or Encounter for chemotherapy, V58.1.

C. When an episode of inpatient care involves surgical removal of a primary site or secondary site malignancy followed by adjunct chemotherapy or radiotherapy, code the malignancy as the principal diagnosis, using codes in the 140-198 series or where appropriate in the 200-203 series.

D. When the reason for admission is to determine the extent of the malignancy, or for a procedure such as paracentesis or thoracentesis, the primary malignancy or appropriate metastatic site is designated as the principal diagnosis, even though chemotherapy or radiotherapy is administered.

E. When the primary malignancy has been previously excised or eradicated from its site and there is not adjunct treatment directed to that site and no evidence of any remaining malignancy at the primary site, use the appropriate code from the V10 series to indicate the former site of primary malignancy. Any mention of extension, invasion, or metastasis to a nearby structure or organ or to a distant site is coded as a secondary malignant neoplasm to that site and may be the principal diagnosis in the absence of the primary site.

F. When a patient is admitted because of a primary neoplasm with metastasis and treatment is directed toward the secondary site only, the secondary neoplasm is designated as the principal diagnosis even though the primary malignancy is still present.

G. Symptoms, signs, and ill-defined conditions listed in Chapter 16 characteristic of, or associated with, an existing primary or secondary site malignancy cannot be used to replace the malignancy as principal diagnosis, regardless of the number of admissions or encounters for treatment and care of the neoplasm.

H. Coding and sequencing of complications associated with the malignant neoplasm or with the therapy thereof are subject to the following guidelines:

When admission is for management of an anemia associated with the malignancy, and the treatment is only for anemia, the anemia is designated at the principal diagnosis and is followed by the appropriate code(s) for the malignancy.
When the admission is for management of an anemia associated with chemotherapy or radiotherapy and the only treatment is for the anemia, the anemia is designated as the principal diagnosis followed by the appropriate code(s) for the malignancy.
When the admission is for management of dehydration due to the malignancy or the therapy, or a combination of both, and only the dehydration is being treated (intravenous rehydration), the dehydration is designated as the principal diagnosis, followed by the code(s) for the malignancy.
When the admission is for treatment of a complication resulting from a surgical procedure performed for the treatment of an intestinal malignancy, designate the complication as the principal diagnosis if treatment is directed at resolving the complication.

2.14 Poisoning

When coding a poisoning or reaction to the improper use of a medication (e.g., wrong dose, wrong substance, wrong route of administration) the poisoning code is sequenced first, followed by a code for the manifestation. If there is also a diagnosis of drug abuse or dependence to the substance, the abuse or dependence is coded as an additional code.

ICD-9-CM Coding Guidelines (FY01)

2.15 Complications of surgery and other medical care.

When the admission is for treatment of a complication resulting from surgery or other medical care, the complication code is sequenced as the principal diagnosis. If the complication is classified to the 996-999 series, an additional code for the specific complication may be assigned.

2.16 Complication of pregnancy.

When a patient is admitted because of a condition that is either a complication pregnancy or that is complicating the pregnancy, the code for the obstetric complication is the principal diagnosis. An additional code may be assigned as needed to provide specificity.

3. REPORTING OTHER (ADDITIONAL) DIAGNOSES

A joint effort between the attending physician and coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures.
These guidelines have been developed and approved by the Cooperating Parties to assure both the physician and the coder in identifying those diagnoses that are to be reported in addition to the principal diagnosis. Hospitals may record other diagnoses as needed for internal data use.
The UHDDS definitions are used by acute care short-term hospitals to report inpatient data elements in a standardized manner. These data elements and their definitions can be found in the July 31, 1985, Federal Register (Vol. 50, No, 147), pp. 31038-40.
The UHDDS item #11-b defines Other Diagnoses as "all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded".
GENERAL RULE
For reporting purposes the definition for "other diagnoses" is interpreted as additional conditions that affect patient care in terms of requiring:

clinical evaluation; or
therapeutic treatment; or
diagnostic procedures; or
extended length of hospital stay; or
increased nursing care and/or monitoring.

The following guidelines are to be applied in designating "other diagnoses" when neither the Alphabetic Index nor the Tabular List in ICD-9-CM provide direction.
The listing of the diagnoses on the attestation statement is the responsibility of the attending physician.

3.1 Previous conditions.

If the physician has included a diagnosis in the final diagnostic statement, such as the discharge summary or the face sheet, it should ordinarily be coded. Some physicians include in the diagnostic statement resolved conditions or diagnoses and status-post procedures from previous admission that have no bearing on the current stay. Such conditions are not to be reported and are coded only if required by hospital policy. However, history codes (V10-V19) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment.

3.2 Diagnoses not listed in the final diagnostic statement.

When the physician has documented what appears to be a current diagnosis in the body of the record, but has not included the diagnosis in the final diagnostic statement, the physician should be asked whether the diagnosis should be added.

3.3 Conditions that are an integral part of a disease process.

Conditions that are integral to the disease process should not be assigned as additional codes.

3.4 Conditions that are not an integral part of a disease process.

ICD-10-CM Official Guidelines for Coding and Reporting
FY 2018
(October 1, 2017 - September 30, 2018)

Narrative changes appear in bold text
Items underlined have been moved within the guidelines since the FY 2017 version
***Italics* are used to indicate revisions to heading changes**

The Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS), two departments within the U.S. Federal Government's Department of Health and Human Services (DHHS) provide the following guidelines for coding and reporting using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). These guidelines should be used as a companion document to the official version of the ICD-10-CM as published on the NCHS website. The ICD-10-CM is a morbidity classification published by the United States for classifying diagnoses and reason for visits in all health care settings. The ICD-10-CM is based on the ICD-10, the statistical classification of disease published by the World Health Organization (WHO).

These guidelines have been approved by the four organizations that make up the Cooperating Parties for the ICD-10-CM: the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), CMS, and NCHS.

These guidelines are a set of rules that have been developed to accompany and complement the official conventions and instructions provided within the ICD-10-CM itself. The instructions and conventions of the classification take precedence over guidelines. These guidelines are based on the coding and sequencing instructions in the Tabular List and Alphabetic Index of ICD-10-CM, but provide additional instruction. Adherence to these guidelines when assigning ICD-10-CM diagnosis codes is required under the Health Insurance Portability and Accountability Act (HIPAA). The diagnosis codes (Tabular List and Alphabetic Index) have been adopted under HIPAA for all healthcare settings. A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. These guidelines have been developed to assist both the healthcare provider and the coder in identifying those diagnoses that are to be reported. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated.

The term encounter is used for all settings, including hospital admissions. In the context of these guidelines, the term provider is used throughout the guidelines to mean physician or any qualified health care practitioner who is legally accountable for establishing the patient's diagnosis. Only this set of guidelines, approved by the Cooperating Parties, is official.

The guidelines are organized into sections. Section I includes the structure and conventions of the classification and general guidelines that apply to the entire classification, and chapter-specific guidelines that correspond to the chapters as they are arranged in the classification. Section II includes guidelines for selection of principal diagnosis for non-outpatient settings. Section III includes guidelines for reporting additional diagnoses in non-outpatient settings. Section IV is for

outpatient coding and reporting. It is necessary to review all sections of the guidelines to fully understand all of the rules and instructions needed to code properly.

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

MEMORANDUM IN SUPPORT OF
UNITED'S MOTION FOR SUMMARY JUDGMENT

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.

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.

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

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

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

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 *over*paid. 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 *under*payment. *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

Abid R. Qureshi
Direct Dial: 202.637.2240
Email: abid.qureshi@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

LATHAM & WATKINS LLP

November 7, 2017

VIA FED EX & EMAIL

John E. Lee
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995

Kathleen A. Lynch
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830

Carol L. Wallack
Justin Draycott
Jessica Krieg
Paul Perkins
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486

Re: Deficiencies in the United States' Responses & Objections to Defendant UHC of California's Requests for Production of Documents (Set No. One) – *United States ex rel. Poehling v. UnitedHealth Group, Inc. et al.*

Dear Counsel:

We write regarding the government's September 25, 2017 Responses to UHC of California's First Request for the Production of Documents to the Government (Set No. One) (the "Responses") in connection with the above-captioned matter.

While it is important to first highlight issues in correspondence, we believe engaging in a dialogue about discovery issues following such correspondence is most likely to facilitate resolution of any disputes. Accordingly, please do let us know if you are available to attend a meet-and-confer next week to discuss the issues highlighted below. During the meeting, we also propose to discuss the parties' timelines for making substantive productions and exchanging privilege logs. UnitedHealth expects to make its first production of documents to the government the week of December 4, 2017. Please confirm that the government will reciprocate and produce documents before or during the same week so that the parties may make meaningful progress on discovery.

To facilitate the parties' expeditious exchange of documents, we have drafted an ESI agreement and proposed protective orders which we expect to provide to you for your review and consideration shortly.

A. The Government Should Not Object to Producing Documents It Previously Agreed to Provide

The government's Responses are inconsistent with positions adopted and accommodations reached during discovery in a proceeding the government has characterized as related, *United States ex rel. Swoben v. Secure Horizons*, CV-09-5013-JFW (JEM) (the "*Swoben* Action"). While the government did voluntarily dismiss the *Swoben* Action, it should not discard the substantial progress the parties made in that case.

As you know, last month, following the parties' exchange of lengthy correspondence and participation in a meet-and-confer, the government agreed to include certain custodians and produce certain categories of documents requested in UnitedHealth's Requests for Production in the *Swoben* Action. *See, e.g.*, UnitedHealth September 25, 2017 Letter in Response to Rule 37 Meet and Confer; DOJ October 3, 2017 Letter Regarding September 25, 2017 Letter in Response to Rule 37 Meet and Confer. Yet the government's Responses in this case include objections and refusals to produce information that are inconsistent with the agreements reached between the parties in that case just a few weeks ago. This about-face seems particularly perplexing in light of the fact that the government has repeatedly taken the position that the scope of its claims in *Poehling* is much broader than in *Swoben*.

Please confirm that the government will abide by its previous commitments when responding to the following Requests:

- **RFPs 17**, **18**, **19**, **23**, **25-28**, **30**, and **37**: Please include the Agency for Healthcare Research as custodians for RFPs **17**, **18**, **19** and the Secretary of the Department of Health & Human Services for RFPs **23** and **25-28**.

- **RFPs 13-15**, **17-19**, **38**, **40-41**, and **47** (documents related to other MA Plans): Please produce: (1) other MA Plans' Risk Adjustment Attestations; (2) documents in CMS' possession specifically related to general practices responsive to an RFP above without mentioning a specific MA Plan; and (3) documents in CMS' possession responsive to an RFP above that are related to other MA Plans' risk adjustment attestations, chart review practices, and validation, submission, or deletion of diagnosis codes as those issues pertain to Risk Adjustment.

- **RFPs 20**, **27**, **28**, **33** and **34** (documents related to the CMS Overpayment Rule and related guidance): Please produce documents relating to internal discussions about whether to incorporate a fee-for-service adjuster into the CMS Overpayment Rule.

- **RFPs 21** and **22** (documents related to UnitedHealth and MA plan bids): The government previously indicated during the meet and confer process that it would produce certain bid-related documents. The parties have discussed the relevancy of the bid documents and UnitedHealth requests that the government produce documents responsive to these requests.

- **RFPs 24** and **36** (documents related to risk adjustment payment methodology): Please search for and produce documents related to the methodology by which CMS calculates Risk Adjustment Factors and that establish that CMS projects its own costs and expenditures on claims data rather than medical charts.

Please note that the list above identifies only the subset of responsive documents the government previously agreed to provide. Of course, UnitedHealth reserves its right to seek all documents responsive to the Requests itemized above.

B. The Government Should Withdraw its Additional Unwarranted Objections

Apart from the issues the parties have already addressed, the government refuses to produce a number of additional categories and sub-categories of documents. As described further below, these objections are unwarranted and inconsistent with the government's discovery obligations. Indeed, the government's own discovery requests seek information based on the very same topics it asserts are somehow irrelevant to the claims and defenses in this case.

Please confirm that the government will not stand on its objections and will instead produce documents responsive to the following Requests:

- **RFPs 5** and **9** (documents related to RADV): The government unilaterally narrows the scope of these requests to include only documents "generally referring to the final results of the CMS National RADV audit for all MA Plans, final results of CMS contract level audits for the 2007 Pilot RADV Audits for all MA Plans, and OIG audit results directly relating to UnitedHealth's MA Plans" and documents "(a) generally referring to RADV (unconnected to a specific non-UnitedHealth MAO or MA plan), (b) generally referring to HCC coding criteria and analysis (unconnected to a specific beneficiary in a non-UnitedHealth plan), and (c) RADV and/or HCC coding criteria related to UnitedHealth's MA Plans." UnitedHealth requests that the government produce all documents responsive to the requests. Documents related to preliminary results of CMS audits, OIG audit results for non-UnitedHealth plans, and communications with Signature Consulting Group specifically referring to RADV and HCC coding criteria, including those related to non-UnitedHealth plans are clearly relevant to both the claims and defenses in this matter. The government's own complaint relies heavily on RADV audits in articulating its theory of liability and the government must allow UnitedHealth to defend itself against the full scope of its theory. *See, e.g.*, Comp. ¶¶ 92, 107, 113, 150, 151.

- **RFPs 6**, **30**, and **35** (fee-for-service coding and error rate adjuster and the Medicare + Choice Program Final Rule): The government refuses to produce documents responsive to UnitedHealth's requests related to the fee-for-service coding and error rate adjuster and the Medicare + Choice Program Final Rule on the basis that some or all are protected by the deliberative process privilege. As the parties discussed during its prior meet and confer process, the deliberative process privilege is very narrow in scope. Contrary to the government's assertions, documents "regarding a topic on which CMS has not yet adopted a policy" are not "necessarily protected by the deliberative process privilege" since these documents may be non-deliberative or factual in nature. *See, e.g.* Resp. to **RFPs 6** and **35**. Moreover, the fact that **RFP 30** requests "internal discussions, analyses and/or calculations" does not warrant a categorical assertion of the deliberative process privilege. *See* DOJ October 3, 2017 Letter Regarding September 25, 2017 Letter in Response to Rule 37 Meet and Confer 3 (agreeing to produce "internal discussions about whether to incorporate a fee-for-service adjuster into the CMS overpayment rule"). Please produce responsive non-privileged documents and provide a log of any documents the government determines meet the narrow reach of the deliberative process privilege.

- **RFP 8** and **37** (documents related to fee-for-service claims data and risk scores): These documents are directly relevant to UnitedHealth's defense that the data verification requirements imposed on MA Plans versus fee-for-service providers violate the governing statute's actuarial equivalence language. Moreover, the government made no relevancy objection to a request for documents on the same topic. *See, e.g.,* Response to **RFP 6**; *see also,* DOJ October 3, 2017 Letter Regarding September 25, 2017 Letter in Response to Rule 37 Meet and Confer (agreeing to produce documents responsive to *Swoben* RFPs 6 and 28). Finally, the government's discovery requests ask for materials on this topic. *See* United States' First Request for Production of Documents from the United Defendants, **RFP 24** ("All Document [sic] relating in any manner to" actuarial equivalence and fee-for-service error rates).

- **RFP 30** (documents related to the Medicare + Choice Program Final Rule): Documents related to this rule are clearly relevant. The government has relied on 65 Fed. Reg. 40170 (June 29, 2000) and its due diligence requirement in this very action as an obligation on UnitedHealth regarding its submissions to CMS. *See, e.g.,* Compl. ¶ 67.

- **RFP 48** (documents related to Marilyn Tavenner's email deletion): Contrary to the government's assertion, documents responsive to **RFP 60** do not relate to whether Ms. Tavenner's emails were preserved nor whether she conducted CMS business through her private email, and these issues are relevant to identifying responsive documents in this case. While UnitedHealth reserves the right to seek document responsive to the full scope of Request 48, as a preliminary subset, please produce documents related to (1) the deletion of emails from Ms. Tavenner's CMS email accounts and (2) her use of a private email address to correspond regarding risk adjustment.

- **RFPs 3, 23, 25, 30, 39** (documents evidencing unofficial interpretations of a statute, regulation or rule): Unofficial interpretations are relevant to this case as they may well demonstrate that certain government employees shared UnitedHealth's understanding of CMS's diagnoses verification requirements. This is a fraud case, and more than an agency's official interpretation of a regulation is relevant to an FCA defendant's defenses.

- **RFP 54** (documents related to deposition testimony of CMS officials): The government's narrowing of UnitedHealth's request to only deposition testimony and to one-way/one-sided chart reviews or to MAOs and MA Plans' obligations to submit diagnoses supported by the beneficiaries' medical records impermissibly excludes relevant materials proportionate to the needs of this case. UnitedHealth requests that the government produce documents related to both depositions and interviews, and materials that relate to all risk adjustment issues – not just the narrow sub-topics that the government believes are most helpful to its enforcement theory.

* * *

Please know this correspondence is not intended to instigate a letter-writing campaign. Instead, UnitedHealth seeks to engage in a productive dialogue to resolve discovery issues promptly. The itemized list of issues above is intended to make such a dialogue more efficient. We look forward to hearing of your availability next week (Nov. 13-17). In addition, UnitedHealth is continuing to study the Responses and reserves all rights, including the right to raise additional issues regarding the sufficiency of the government's compliance with its discovery obligations.

Sincerely yours,

Abid R. Qureshi
of LATHAM & WATKINS LLP

cc: Counsel of Record

CHAD A. READLER
Acting Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
JOHN E. LEE (CBN 128696)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; Fax: (716) 551-3052
Email: 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.* BENJAMIN POEHLING, Plaintiffs, v. UNITEDHEALTH GROUP, INC., *et al.*, Defendants.	No. CV 16-08697 MWF (SSx) [PROPOSED] STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW Date: July 30, 2018 Time: 10:00 a.m. Court: 5A. Hon. Michael W. Fitzgerald

Additional Attorneys (continued from previous page):

ERIC R. HAVIAN (CBN 102295)
ehavian@constantinecannon.com
HARRY LITMAN (CBN 127202)
hlitman@constantinecannon.com
JESSICA T. MOORE (CBN 183431)
jmoore@constantinecannon.com
HENRY C. SU (CBN 211202)
hsu@constantinecannon.com
Constantine Cannon LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Facsimile: (415) 639-4002

STEPHEN HASEGAWA (CBN 198472)
shasegawa@phillipsandcohen.com
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Facsimile: (415) 836-9001

WILLIAM CHRISTOPHER CARMODY (*pro hac vice*)
wcarmody@susmangodfrey.com
ARUN SUBRAMANIAN (*pro hac vice*)
asubramanian@susmangodfrey.com
GENG CHEN (*pro hac vice*)
gchen@susmangodfrey.com
Susman Godfrey L.L.P.
1301 Avenue of the Americas, 32nd Floor
New York, New York 10019-6023
Tel: (212) 336-8330
Facsimile: (212) 336-8340

MENG XI (CBN 280099)
mxi@susmangodfrey.com
CATRIONA LAVERY (CBN 310546)
clavery@susmangodfrey.com
Susman Godfrey L.L.P.
1900 Avenue of the Stars, Suite 1400
Los Angeles, California 90067
Tel: (310) 789-3100
Facsimile: (310) 789-3100

Attorneys for Relator Benjamin Poehling

Upon consideration of the United States' and relator Benjamin Poehling's joint Motion for Partial Summary Judgment, and good cause appearing, the Court hereby finds and concludes as follows:

FINDINGS OF FACT

A. Medicare Parts A, B, and C

1. Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, administered by the Centers for Medicare and Medicaid Services ("CMS"), an agency of the United States Department of Health and Human Services ("HHS").

2. Medicare Part A "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).

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. *Id.* at 2 (citing 42 U.S.C. §§ 1395j to 1395w-4).

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 Advantage Organizations ("MAOs"). *See* 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, *see* 42 U.S.C. § 1395w-22(a)(1), and may also offer supplemental benefits approved by the Secretary of [HHS], *see* 42 U.S.C. § 1395w-22(a)(3)." *Matthews v. Leavitt*, 452 F.3d 145, 146 n.1 (2d Cir. 2006).

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. *See, e.g.* Medicare Advantage

Contract Between United Healthcare of California and CMS ("MA Contract"), 2011, Article IV, CMS Payment to MA Organization (Exhibit 1).[1]

7. Under Parts A and B, CMS pays providers directly for medical services rendered to beneficiaries under a "fee-for-service" regime. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994).

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).

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." *Id.* § 1395w-23(a)(1)(C)(i).

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).

11. MAOs thus receive more for providing benefits to older and sicker people, and less for younger and healthier ones.

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. *Id.*

[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.

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 health status and other demographic factors." *Id.* § 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.

15. Since 2004, the Secretary has used the Hierarchical Condition Category (HCC) model to determine these amounts under Part C.

16. The Secretary has used a similar model (the RxHCC model) to risk adjust for health status under Part D. *See* 42 C.F.R. § 423.329(b)(1), (2).

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.

18. The model includes a set of multipliers – that is, "coefficients" – used to determine "the marginal (additional) cost" of each medical "condition or demographic factor (*e.g.*, 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. *See* 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).

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

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]

21. MAOs submit diagnosis codes to CMS so the agency can apply the multipliers for each beneficiary's health status.

22. Since 2004, they have submitted the codes through CMS's Risk Adjustment Processing System ("RAPS").

23. In the last several years, they submit the codes through RAPS and CMS' Encounter Data System ("EDS").

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. *See, e.g.*, 2013 Medicare Managed Care Manual, Pub. 100-16, chapter 7 at § 120.2.3 (Exhibit 5).

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. *Id*.

[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 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).

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.

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 its payments as part of a routine process. 42 C.F.R. § 422.310(g)(2)(ii).

28. EDS works much the same way with respect to the deletion of invalid diagnosis codes. *See* CMS 2012 Regional Technical Assistance Participant Guide, Encounter Data, at 3-32 to 3-33 (Exhibit 8).

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.

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.

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. *See* 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"); *see also* 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).

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 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.

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).

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. *See e.g.* Signature Attestation page at the end of Exhibit 1.

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. *See, e.g.*, Section A of Article II and Section A(1) of Article IX of the Part C contract, which is part of Exhibit 1.[4]

36. The contracts also required defendants to implement an effective compliance program in accordance with the Part C and D compliance regulations. *See, e.g.*, Section F of Art. III of the MA Contract and Section J of Art. II of the Part D Addendum, also part of Exhibit 1.

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. *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1174 (9th Cir. 2016) (citing 42 C.F.R.

[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.

§ 422.503(b)(4)(vi), (vi)(F), (vi)(G) (2005)); *see also* 42 C.F.R., § 423.504(b)(4)(vi), (vi)(F), (vi)(G) (2007) (Part D compliance regulation setting forth same requirements).

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); s*ee also* 42 C.F.R., § 423.504(b)(4)(vi)(G)(2) (Part D) (same).

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. *See, e.g.,* 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").

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. *See* Section D.2 of Article IV of the MA Contract (Exhibit 1).[5]

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). *Id.*

42. Importantly, this contractual and regulatory attestation requirement imposed affirmative duties on the MAOs and their related entities and contractors.

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

[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).

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. *Swoben*, 848 F.3d at 1174 (citing 65 Fed. Reg. at 40,268); *see also* 2004 Manual (Exhibit 4), § 111.7 (discussing this requirement).

44. Thus, MAOs and their related 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. *Id*. at 1174.

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. *See, e.g.*, 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").

46. The Manual, in accordance with federal regulation, also has long specified that diagnoses be coded according to *International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting* and the ICD Guidelines have long specified that the medical record must substantiate the diagnosis coding. *See, e.g.*, 2013 Manual § 40 (Exhibit 5); *see also* 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).

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); *see also id*. 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").

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 documentation in the medical record cannot be overemphasized").

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)." *See* Section B.7 of Art. VI and Section B.1(a)(vii) of Article VIII of the MA Contract.[6]

50. One of the requirements of § 422.310 (a Part C regulation) pertains to the "[v]alidation of risk adjustment data."

51. Section 422.310(e) also establishes the medical record as the source for determining the validity of risk adjustment data: "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."

52. "There may be penalties for submission of false data." 42 C.F.R. § 422.310(e).[7]

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[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).

[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.

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).

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]." *See*, *e.g.*, Section A.2(b), (d) of Article VI of the MA Contract (Exhibit 1).

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.

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, including diagnoses, to CMS' RAPS and EDS and to receive payments. *See*, *e.g.*, Electronic Data Interchange Agreement Between United and CMS (Exhibit 2); *see also* 2004 Manual (Exhibit 4), § 111.6.1 (discussing this requirement).

57. Pursuant to the EDI Agreements, the defendant MAOs and Optum (and its predecessor, Ingenix) agreed that they were responsible for all risk adjustment data submitted by themselves, their employees, and agents and that "[b]ased on best knowledge, information, and belief, [they would] submit risk adjustment data that are accurate, complete, and truthful." *Id*. at Sections A.1 and 5.

58. Moreover, they agreed to "correct risk adjustment data discrepancies." *Id*. at Section A.11.

59. Of equal significance, pursuant to the EDI Agreements, they also agreed that the government had the 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. *Id*. at Section A.4.

60. Thus, the EDI Agreements also established the medical records as the "source of truth" for validating diagnosis data and Defendants' entitlement to payments.

61. Any conclusion of law that is deemed a finding of fact is incorporated herein by this reference.

CONCLUSIONS OF LAW

1. Rule 1 of the Federal Rules of Civil Procedure provides that the federal rules should be construed to secure a "just, speedy, and inexpensive determination of every action." Contentions or defenses lacking either merit or relevance should not be the basis for unnecessary discovery nor allowed to consume the time and resources of the Court or parties.

2. A party may file a motion for summary judgment "at any time until 30 days after the close of all discovery." Fed. R. Civ. P. 56(b).

3. While, in some cases, a summary judgment motion may properly await some amount of discovery, where, as here, the legal issues are clear, partial summary judgment can and should be granted, even before discovery has been completed. *See, e.g., Parra v. Wright*, 2013 WL 6669235, at *7 (W.D.N.Y. Dec. 18, 2013) (granting pre-discovery summary judgment motion where "the legal principles are clear").

4. Partial summary judgment is appropriate to resolve purely legal questions. *See In Re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 284, 288 (D. Mass. 2006) (granting partial summary judgment on meaning of statutory phrase "average wholesale price" under "plain language canon of statutory construction"); *see also* 10A C. Wright, A. Miller, & M. Kane, Fed. Practice and Procedure § 2725 at 416 (4d ed. 2016) ("when the only issues to be decided in the case are issues of law, summary judgment may be granted"); *id*. at 422-23 ("fact that difficult questions of law

exist or that the parties differ on the legal conclusions to be drawn from the facts is not in and of itself a ground for denying summary judgment in as much as refusing to grant the motion does not obviate the court's obligation to make a difficult decision") (footnotes omitted).

5. United's actuarial and data equivalence arguments fail as a matter of law and are not a defense to liability in this action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. According to United, because claims submitted by healthcare providers under Parts A and B of the Medicare Program (the fee-for-service or FFS programs) likely contain diagnosis coding errors, United is allowed to knowingly submit erroneous diagnoses codes to Medicare (or refrain from withdrawing such codes) for payments under the MA program.

6. First, United's argument violates not just regulatory, but also contractual provisions with which Defendants expressly promised compliance.

7. To begin, United, when submitting claims for Medicare funds, cannot agree to comply with applicable payment requirements and then unilaterally declare those same requirements void. *See City and County of San Francisco v. Tutor-Saliba Corp.*, 2005 WL 645389, at *8 (N.D. Cal. Mar. 17, 2005) (rejecting argument in state FCA case that "allegedly fraudulent conduct should be excused because part of the contract [in which fraud occurred] is invalid" and that "invalid portion of the contract is no excuse for fraudulent behavior"); *see also Bryson v. United States*, 396 U.S. 64, 68 (1969) ("One who elects [fraud] as a means of self-help may not escape the consequences by urging that his conduct be excused because the statute which he sought to evade is [invalid]."") (quoting *Dennis v. United States*, 384 U.S. 855, 867 (1966)); *Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 769 (9th Cir. 1997) (purported "invalidity" of payment rule held "no defense" to submission of false claims in violation of challenged rule) (citing *Bryson*); *United States v. Weiss*, 914 F.2d 1514, 1522-23 (2d Cir.1990) (holding that the fact that a Medicare Manual provision requiring filing of statements had not undergone statutorily-required approval procedures was no defense to charge of false

statements).

8. Second, the Ninth Circuit already rejected essentially the same argument in *Swoben*. United previously challenged the medical record requirement in *Swoben*. 848 F.3d at 1179. In that case, instead of relying on the statutory term "actuarial equivalence," United pointed to a regulation which requires that MAOs "must submit data that conform to CMS' requirements for *data equivalent* to Medicare fee-for-service data." *Id.* (citing 42 C.F.R. § 422.310(d)) (emphasis supplied). United argued that this data equivalency requirement was somehow inconsistent with the requirement that diagnoses be supported by the medical record and therefore excused its knowing submission of erroneous diagnosis codes. The Ninth Circuit not only rejected this argument on the merits, but concluded that it did not provide a defense to the Defendants' FCA liability in light of their bad faith in conducting medical record reviews of their beneficiaries.

9. The Ninth Circuit's reasoning applies with equal force to United's similar actuarial equivalence argument here. In *Swoben*, the Ninth Circuit rejected United's data equivalence argument, holding that "because nothing in § 422.310(d) speaks to [an MAO's] obligations to ensure the accuracy of risk adjustment data, it does not modify [an MAO's] obligations under §§ 422.503(b)(4)(vi) and 422.504(l)." *Id*. at 1179. The appellate court explained that under these sections and others, CMS has made "clear" that MAOs "have always had 'an obligation to undertake steps to ensure the accuracy, completeness and truthfulness of encounter data'" submitted to CMS. *Id*. at 1174.

10. There is no significant difference between United's current legal argument based on the term "actuarial equivalence" and its previous one based on "data equivalence." Neither the statute nor the regulation alter United's obligation to delete invalid diagnosis codes.

11. The provision United relies on here, 42 U.S.C. § 1395w-23(a)(1)(C)(i), merely directs the Secretary to "adjust the . . . amount" of the Part C payments 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." *Id*. Just like section 422.310(d), as the Ninth Circuit held, does not modify United's other regulatory obligations requiring the submission of valid data and deletion of invalid data, the statute does not give United any right to submit invalid diagnosis codes or to refrain from deleting them.

12. The Ninth Circuit also found United's data equivalency argument inapposite in light of the conduct alleged by the Relator in *Swoben* concerning United's medical record reviews. In *Swoben*, United had noted that diagnostic codes are, in the first instance, determined by the healthcare providers who treat the beneficiaries, and argued that there was no "authority indicat[ing] that a [MAO] was obligated to undertake affirmative steps to unearth potentially unsupported codes . . . ." *Swoben*, 848 F.3d at 1173.

13. The Ninth Circuit found this argument entirely missed the mark: "Defendants' attempts to portray themselves as the passive victims of their providers' errors wholly misstates Swoben's legal theory, which focuses on the defendant's own conduct in allegedly conceiving, directing and conducting retrospective reviews designed to identify only favorable coding errors." *Id*. at 1174. After considering, first, whether Part C regulations on their face, supported United's defense, the appellate court added that, "[s]econd, this is not a case about whether [MAOs] have *to take* affirmative steps to verify risk adjustment data. [United] indisputably took such steps by conducting retrospective reviews." *Id.* at 1179 (emphasis in original). Importantly, it then added that, when MAOs adopts "affirmative verification procedures, [they] have to conduct them in good faith." *Id.*

14. The Ninth Circuit's unequivocal rejection of United's data equivalence argument does not leave room for United's argument that actuarial equivalence, as it relates to risk adjusted payments, entitles it to payment for unsupported diagnoses or would allow United to disregard its obligation to correct diagnostic data when

information is available to it about the invalidity of such data.

15. United's attempt to resurrect and rename its "data equivalence" argument, which is plainly at odds with the Ninth Circuit's decision, lacks merit.

16. Third, the data equivalency argument cannot be applied where United reviewed medical records to add additional diagnosis codes not reported by providers. United contends that an actuarial principle mandates that provider-reported health status information, *i.e.*, diagnosis codes, should not be subject to further medical record review or verification – yet United did precisely that when it added codes based on its own medical record reviews.

17. United violated the very principle it relies upon. United's role with respect to diagnosis codes was *not* that of a passive conduit of data supplied by healthcare providers. Even assuming United's actuarial equivalence argument had any merit – which it does not – United's own conduct makes application of that principle impossible with respect to the diagnostic data that is the subject of this case.

18. By conducting medical record reviews and *adding* diagnosis data (which increased its beneficiaries' risk scores) based on those reviews, United tampered with the provider-reported diagnosis data and created the very data inconsistencies that it contends are illegitimate and preclude it from being required to delete unsubstantiated diagnoses.

19. Fourth, United's construction of 42 U.S.C. § 1395w-23(a)(1)(C)(i) and the term "actuarial equivalence" is devoid of any merit.[8] The agency's interpretation of this phrase is reasonable and consistent with the language and intent of the statute.

20. In construing a statute, courts "first evaluate whether the meaning of the

[8] This subsection reads follows: "Subject to subparagraph (I), the Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i).

statute is plain and unambiguous and, therefore controlling." *Arizona State Bd. For Charter Schs. v. U.S. Dept. of Educ.*, 464 F.3d 1003, 1007 (9th Cir. 2006).

21. The starting point is to "engage in a textual analysis of the relevant statutory provisions and to read the words of a statute in their context and with a view to their place in the overall statutory scheme." *Id.*

22. "Statutory interpretations which would produce absurd results are to be avoided." *Id.* at 1008 (quoting *Ma v. Ashcroft*, 361 F.3d 553, 558 (9th Cir. 2004)). "When a natural reading of the statutes leads to a rational, common-sense result, an alteration of meaning is not only unnecessary, but also extrajudicial." *Id.*

23. The Medicare statute directs that the Secretary of HHS "adjust the . . . amount" of the monthly payments to MAOs 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).

24. The Secretary may develop an adjustment methodology "as he determines to be appropriate," *id.*, a phrase that is used 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) (construing a Federal Energy Regulatory Commission rule).

25. The language of 42 U.S.C. § 1395w-23(a)(1)(C)(i) is discretionary because it allows the Secretary to take into account "such other [risk] factors as the Secretary determines to be appropriate" and says that he "may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence."

26. Similar language has also been understood to be discretionary. *See United Food and Commercial Workers Union, Local 1036 v. NLRB*, 307 F.3d 760, 770-72 (9th Cir. 1986) (rejecting that "statutory equivalence" means "identical" and stating, "[t]he practical effect of the nonmembers' argument would be to deprive the NLRB of its

jurisdiction to make factual determinations").[9]

27. The MA risk adjustment model (*i.e.*, the HCC model) is designed to satisfy the actuarial equivalence provision by paying MAOs a sum commensurate with the expected cost of providing traditional Medicare benefits to a given beneficiary.

28. And 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.

29. This construction leaves no room for United's argument that it was free to disregard the medical record requirements of CMS's risk adjustment system – the implementation of which, by statute, falls within the Secretary's discretion – and reconfigure it in a way that permits United to ignore the medical record requirement and knowingly retain payments for unsupported diagnoses.

30. United's APA case contends that the per-beneficiary payments calculated by the Secretary systematically underestimate the costs associated with any given disease. United claims that the system can nonetheless function properly, because insurers regularly claim payments for diagnoses that are not substantiated by the beneficiaries' medical records, 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. United argues that it is therefore unlawful for the Secretary to limit insurers to claiming payment for the medical conditions that are actually substantiated by their beneficiaries' medical records. If MAOs are not allowed to submit diagnoses not

[9] Such language has also been held to be procedural only and not a basis for creating substantive rights. *See Rhoades, McKee & Boer v. United States*, 43 F.3d 1071, 1075 (6th Cir. 1995) (26 U.S.C. § 412(c)(3)'s "best estimate" requirement is "procedural only," does not place a "substantive" requirement on actuarial assumptions); *Wachtell, Lipton, Rosen & Katz v. Comm'r*, 26 F.3d 291, 296 (2d Cir. 1994) (§ 412(c)(3)'s "best estimate" requirement is procedural only and "factoring in a discount for conservatism after an actuary has [already] arrived at his or her best estimate of anticipated experience would be contrary to the statutory mandate"); *Vinson & Elkins v. Comm'r*, 7 F.3d 1235, 1238 (5th Cir. 1993) (stating that Congress "intended to give actuaries some leeway and freedom from second-guessing" and that it was inappropriate for anyone to "substitute his judgment . . . for that of a qualified actuary").

reflected in their beneficiaries' medical records, the argument goes, they may be undercompensated. United argues that the submission of invalid diagnoses (and the receipt of payments for them) not only is permitted, but is, as a practical matter, required.

31. United's interpretation of "actuarial equivalence" would lead to absurd results.

32. Its argument – that it is legally entitled to retain payments for conditions it knows are not substantiated by its beneficiaries' medical records -- is utterly at odds with the regulatory and contractual regime that has been in place in the MA Program for the last two decades and is utterly untenable given the Ninth Circuit's unequivocal holding that MAOs "have an obligation to undertake 'due diligence' to ensure the accuracy . . . and truthfulness" of the risk adjustment data "submitted to [CMS]" for Medicare payments. *Swoben*, 848 F.3d at 1169 (quoting 2000 Rule, 65 Fed. Reg. at 40,268).

33. Nothing exempts United from compliance with this obligation. Congress has never embraced the notion of Medicare payments based on invalid data.

34. In sum, there is nothing in the statute or its legislative history that supports the notion that United could engage in an *ad hoc* restructuring of the legal obligations established by the Secretary and set out in Part C and D contracts and regulations.

35. Nor does the statute or legislative history support the notion that United was entitled to ignore the longstanding medical documentation requirement and submit some percentage of invalid diagnoses as compensation for purported imperfections in the multipliers for the HCC model and the amount of the risk- adjusted payments. United's arguments to the contrary fail as a matter of law.

36. Any finding of fact that is deemed a conclusion of law is incorporated herein by this reference.

IT IS SO ORDERED.

Dated:_____

_____
UNITED STATES DISTRICT JUDGE

CHAD A. READLER
Acting Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
JOHN E. LEE (CBN 128696)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
DANIEL R. ANDERSON
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA KRIEG
PAUL PERKINS
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
Acting United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; Fax: (716) 551-3052
Email: 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.* BENJAMIN POEHLING, Plaintiffs, v. UNITEDHEALTH GROUP, INC., *et al.*, Defendants.	No. CV 16-08697 MWF (SSx) [PROPOSED] ORDER GRANTING UNITED STATES' AND RELATOR POEHLING'S JOINT MOTION FOR PARTIAL SUMMARY JUDGMENT Date: July 30, 2018 Time: 10:00 a.m. Court: 5A. Hon. Michael W. Fitzgerald

Additional Attorneys (continued from previous page):

ERIC R. HAVIAN (CBN 102295)
ehavian@constantinecannon.com
HARRY LITMAN (CBN 127202)
hlitman@constantinecannon.com
JESSICA T. MOORE (CBN 183431)
jmoore@constantinecannon.com
HENRY C. SU (CBN 211202)
hsu@constantinecannon.com
Constantine Cannon LLP
150 California Street, Suite 1600
San Francisco, CA 94111
Tel: (415) 639-4001
Facsimile: (415) 639-4002

STEPHEN HASEGAWA (CBN 198472)
shasegawa@phillipsandcohen.com
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Facsimile: (415) 836-9001

WILLIAM CHRISTOPHER CARMODY (*pro hac vice*)
wcarmody@susmangodfrey.com
ARUN SUBRAMANIAN (*pro hac vice*)
asubramanian@susmangodfrey.com
GENG CHEN (*pro hac vice*)
gchen@susmangodfrey.com
Susman Godfrey L.L.P.
1301 Avenue of the Americas, 32nd Floor
New York, New York 10019-6023
Tel: (212) 336-8330
Facsimile: (212) 336-8340

MENG XI (CBN 280099)
mxi@susmangodfrey.com
CATRIONA LAVERY (CBN 310546)
clavery@susmangodfrey.com
Susman Godfrey L.L.P.
1900 Avenue of the Stars, Suite 1400
Los Angeles, California 90067
Tel: (310) 789-3100
Facsimile: (310) 789-3100

Attorneys for Relator Benjamin Poehling

The joint motion of the United States of America and relator Benjamin Poehling for partial summary judgment came on regularly for hearing. Upon consideration of the United States' and Relator Poehling's moving and reply papers, the opposition of Defendants UnitedHealth Group, Inc.; United Healthcare Services, Inc.; United Healthcare, Inc.; UnitedHealthcare Insurance Company; Ovations, Inc.; Optum, Inc.; OptumInsight, Inc., and the Defendant Medicare Advantage Organizations (collectively, "United Defendants"), and the arguments of counsel, and good cause appearing, the Court hereby GRANTS the United States' and Relator Poehling's joint motion. Accordingly,

IT IS HEREBY ORDERED, ADJUGED, AND DECREED that there is no genuine issue that the United Defendants were, during the time period 2009 to 2017, legally obligated to delete diagnosis codes that they knew (as that term is used in the False Claims Act, 31 U.S.C. § 3729(b)(1)) were unsupported by their beneficiaries' medical records.

IT IS SO ORDERED.

Dated:_____

_____
UNITED STATES DISTRICT JUDGE