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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

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

Assigned to Hon. Michael W. Fitzgerald

UNITED'S NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-PARTIAL-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

[*Declaration of David J. Schindler and [Proposed] Order filed concurrently herewith*]

Date: January 29, 2018
Time: 10:00 a.m.
Ctrm: 5A

TO THE COURT, ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that, on January 29, 2018, at 10:00 a.m., or as soon thereafter as the parties may be heard, in Courtroom 5A of the United States District Court, Central District of California, located at 350 W. 1st Street, Los Angeles, California 90012, Honorable Michael W. Fitzgerald presiding, Defendants UnitedHealth Group Incorporated, United HealthCare Services, Inc., UnitedHealthcare, Inc., UnitedHealthcare Insurance Company, Ovations, Inc., Optum, Inc., OptumInsight, Inc., AmeriChoice of New Jersey, Inc., AmeriChoice of New York, Inc., Arizona Physicians IPA, Inc., Care Improvement Plus of Maryland, Inc., Care Improvement Plus of Texas Insurance Company, Care Improvement Plus South Central Insurance Company, Care Improvement Plus Wisconsin Insurance Company, Optum Insurance Co., Citrus Health Care, Inc., Health Plan of Nevada, Inc., Medica HealthCare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., PacifiCare Life and Health Insurance Company, PacifiCare of Arizona, Inc., PacifiCare of Colorado, Inc., PacifiCare of Nevada, Inc., Physicians Health Choice of Texas, LLC, Preferred Care Partners, Inc., Rocky Mountain Health Maintenance Organization, Incorporated, Sierra Health and Life Insurance Company, Inc., Symphonix Health Insurance, Inc., UHC of California (f.k.a. PacifiCare of California), United Health Care Ins. Co. and United New York, Unison Health Plan of Tennessee, Inc., UnitedHealthcare Benefits of Texas, Inc. (f.k.a. PacifiCare of Texas, Inc.), UnitedHealthcare Community Plan of Ohio, Inc. (f.k.a. Unison Health Plan of Ohio, Inc.), UnitedHealthcare Community Plan of Texas, L.L.C. (f.k.a. Evercare of Texas, L.L.C.), UnitedHealthcare Community Plan, Inc. (f.k.a. UnitedHealthcare of the Great Lakes Health Plan, Inc.), UnitedHealthcare Insurance Company of New York, UnitedHealthcare of Alabama, Inc., UnitedHealthcare of Arizona, Inc., UnitedHealthcare of Arkansas, Inc., UnitedHealthcare of Florida, Inc., UnitedHealthcare of Georgia, Inc.,

UnitedHealthcare of New England, Inc., UnitedHealthcare of New York, Inc., UnitedHealthcare of North Carolina, Inc., UnitedHealthcare of Ohio, Inc., UnitedHealthcare of Oklahoma, Inc. (f.k.a. PacifiCare of Oklahoma, Inc.), UnitedHealthcare of Oregon, Inc. (f.k.a. PacifiCare of Oregon, Inc.), UnitedHealthcare of Pennsylvania, Inc. (f.k.a. Unison Health Plan of Pennsylvania, Inc.), UnitedHealthcare of Tennessee, Inc., UnitedHealthcare of the Midlands, Inc., UnitedHealthcare of the Midwest, Inc., UnitedHealthcare of Utah, Inc., UnitedHealthcare of Washington, Inc. (f.k.a. PacifiCare of Washington, Inc.), UnitedHealthcare of Wisconsin, Inc., and UnitedHealthcare Plan of the River Valley, Inc. (collectively, "United") will, and hereby do, move the Court for dismissal of this action (the "Motion").

This Motion is and will be made on the grounds that (1) the Government fails adequately to plead that United's supposed regulatory violations were material to the Centers for Medicare and Medicaid Services' decision to pay United; and (2) the Government's First Cause of Action does not apply to alleged overpayments that were identified prior to the 2009 Amendment to the False Claims Act.

This Motion is based upon the accompanying Memorandum of Points and Authorities, the Declaration of David J. Schindler filed concurrently herewith, the pleadings and other papers on file herein, and such argument and evidence 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 November 21, 2017.

Dated: December 8, 2017

LATHAM & WATKINS LLP

DAVID J. SCHINDLER
DANIEL MERON
ABID R. QURESHI

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

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INTRODUCTION

On October 5, 2017, Judge Walter dismissed a separate False Claims Act case against UnitedHealth Group, Inc. and certain of its subsidiaries ("United") on the ground that the Department of Justice ("DOJ") failed "to allege that CMS"—the Centers for Medicare and Medicaid Services—"would have refused to make risk adjustment payments to the United Defendants if it had known the facts." *United States ex rel. Swoben v. Scan Health Plan*, CV 09-5013-JFW (JEMx), 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017). Several days later, United notified DOJ that it intended to move for dismissal on that same ground in this case, which likewise presents questions about CMS risk adjustment payments.

DOJ responded by requesting an extra month to file an amended complaint first, before United filed that motion. Yet, while the Amended Complaint-in-Intervention ("Amended Complaint" or "Compl."), ECF No. 171, includes more than a hundred new paragraphs of allegations, it still suffers from the same fundamental defect: It fails to contain *any* allegation—even a cursory one—"that CMS would have refused to make risk adjustment payments to the United Defendants if it had known the facts." *Swoben*, 2017 WL 4564722, at *6. That omission infects all of DOJ's claims and warrants dismissal.

The omission is no mere oversight, either. DOJ has not made that allegation because it *cannot* do so. DOJ's claims rest on the premise that MA plans are entitled to risk adjustment payments only for medical conditions that are adequately documented in a patient's *medical charts* (as opposed to those conditions that are separately and sometimes incorrectly identified in provider-based coding included in *claims submissions*), notwithstanding the presence of similar discrepancies in CMS's own data. That premise implicates an industry-wide regulatory discussion that has lasted the better part of a decade. During that time, senior officials at CMS have acknowledged that the theory DOJ is pressing here would, if correct, result in Medicare Advantage plans being *under*paid for the

insurance risk they assume from CMS. This motion does not present the merits of that issue, which are pending in an Administrative Procedure Act case United filed in the U.S. District Court for the District of Columbia. But the issue nevertheless is highly relevant, because it explains why DOJ has been unable to make essential *factual* allegations here.

Put simply, the Amended Complaint lacks the essential allegations because DOJ knows the true facts: namely, that CMS has been aware of errors in coding data submitted by United (and every MA insurer) and has never once sought to withhold payment. And while at times in this litigation DOJ has asserted that it should have the final say about how the Medicare Advantage program operates, it is CMS that has the statutory authority to run that program and decide what kinds of alleged violations warrant withholding payment. DOJ cannot override that authority by converting an alleged regulatory violation the client agency *itself* has deemed immaterial into a vehicle for imposing draconian penalties and fines under the False Claims Act. Because DOJ does not and cannot allege that CMS would have withheld payment if it had known the facts, the Amended Complaint should be dismissed in its entirety.

Seeking to avoid that outcome, DOJ asserts a *new* "First Claim for Relief" in the Amended Complaint under 31 U.S.C. § 3729(a)(1)(G), the so-called "reverse false claims" provision of the False Claims Act. DOJ alleges there that even if CMS would not have denied payment if it had known the facts, CMS's computer system would have automatically accepted repayment if *United* had voluntarily cancelled its claims. As a result, DOJ asserts, United's failure to rescind its claims was "inexorably material." That novel and unsupported theory ignores that materiality is determined by how the *government* would have responded if it knew the facts, not by what would have happened if the defendant in a False Claims Act case had voluntarily repaid claims. Otherwise, DOJ could convert literally any alleged regulatory violation, however immaterial, into a reverse false claim case

simply by alleging that if the defendant had mailed the government a check for repayment, the government would have cashed it. To borrow the Supreme Court's recent language, "[t]he False Claims Act does not adopt such an extraordinarily expansive view of liability." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2004 (2016). This portion of Section 3729(a)(1)(G) does not, in any event, even apply to overpayments DOJ alleges United received and had knowledge of before May 2009, when the language was added to the False Claims Act and made expressly prospective.

For these reasons, the Court should dismiss the Amended Complaint.[1] And given that DOJ was aware of the importance of pleading "that CMS would have refused to make risk adjustment payments to the United Defendants if it had known the facts" yet was unable after a month-long amendment process to make that indispensable allegation in good faith, the dismissal should be with prejudice.

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 based on the claims those professionals submit for the services

[1] The United States has intervened in this case as to all of the claims brought against United, and its Amended Complaint is therefore the operative complaint. Relator Benjamin Poehling has indicated that he does not intend to pursue any claims beyond those asserted by the United States, *see* ECF No. 117 at 2, and has agreed that there is no need for United to respond to his Second Amended Complaint.

they render. For this reason, traditional Medicare beneficiaries are often referred to as fee-for-service ("FFS") beneficiaries.

This case concerns the Medicare Advantage program created under Part C of the Medicare Act. *See id.* § 1395w-21 *et seq*. Medicare Advantage (sometimes referred to here as "MA") 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 as traditional Medicare, and for ensuring that providers are paid for their services. In return, CMS makes fixed (or "capitated") per-member-per-month payments to the MA plans—effectively insurance premiums. *See generally id.* § 1395w-23.

As with other types of insurance, it costs more to insure sicker beneficiaries or beneficiaries who are projected to be sicker in the near future than healthier beneficiaries. The Medicare Advantage program addresses that fact through an annual risk adjustment process. Each year, an MA plan signs a contract with CMS in which it agrees on the payment it will require from CMS to provide the benefits covered by Medicare Parts A and B to a Medicare "enrollee with a national average risk profile." *Id.* § 1395w-24(a)(6)(A); *see also* 42 C.F.R. § 422.254(b)(1). That payment amount generally must be less than or equal to CMS's actual costs for providing healthcare to an average FFS beneficiary in the same area. 42 U.S.C. § 1395w-23(a)(1)(B). CMS then adjusts that payment amount to reflect the level of risk posed by the MA plan's actual beneficiaries. If the MA plan's beneficiaries are more risky than average, the plan's payment amount will go up; if they are less risky, it will go down.

CMS designed, and implemented, a model to determine how much to pay an MA plan in each year. It was, and is, predicated on an analysis of medical diagnosis codes, which are numerical codes used by doctors and other medical professionals on claims and other forms to designate a particular medical

diagnosis. *See* Compl. ¶ 63. Using the diagnosis codes and cost data for its own FFS beneficiaries, CMS predicts how much it will cost an MA plan to care for a beneficiary who has a given diagnosis code.[2] The model might indicate, for example, that Medicare beneficiaries who have a diagnosis code for diabetes cost 30 percent more to care for in the FFS program (on average) than they would if they did not have that code. CMS assumes that MA plans will see a similar relationship between diagnosis codes and medical costs, and so it uses the analysis of its own FFS program codes and costs to adjust MA plans' payment amounts as well. Thus, roughly speaking, an MA plan would receive an incremental payment of 30 percent of its agreed-upon payment amount for each of its patients with the diabetes code, in order to account for the increased risk associated with that code. CMS's model relies entirely on the codes it receives from third-party providers and, more importantly, CMS knows that a substantial number of those codes are not supported in the underlying medical charts. Indeed, the projected payments assume that some of the codes reflect conditions that the patient does not actually have.

DOJ's allegations here concern United's submission of risk adjustment data generated by the medical professionals who treat United's MA plan members. Although the Complaint is exceedingly detailed in some respects, it boils down to the theory that United submitted risk adjustment codes that did not accurately measure the risk of its patient population because the codes lacked adequate support in the associated *medical charts* of its members. *See, e.g.*, Compl. ¶¶ 11-12. In simplest terms, DOJ claims that United knew, or should have known, that the third party coding it passed along to CMS contained errors. DOJ notes that

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[2] United's motion for summary judgment in its APA case explains CMS's risk-adjustment model in greater detail. *See* United's Mem. in Supp. of Mot. for Summ. J. 9-12, *UnitedHealthcare Insurance Co. v. Price*, No. 1:16-cv-00157 (D.D.C. Oct. 17, 2017), ECF No. 47-1.

United reviewed the medical charts of some of its plan members to find additional codes that *should* have been submitted (but were not), and claims that this review process put United on notice of the codes that should *not* have been submitted (but were). *See, e.g.*, *id.* ¶¶ 12-13.[3] DOJ further alleges that United violated the False Claims Act when it submitted Attestations certifying that the codes it had submitted were accurate to the best of its knowledge, information, and belief. *See, e.g.*, *id.* ¶¶ 98-102 (allegations about Attestations); *id.* ¶¶ 345-46 (identifying Attestations as basis for Second Claim for Relief); *id.* ¶¶ 349-50 (identifying Attestations as basis for Third Claim for Relief); *id.* ¶¶ 353-54 (identifying Attestations as basis for Fourth Claim for Relief).

Long before this False Claims Act suit was filed, CMS and the health insurance industry began a discussion of their own over the existence and implications of unsupported diagnosis codes in their respective sets of data. Insurance providers have argued that unsupported codes submitted by MA plans simply offset the unsupported codes similarly submitted by providers in the FFS program, such that MA plans would actually be *under*paid if they were required to delete codes that lacked support in their members' charts. DOJ has repeatedly framed its allegations as showing that United has been paid for conditions that its plan members do not have (and will no doubt offer that framing again here). But the reality is that CMS knew full well that some diagnosis codes reflect conditions

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[3] While United is required to accept DOJ's factual allegations for purposes of this motion, it vigorously disputes the suggestion that merely because a retrospective chart reviewer doing a "blind" chart review did not identify every diagnosis code that the provider's own coder had found, the provider's own codes were necessarily wrong or suspect. There are many reasons that the billing staff in a doctor's office might capture a code that a later reviewer would not, such as greater familiarity with the doctor's handwriting or recordkeeping practices. And given that medical charts of Medicare-eligible patients often span dozens, and sometimes even *hundreds*, of pages, it would be remarkable if either the first *or* second coder consistently captured every code that was supported in a given patient's charts.

that patients do not have, and it built the presence of those codes into its payment system.

The payments that CMS makes to MA plans are lower than they otherwise would be because they already take into account the existence of unsupported diagnosis codes throughout the health system. When CMS calculates the average incremental cost associated with a given code in the FFS program, it does not confirm that its FFS diagnosis codes seen in claims are supported by associated medical charts. Some of the patients CMS uses to calculate the average cost associated with a diagnosis code thus do not actually have the condition with which the code is associated. This reduces the cost associated with the code compared to a hypothetical model in which only patients with *verified* codes were included. MA plans have argued that it would violate basic principles of actuarial science—and the Medicare Act itself—to use the risk associated with *unverified* codes in the FFS population to determine payment amounts for *verified* codes in the MA population. More concretely, doing so would result in a windfall to CMS, which reduces its per-code payments in the first place because of the presence of unsupported codes, and would then recover essentially that same money a second time by requiring plans to delete any codes that are not supported.

At times, CMS has acknowledged the merit of that position, which is directly contrary to DOJ's theory in this case. The most notable instance came in connection with CMS's Risk Adjustment Data Validation ("RADV") audits, through which CMS identifies and recovers overpayments it has made to MA plans. In 2008, CMS announced its intent to use RADV audits on samples of MA plans' diagnosis codes to estimate the plans' overall rates of unsupported codes, and to then reduce the plans' overall payment amounts in a way that would effectively deny them payment for unsupported codes. *See* 2009 Proposed RADV Rule, 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009). The plans responded that doing so would leave the plans underpaid, for the reasons explained above. *See, e.g.*,

Aetna Inc. Comments on Proposed Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits at Exhibit 1, p. 21-25; Humana Comment on RADV Sampling and Error Calculation Methodology at Exhibit 2, p. 42-45.[4] And CMS eventually agreed. Internally, its Division of Payment Validation determined that MA plans would be undercompensated unless CMS accounted for its own use of diagnosis codes from FFS "beneficiaries who don't actually have the disease," which "tends to reduce the estimated average cost of various conditions" that CMS uses to calculate risk adjustment payments. United's Motion to Supplement the Administrative Record 13, *UnitedHealthcare Insurance Co. v. Price* ("*UnitedHealthcare v. Price*"), No. 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017), ECF No. 44 (quoting agency briefing materials released under FOIA attached as Exhibit C thereto, ECF No. 44-4). Following that determination, CMS announced that it would develop a "FFS adjuster" for use in its RADV audits that would "account[] for the fact that the documentation standard used in RADV audits to determine [an MA] contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)." CMS, Notice of Final Payment Error Calculation Methodology (Feb. 24, 2012), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

To be sure, CMS has not *always* agreed entirely with the MA plans' approach. As this Court knows, United brought an administrative lawsuit in the

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[4] The regulatory comments cited in this brief, which are attached as Exhibits to the accompanying Declaration of David J. Schindler for ease of reference, have all been designated by CMS as part of the administrative record in the pending Administrative Procedure Act suit that raises these issues, *UnitedHealthcare Insurance Co. v. Price* ("*UnitedHealthcare v. Price*"), No. 1:16-cv-00157-RMC (D.D.C.).

U.S. District Court for the District of Columbia challenging a 2014 CMS rule that relies on the same theory that DOJ is pursuing here, and wholly fails to account for errors in FFS data when assessing overpayment amounts. *See UnitedHealthcare v. Price*, Order Denying Motion to Transfer 3-4, ECF No. 154 (discussing APA suit). Again, the merits of that dispute are not presently before this Court.[5] For present purposes, the important point is that CMS has been aware of and engaged in this ongoing debate for a long time—and that its views have, at times, departed sharply from the understanding on which DOJ's theory here rests. That reality helps to explain why DOJ has been unable to allege that if CMS had known the "truth" about United's risk adjustment data Attestations and the alleged absence of chart support for United's diagnosis codes, it would have refused to pay United's claims.

B. The Government's Initial Complaint

Qui tam relator Benjamin Poehling filed this False Claims Act case in the Western District of New York in 2011. *See* First Am. Compl., ECF No. 8. DOJ then spent more than five years deciding whether to pursue the case, ultimately opting to intervene in late 2016 after the Ninth Circuit reversed the dismissal of a different False Claims Act case against United involving risk adjustment. *See United States ex rel. Swoben v. United Healthcare Ins. Co.*, 832 F.3d 1084 (9th Cir.), *amended on reh'g*, 848 F.3d 1161 (9th Cir. 2016). Expressly declaring its desire to avoid "inconsistent judicial decisions," DOJ asked the Western District of New York on November 7, 2016 to transfer Poehling's suit to this District.

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[5] United and the Secretary of Health and Human Services have already filed lengthy cross-motions for summary judgment in that case, where the District Court has before it a 12,000-page Administrative Record that covers the past instances in which CMS has taken differing approaches on the question. *See UnitedHealthcare v. Price*, United's Mem. in Supp. of Mot. for Summ. J., ECF No. 47-1; *UnitedHealthcare v. Price*, Defs.' Mem. in Supp. of Cross-Mot. for Summ. J., ECF No. 57-1. America's Health Insurance Plans is also supporting United in that case as an amicus, presenting the views of the insurance industry more widely.

Memorandum of Law In Support of Unopposed Motion of the United States to Transfer Venue 6, ECF No. 49. The Western District of New York agreed, *see* ECF No. 50, and DOJ thereafter formally intervened in the case and filed a Complaint-In-Intervention on May 16, 2017. *See* ECF No. 114. The complaint contained five counts—three counts asserting claims under the False Claims Act, and two asserting tag-along common law claims for Unjust Enrichment and Payment By Mistake. *Id.* ¶¶ 234-52.

In July 2017, United moved to transfer this case to the District of Columbia, where it could be coordinated with United's pending APA action. *See* ECF No. 134. This Court denied that motion on September 28, 2017, and ordered United to respond to DOJ's Complaint within 20 days. *See* ECF No. 154 at 12; *see also* ECF No. 133.

C. Judge Walter's Dismissal Of The Swoben *Complaint And DOJ's Resulting Amendment In This Case*

An intervening event interrupted that schedule. On October 5, 2017, Judge Walter issued a decision dismissing DOJ's claims against United in *Swoben*—the case that led DOJ to seek a transfer to this District in the first place in order to avoid inconsistent judicial decisions. *See Swoben*, 2017 WL 4564722, at *1-9. Judge Walter held (among other things) that DOJ's *Swoben* complaint "fail[ed] to allege that CMS would have refused to make risk adjustment payments to the United Defendants if it had known the facts about the United Defendants' alleged involvement with the . . . chart review process" at issue there. *Id.* at *6. Under the Supreme Court's decision in *Escobar*, Judge Walter held, that was fatal: In order to survive a motion to dismiss, DOJ was required to plead "that [CMS] would not have paid these claims had it known of these violations." *Id.* (quoting *Escobar*, 136 S. Ct. at 2004).

Judge Walter granted DOJ leave to amend its complaint in order to attempt to plead adequately that CMS would not have paid the claims in question. *Id.*

DOJ instead elected to dismiss its claims against United in the *Swoben* suit in their entirety. Notice of Dismissal Without Prejudice Pursuant to Federal Rules of Civil Procedure 41(a) or (c), *Swoben* (C.D. Cal. Oct. 12, 2017), ECF No. 341.

Following the *Swoben* dismissal, United and DOJ conferred about United's upcoming motion to dismiss in this case. United expressed its intent to make a nearly identical materiality argument regarding the deficiencies in DOJ's complaint here. DOJ responded that it planned to file an amended Complaint-in-Intervention. *See* ECF No. 165 at 1. The parties thereafter agreed to, and this Court approved, a month-long extension that would allow DOJ adequate time to file an amended complaint. *See* ECF No. 166.

On November 17, 2017, DOJ filed the Amended Complaint, which added a new lead count. *See* ECF No. 171. The "First Claim for Relief" in the Amended Complaint now asserts violations of the "second part" of the so-called "Reverse False Claims" provision of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G). *Id.* ¶¶ 341-42. DOJ appears to have made that provision the basis for its new first count because it was not directly at issue in Judge Walter's recent *Swoben* dismissal (having been waived before the Ninth Circuit) and does not depend—at least according to DOJ—on the materiality of United's Attestations. *See Swoben*, 2017 WL 4564722, at *7-8; Compl. ¶ 342 (making no mention of United's Attestations, unlike the other three False Claims Act counts).

ARGUMENT

I. DOJ Still Fails Adequately To Allege That The Challenged Conduct Was Material To The Government's Decision To Pay United

The Amended Complaint fails adequately to allege that United's supposed regulatory violations were material to CMS's decision to pay United. As with its complaint in *Swoben*, the Amended Complaint here repeatedly affixes the "material" *label* to those alleged violations, *see, e.g.*, Compl. ¶¶ 334-35, but fails ever to allege that CMS would not have paid United's claims if it had known the

"truth" (as DOJ alleges it) about the accuracy of United's Risk Adjustment Attestations. As with its complaint in *Swoben*, therefore, the Amended Complaint here should be dismissed in its entirety for that basic pleading deficiency. Moreover, because DOJ was plainly on notice of the need to include such allegations, and took a month to do all it could to shore up its allegations following the *Swoben* dismissal (after a years-long investigation to ascertain the facts), the dismissal should be with prejudice.

A. DOJ Was Required To Plead That But For The Supposed Violations, CMS Would Not Have Paid The Relevant Claims

The Supreme Court held in *Escobar* that, in order to be actionable under the False Claims Act, a "misrepresentation must be material to the other party's course of action," which generally means "the Government's payment decision." 136 S. Ct. at 2001, 2002.[6] This "materiality standard is demanding." *Id*. at 2003. The fact that the government "would have the option to decline to pay if it knew of the defendant's noncompliance," the Court held, is not "sufficient for a finding of materiality." *Id*. Even where the government has "designate[d] compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment," that is insufficient. *Id*. A complaint must instead allege factually, as a matter of "'likely or actual behavior'" rather than mere legal entitlement, "that the [government] would not have paid these claims had it known of these violations." *Id*. at 2002, 2004 (citation omitted); *see also id.* at 2003 n.5 (recognizing that plaintiff must allege that if the false statement "had . . . not been made, the party complaining of the fraud *would not have taken* the action alleged to have been induced by the misrepresentation" (emphasis added)).

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[6] The same materiality requirement also applies to DOJ's common law claims for unjust enrichment and payment by mistake. *See, e.g.*, *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970).

The Supreme Court also made clear that this "rigorous materiality requirement" should be enforced vigilantly at the motion-to-dismiss stage, specifically directing that "False Claims Act plaintiffs must . . . plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Id.* at 1996, 2004 n.6. In the year-and-a-half since *Escobar*, courts have done just that. *Swoben* is one obvious (and directly applicable) example, *see* 2017 WL 4564722, at *6, but there are many others. In *United States ex rel. Dresser v. Qualium Corp.*, for example, the Northern District of California dismissed a DOJ complaint that "allege[d] in several places that the government would not have paid Defendants' claims had they known of fraudulent conduct" because the complaint "d[id] not explain why." No. 5:12-cv-0745-BLF, 2016 WL 3880763, at *6 (N.D. Cal. July 18, 2016). And in *United States ex rel. Mateski v. Raytheon Corp.*, Judge Wright held that an allegation that "'[t]he United States would not have paid Raytheon's Requests for Payment if the United States Government knew . . . that Raytheon had not performed . . . in conformity with the requirements and specifications of the . . . Contract'" was "'insufficient'" because "it does not show *how* Raytheon's misrepresentations were material." No. 2:06-cv-03614-ODW(KSx), 2017 WL 3326452, at *7 (C.D. Cal. Aug. 3, 2017) (citations omitted). If generic allegations that the government would not have paid are insufficient under *Escobar*, it necessarily follows that the wholesale failure even to make that boilerplate allegation is insufficient as well.

B. DOJ's Complaint Conspicuously Fails To Allege That CMS Would Not Have Paid Had It Known About The Supposed "Falsity" Of United's Attestations

The Amended Complaint falls well short of *Escobar*'s "demanding" and "rigorous" standard. While it includes bare-bones assertions that United's Risk Adjustment Attestations were "material," *see, e.g.*, Compl. ¶ 349 ("Defendants

knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation material to a false or fraudulent claim . . . ."), it fails to allege (let alone plausibly or with particularity) that CMS would have refused to make risk adjustment payments to United if it had known the "facts" behind those Attestations.

This deficiency is especially conspicuous because DOJ took a month to attempt to bolster its allegations on precisely this point following Judge Walter's decision in *Swoben*. DOJ *knew* that if it hoped to preserve its claims based on the materiality of the Attestations, it needed to allege that CMS would not have paid had it known that the Attestations were false. *Swoben*, 2017 WL 4564722, at *6. The only explanation for its failure to make that allegation is that it *cannot* make it without running afoul of the good faith pleading requirements of Rule 11.

The government has known of Poehling's claims for six years, and has investigated those allegations exhaustively. Indeed, some of the sources DOJ cites to show that United was on notice of the supposed falsity of its claims were CMS audits. *See, e.g.*, Compl. ¶ 155. If those audits were sufficient to put United on notice of the supposed falsity, then they were sufficient to put CMS on notice as well. And at the very least, it is "difficult[to] understand[] how the [government] remained unaware that the claims were false after the lawsuit was filed." *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1079 (N.D. Ill. 2016). Yet CMS has continued to make risk adjustment payments to United, without ever once holding back a payment because of doubts about whether United's Attestations are accurate. DOJ cannot plausibly allege that CMS would not pay United on these claims because it knows full well that CMS *is* paying them.

Instead, this case is a clear example of DOJ pressing a theory that is at odds with—or at the very least unsupported by—the government agency that is actually charged with responsibility for deciding whether to pay the claims in question. *Cf. United States v. BAE Sys. Tactical Vehicle Sys., LP*, No. 15-12225, 2017 WL

1457493, at *2 (E.D. Mich. Apr. 25, 2017) (describing DOJ's decision to pursue False Claims Act suit even after Army withdrew underlying contract claim on which False Claims Act allegations were based). As discussed above, at least some senior CMS officials have long agreed with United's position that MA plans would be underpaid if—as DOJ's theory here would effectively require—they were paid only for *verified* diagnosis codes, but using payment amounts calculated with *unverified* FFS data. *See supra* at 6-8. United and CMS are currently litigating that issue in an important APA challenge, and the dispute stretches back to well before Poehling's *qui tam* complaint was first filed in 2011. *See, e.g.*, American Academy of Actuaries Comment on RADV Sampling and Error Calculation Methodology at Exhibit 3, p. 69-70; Aetna Inc. Comments on Proposed Rule Regarding Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, at Exhibit 4, p. 89; America's Health Insurance Plans Comment on Proposed Rulemaking Regarding Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, at Exhibit 5, p. 141-42. And United employees have repeatedly discussed these issues with senior leadership at CMS, as the Complaint itself painstakingly acknowledges. *See* Compl. ¶¶ 224-29.

DOJ has sought to insert itself as the relevant decision-maker in this process. In its initial complaint, it went so far as to assert that because DOJ was not present at United's meetings with CMS, the senior CMS officials who participated "were not authorized to provide legal advice about United's obligations under the FCA *or any other laws*," including the Medicare Act. First Complaint-in-Intervention ¶ 183, ECF No. 114 (emphasis added). But arguments like that one cannot change the fact that it is CMS, not DOJ, that administers the Medicare Advantage program, and thus CMS, not DOJ, that decides whether an asserted regulatory violation is one over which the government will withhold payment. That is

likewise why DOJ cannot allege consistent with Rule 11 that the government would not have paid United's claims if it had known the facts about United's Attestations that DOJ now asserts.

Without that allegation, *Escobar* requires dismissal of DOJ's claims based on the Attestations. *See* 136 S. Ct. at 2004. As in *Swoben*, DOJ's failure to allege adequately that the supposed falsity of United's Attestations was material to CMS's decision to pay dooms each of those Counts. *See* Compl. ¶ 345 (Second Claim for Relief, asserting liability under 31 U.S.C. § 3729(a)(1)(A) and its predecessor provision based on "a false or fraudulent Risk Adjustment Attestation"); *id.* ¶ 349 (Third Claim for Relief, asserting liability under 31 U.S.C. § 3729(a)(1)(B) and its predecessor provision based on "a false Risk Adjustment Attestation"); *id.* ¶ 353 (Fourth Claim for Relief, asserting liability under 31 U.S.C. § 3729(a)(1)(G) and its predecessor provision based on "a false Risk Adjustment Attestation").

C. DOJ's Allegation That CMS Would Have Accepted Repayments If United Had Deleted Unsupported Codes Cannot Establish The Materiality Of Its Reverse False Claims Allegations

Unable to establish that the Attestations' supposed falsity was material, DOJ has tried to reshape its case around a new "reverse false claims" count that was not considered in *Swoben*, by either the Ninth Circuit or in the materiality decision on remand. *See* 848 F.3d at 1172 n.6 (noting that reverse false claims theory had been waived); 2017 WL 4564722, at *7-8 (refusing to consider waived reverse false claims theory on remand). As noted above, the First Claim for Relief of DOJ's Amended Complaint is now a claim under "the second part of 31 U.S.C. § 3729(a)(1)(G)," which DOJ has attempted to plead without reference to the materiality of the Attestations. Compl. ¶ 342. Instead, DOJ focuses that first count on the alleged falsity of *specific* diagnosis codes rather than (as in the other counts) the Attestations. *Id.* And it pleads that the codes are "inexorably material to the

amount (if any) paid" because "[i]f Defendants had complied with their obligation to delete invalid diagnoses . . ., Medicare's Risk Adjustment System . . . would have processed the corrected data and recalculated the risk score . . . automatically." *Id.* ¶¶ 333-34.

That novel and unsupported theory, if correct, would eviscerate the False Claims Act's materiality requirement in every case. As the Supreme Court explained in *Escobar*, a proper materiality analysis focuses on the hypothetical response of "the party complaining of the fraud"—*i.e.*, the government—if it had known of the violations. 136 S. Ct. at 2003 n.5. DOJ's Complaint, however, focuses instead on hypothetical different actions that the *defendant*, United, allegedly should have taken, and pleads that if United had attempted to return the payments, then of course CMS "automatically" would have accepted them. Compl. ¶¶ 333-34. But that will always be true, regardless of the agency's view of how important the underlying violation is.

Escobar itself illustrates the problem with DOJ's approach. There, the government conceded at oral argument that under its view of materiality, "[i]f the Government contracts for health services and adds a requirement that contractors buy American-made staplers, anyone who submits a claim for those services but fails to disclose its use of foreign staplers violates the False Claims Act" because "the defendant's use of foreign staplers would entitle the Government not to pay the claim in whole or in part." 136 S. Ct. at 2004. "The False Claims Act," the Court responded, "does not adopt such an extraordinarily expansive view of liability." *Id.* It simply cannot be that the exact same use of foreign staplers would result in a violation of the *reverse* false claims provision merely because the government pleads that it would accept repayment if a contractor, having realized that it had violated that contractual provision, mailed back a check or rescinded previously submitted claims for payment.

DOJ has tried similar arguments before, without success. In *Knudsen v. Sprint Communications Co.*, Judge Breyer considered a relator's allegations that a telephone company had failed to provide discounts to the government required under a "price reduction clause" of the government's contract. Nos. C13-04476 CRB et al., 2016 WL 4548924, at *13 (N.D. Cal. Sept. 1, 2016). The relator argued that the reductions were "per se material" because they affected the price the government would pay, *id.*, and DOJ argued in a statement of interest that the materiality standard was "easily met" because a price reduction clause "dictates how much the government pays" and is thus "manifestly material to the government's payment decision," United States' Statement of Interest, *Knudsen* 4 (N.D. Cal. July 7, 2016), ECF No. 89. Indeed, DOJ contended that it was "difficult to imagine a violation that more clearly has a natural tendency to affect the government's payment decision." *Id.* Judge Breyer, however, dismissed the complaint. While it might have been possible that the price reduction clause was material, he held, the complaint lacked factual allegations showing that this was *in fact* true. *Knudsen*, 2016 WL 4548924, at *13. Merely pointing to the clause's language and *potential* effect on the price the government would have paid, he held, was not enough. *See id.* Instead, the complaint had to include factual allegations of the sort that the Supreme Court identified in *Escobar* about the actual effect on the government's behavior. *See id.* The exact same thing is true here: DOJ's new First Claim for Relief lacks the necessary allegations that the codes were not just potentially but *actually* material, and therefore should be dismissed along with the rest of DOJ's claims.

II. DOJ's First Claim For Relief Does Not Apply To Alleged Overpayments Identified Before The 2009 Amendment To the False Claims Act

DOJ's new First Claim for Relief also has an additional problem. DOJ appears to assert that claim with respect to conduct as far back as 2005, but the

portion of the False Claims Act on which it relies applies only to overpayments that United allegedly first learned of after May 20, 2009.

A central aspect of DOJ's theory is that when United undertook chart reviews for the purpose of identifying additional diagnosis codes for submission to CMS, those same reviews also put it on notice of codes that previously had been submitted but that lacked adequate chart support. *See, e.g.*, Compl. ¶ 122. DOJ alleges that based on these chart reviews, United knew as far back as 2005 that it supposedly had been overpaid for those codes, but "knowingly and improperly avoided repaying Medicare" for them. *Id.* Until May 20, 2009, however, "retention of overpayment did not create an obligation" and thus was not a basis for liability under the False Claims Act. *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 636 F. Supp. 2d 739, 752 (N.D. Ill. 2009), *aff'd*, 652 F.3d 818 (7th Cir. 2011). Even if DOJ otherwise were correct that United received overpayments before then and failed to return them to the government, therefore, that allegation would not state a claim.

As the Complaint describes, Congress amended the False Claims Act in the the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617, adding the portion of Section 3729(a)(1)(G) on which the First Claim for Relief relies. *See* Compl. ¶ 117. Following that amendment, retention of an overpayment *can* create an obligation, the improper avoidance of which can be a basis for liability under Section 3729(a)(1)(G). But Congress made that amendment explicitly prospective, stating that it would apply only to "conduct on or after the date of enactment"—*i.e.*, May 20, 2009. *See* FERA, Pub. L. No. 111-21, § 4(f), 123 Stat. at 1621; *see also, e.g.*, *United States ex rel. Ahumada v. NISH*, 756 F.3d 268, 280 n.7 (4th Cir. 2014) ("[T]he 2009 amendments are generally not

retroactive.").[7] The FERA amendment did not transform United's past acceptance and knowing retention of alleged overpayments into a retroactive basis for treble damages under the False Claims Act.

Nor can DOJ avoid that result by arguing that retention of pre-May 2009 overpayments suddenly became a *prospective* offense upon FERA's enactment that continues indefinitely until the obligation is repaid. Courts have squarely rejected that argument on the ground that the "relevant retroactivity event" is "the moment a person comes to know of overpayments it is retaining." *United States ex rel. Stone v. OmniCare, Inc.*, No. 09 C 4319, 2011 WL 2669659, at *4 (N.D. Ill. July 7, 2011). If the defendant knowingly retained a given overpayment before FERA's enactment, therefore, then imposing liability for the "ongoing retention of overpayments" after the amendment was adopted "would work an impermissibly retroactive effect." *Id.*; *see also* John T. Boese, *Civil False Claims and* Qui Tam *Actions* § 5.01[B][3] (online 2017, 4th ed.).

To hold otherwise "would mean that any claim [a] Defendant has ever made on the United States government would be subject to liability under the FCA, so long as some money from that claim is somewhere in their coffers." *Stone*, 2011 WL 2669659, at *4. Indeed, construing Section 3729(a)(1)(G) to make retention of past overpayments a continuing offense would effectively abolish the six-year statute of limitations and ten-year statute of repose Congress enacted for the False Claims Act as a whole. *See* 31 U.S.C. § 3731(b). That is true not only for the reverse false claims provision itself, but for the other provisions of the False Claims Act as well. Any time-barred suit under Section 3729(a)(1)(A) concerning the submission of a false claim, for example, could simply be resuscitated and

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[7] The only exception is FERA's amendments to Section 3729(a)(1)(B), which Congress made applicable "as if enacted on June 7, 2008." FERA, Pub. L. No. 111-21, § 4(f)(1), 123 Stat. at 1621.

redrafted as a suit under Section 3729(a)(1)(G) based on the defendant's *retention* of the payment that that claim had generated, regardless of how long ago the allegedly false claim had been paid. There is no basis in the text of the statute, or the legislative history, for believing that Congress intended that anomalous result—and it is a "fair assumption that Congress is unlikely to intend any radical departures from past practice without making a point of saying so." *Jones v. United States*, 526 U.S. 227, 234 (1999). Instead, the "language and design of the statute as a whole," *Household Credit Servs., Inc. v. Pfenning*, 541 U.S. 232, 239 (2004) (citation omitted), show that Congress did not silently add a "continuing offense" provision to the False Claims Act that nullifies its statutes of limitations and repose.

CONCLUSION

DOJ filed the Amended Complaint in an attempt to cure the deficiencies that led *Swoben* to be dismissed. It had every incentive to make the necessary allegations about materiality here that had been lacking there. And yet it failed to do so. It has failed adequately to allege that United's Risk Adjustment Attestations (Counts 2-4) or the unsupported diagnosis codes themselves (Counts 1, 5, and 6) were material. And in trying (unsuccessfully) to find a way around that problem that was not already rejected in *Swoben*, it has made the additional error of invoking a legal provision that does not even apply to much of the time period addressed in the Amended Complaint. For all of these reasons, DOJ's Complaint should be dismissed with prejudice.

Dated: December 8, 2017

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

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

Assigned to Hon. Michael W. Fitzgerald

DECLARATION OF DAVID J. SCHINDLER IN SUPPORT OF UNITED'S MOTION TO DISMISS

Date: January 29, 2018
Time: 10:00 a.m.
Ctrm: 5A

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

1. I am an attorney with the law firm of Latham & Watkins LLP, counsel of record for Defendant UnitedHealth Group Incorporated and its affiliated entities named as Defendants in this action (collectively, "United Defendants"). I am admitted to practice law in the State of California and am a member in good standing of the bar of the United States District Court for the Central District of California. I submit this Declaration in support of United's Motion to Dismiss, filed concurrently herewith.[1]

2. Attached hereto as Exhibit 1 is a true and correct copy of Aetna Inc. Comments on Proposed Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits.

3. Attached hereto as Exhibit 2 is a true and correct copy of Humana Comment on RADV Sampling and Error Calculation Methodology.

4. Attached hereto as Exhibit 3 is a true and correct copy of American Academy of Actuaries Comment on RADV Sampling and Error Calculation Methodology.

5. Attached hereto as Exhibit 4 is a true and correct copy of Aetna Inc. Comments on Proposed Rule Regarding Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.

6. Attached hereto as Exhibit 5 is a true and correct copy of America's Health Insurance Plans Comment on Proposed Rulemaking Regarding Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.

[1] The following materials were submitted by the Centers for Medicare & Medicaid Services ("CMS") in the administrative record for *UnitedHealthcare Insurance Co. v. Price*, No. 1:16-cv-00157-RMC (D.D.C.).

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on December 8, 2017, at Los Angeles, California.

/s/ David J. Schindler
David J. Schindler

Exhibit 1

Aetna Inc.'s Comments on Proposed Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits

January 21, 2011

Aetna Inc. welcomes the opportunity to submit comments on the proposed sampling and error calculation methodology for conducting Risk Adjustment Data Validation ("RADV") audits that the Centers for Medicare & Medicaid Services ("CMS") published for comments on December 20, 2010. While Aetna agrees that it is important to ensure accurate payments to Medicare Advantage ("MA") organizations, the process proposed by CMS will reduce, not increase, the accuracy of payments. The proposed methodology is inconsistent with the Medicare Act requirement, as well as CMS's stated purpose for its RADV audits, to ensure that payments to MA organizations are based on the "health status" of the enrollees in their plans.

Aetna is one of the nation's leading diversified health care benefits companies, serving approximately 36.1 million people with information and resources to help them make better informed decisions about their health care. Through its affiliates and subsidiaries, Aetna offers a broad range of traditional and consumer-directed health insurance products and related services, including HMO and PPO plans for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna has offered MA plans since the early years of the program when Medicare Part C (formerly known as "Medicare+Choice") was first established under the Balanced Budget Act of 1997. Aetna's MA members typically receive enhanced benefits over standard Medicare fee-for-service coverage, including reduced cost-sharing for preventive care,

vision, and other services. As of January 1, 2011, Aetna offered Medicare Advantage HMO and PPO plans in 128 counties and 28 states.

INTRODUCTION

Under Part C of Title XVIII of the Social Security Act (the "Medicare Act"), the Secretary of Health and Human Services ("HHS") is required to make adjustments in payments to MA organizations based on the "health status" of the enrollees in their plans, to "ensure actuarial equivalence."[1] This provision requires that, compared to a benchmark payment amount, MA organizations are to be paid a greater amount for an enrollee who is less healthy than the average Medicare beneficiary, and a lesser amount for an enrollee who is healthier than average. Congress's purpose in requiring greater payments to MA organizations for enrollees who are less healthy than average was to ensure that these enrollees, who typically seek more medical services and incur greater medical costs, receive flexible and robust coverage through the Medicare program.[2]

CMS's methodology of making risk adjustments in payments to MA organizations based on diagnoses by their enrollees' medical providers is intended to fulfill this statutory mandate. The stated purpose of the agency's RADV audits of those risk-adjusted payments is to verify that this "payment methodology has been applied correctly and the MA organization has received the amount to which it was entitled under this methodology."[3] In reality, however, CMS's RADV audit process and proposed

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[1] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

[2] See HEALTH CARE FINANCING ADMINISTRATION, OFFICE OF STRATEGIC PLANNING, REPORT TO CONGRESS: PROPOSED METHOD OF INCORPORATING HEALTH STATUS RISK ADJUSTERS INTO MEDICARE+CHOICE PAYMENTS 5-6 (Mar. 1, 1999) ("1999 Report"), available at http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/RTC_RiskAdjusters1999.pdf.

[3] Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,678, 19,745 (Apr. 15, 2010) ("April 2010 Regulations").

sampling and error calculation methodology would do the opposite, by retroactively adjusting payments to MA organizations based on a unique recordkeeping rule, not the health status of MA plans' members.

1. **The One Best Medical Record Requirement Violates The Medicare Act And The Administrative Procedure Act.** The proposed sample and error calculation methodology is flawed from the start because it incorporates the improper "One Best Medical Record" audit rule.[4] Under the One Best Medical Record rule, numerous false discrepancies are identified in the agency's RADV audits. A proper diagnosis by a treating physician will be deemed a "discrepancy" by CMS because a coder finds that there is not a single "best medical record" that meets various arbitrary and restrictive documentation standards unilaterally established by CMS specifically for the audit process. The imposition of the One Best Medical Record requirement is invalid because the rule conflicts with the statutory mandate that MA payments be based on the "health status" of the enrollees in their plans, is inconsistent with current medical recordkeeping practices, and was never subject to proper rulemaking procedures.

2. **The Proposed Methodology Violates Actuarial Principles By Failing To Ensure Consistency With The Fee-For-Service Program.** CMS's RADV audit process also fails to consider coding practices in the fee-for-service ("FFS") program,

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[4] While CMS's December 20, 2010 notice relates primarily to the agency's proposed methodology for calculating payment error, the validity of that methodology depends on, and is intertwined with, additional features of the agency's RADV audit process. As the notice acknowledges, for example, the agency's sampling methodology determines which MA enrollees will be subject to audit. See Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits, Request for Comment, at 1-2 (Dec. 20, 2010) ("December 2010 Proposed Methodology"). The agency then applies its audit requirements and procedures to make enrollee-level determinations, to which the extrapolation methodology is applied to calculate contract-level payment errors. Id. at 2-3. Aetna has therefore included comments on features of CMS's underlying RADV audit process that are incorporated in the payment error calculation methodology, such as the agency's "One Best Medical Record" rule.

despite the fact that CMS relies on coding from FFS claims to calibrate its risk-adjusted payments to MA organizations. Under sound actuarial principles, it is impossible to know whether MA organizations have been paid accurately by conducting a review of the medical records supporting MA coding, without also considering the medical records supporting FFS coding. CMS is therefore ignoring the statutory "actuarial equivalence" requirement, as well as the basic actuarial premise behind the risk adjustment methodology adopted by CMS.

3. **The Proposed Sampling And Stratification Methodology Fails To Provide Data That Can Be Extrapolated To Make Payment Adjustments.** CMS's proposed methodology for calculating payment error would take the agency's audit findings for a small sample of enrollees and extrapolate them to a broader contract-level population, thereby magnifying the impact of CMS's flawed audit requirements and reducing payments to MA organizations for enrollees who are less healthy than average. The application of the proposed methodology is therefore inconsistent with the Medicare Act. In addition, there are numerous statistical flaws with the proposed sampling and error calculation methodology that are likely to further skew the contract-level error calculations and audit results.

4. **The Error Calculation Methodology Conflicts With Current MA Contracts.** If CMS fails to address these concerns, the agency's RADV audits will undermine the financial soundness of the Medicare Advantage program and interfere with existing contracts between MA organizations and CMS. As Congress has recognized, the viability and proper functioning of Medicare Advantage depends on the principle that MA organizations should be paid accurately for the benefits and services

they provide—particularly as to payments with respect to Medicare enrollees with serious medical conditions. Yet CMS proposes to retroactively reduce those payments through its audit process. Ultimately, the burden of CMS's invalid rules and methodologies will fall on Medicare beneficiaries, who will bear the increased costs of the new recordkeeping obligations imposed on providers by CMS's RADV audits. In addition, by undermining the actuarial soundness of the MA program, CMS could even cause some beneficiaries to lose access to the flexible, affordable, and innovative services that the Medicare Advantage program provides.[5]

For these reasons, CMS's RADV audit processes and methodologies are arbitrary, outside the scope of CMS's authority, and inconsistent with the terms of MA organizations' contracts with CMS. Aetna therefore requests that CMS withdraw the proposed payment error calculation methodology. At a minimum, CMS should undertake a complete notice-and-comment rulemaking so that these issues may be addressed by all interested stakeholders.

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[5] See, e.g., H.R. Rep. No. 105-217, at 585 (1997) (Conf. Rep.) (discussing the enactment of Medicare+Choice, the precursor to Medicare Advantage, and stating that the program would "allow beneficiaries to have access to a wide array of private health plan choices in addition to traditional fee-for-service Medicare" and would "enable the Medicare program to utilize innovations that have helped the private market contain costs and expand health care delivery options"); H.R. Rep. No. 108-391, at 524-25 (2003) (Conf. Rep.) (observing that MA organizations must undergo a competitive bidding process, which "encourage[s] beneficiaries to enroll in the most efficient plan, producing savings for both beneficiaries, through reduced premiums, and for taxpayers, through relatively lower Medicare costs").

COMMENTS

1. The "One Best Medical Record" Rule Is Invalid And Produces Inaccurate Audit Results.

The starting point for any methodology designed to calculate payment error is the proper definition of an "error."[6] Here, CMS's proposed methodology for calculating payment error is flawed because the agency's application of that methodology is premised on invalid and inaccurate determinations of what constitutes an error in the agency's RADV audits.

Specifically, CMS has limited its RADV audits to the consideration of the "One Best Medical Record" supporting each Hierarchical Condition Category ("HCC") submitted to the agency by an MA organization.[7] According to the audit criteria specified by CMS, the one medical record must: (1) include a diagnosis supporting the HCC; (2) be recorded in a "single encounter for care" in which the physician or practitioner personally saw the member; (3) occur on a date of service within the audit data collection period; (4) include the physician or practitioner's credentials; and (5) be signed by the physician or practitioner who meets CMS criteria.[8] A record that does not satisfy these requirements will not be considered to validate an HCC for an MA organization's member, whether or not the member is correctly diagnosed with the health condition corresponding to that HCC. As described further below, CMS's One Best Medical Record rule is both substantively and procedurally deficient.

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[6] "Research teams sometimes restrict the role of sampling to the single question of sample size. To improve the validity and reduce total error, the implications of sampling must be included throughout the study." G.T. HENRY, PRACTICAL SAMPLING 15-16 (SAGE Publications 1990).

[7] See 42 C.F.R. § 422.311(c)(2)(i)(B); April 2010 Regulations, 75 Fed. Reg. at 19,742-43, 19,748-49.

[8] 42 C.F.R. § 422.2 (defining "one best medical record"); see also April 2010 Regulations, 75 Fed. Reg. at 19,742-43, 19,748-49.

a) The One Best Medical Record Rule Results In Inaccurate Determinations Of The Health Status Of MA Enrollees.

The One Best Medical Record rule violates the Medicare Act's requirement that payments to MA organizations accurately reflect enrollee "health status" because it unreasonably limits the types of supporting documentation that MA organizations may submit and that CMS will consider in RADV audits. The One Best Medical Record rule prevents consideration of alternative sources of information that are available to prove that a member has the condition diagnosed. Absent the One Best Medical Record rule, an HCC could be substantiated by a record from a prior year, or a sworn statement from a physician stating that the patient still had the condition during the audit year.

It makes no sense to eliminate these legitimate sources of information inasmuch as the stated purpose of the audit is to determine whether the individual actually had the condition identified by the HCC.[9] It is also arbitrary not to consider data and records that CMS itself maintains, and that can verify the health status of a Medicare beneficiary. For example, every time a Medicare beneficiary receives inpatient hospital treatment, a bill is generated and sent to CMS, even if the hospital is not seeking payment. These bills include diagnoses that CMS could use to verify these beneficiaries' HCCs.

The record before CMS demonstrates that the One Best Medical Record rule prevents consideration of information verifying the HCCs that have been assigned to MA enrollees and therefore results in erroneous adjustments to MA payments. Aetna, in responding to the 2007 RADV pilot audit, submitted additional documentation beyond the One Best Medical Record for many HCCs. These documents demonstrated that most

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[9] Cf. Baystate Med. Ctr. v. Leavitt, 545 F. Supp. 2d 20, 40-41 (D.D.C. 2008) (requiring HHS to consult numerous additional sources to satisfy the agency's obligation to calculate payments based on the "best available data").

of the HCCs that CMS had challenged were properly assigned based on the providers' diagnoses; yet, under the One Best Medical Record rule, they were not considered by CMS. Indeed, CMS refused to consider numerous attestations by treating physicians that Aetna submitted during the audit process supporting particular HCCs, as well as numerous medical records that did not fit within CMS's overly restrictive rules.

Similarly, MA organizations are not permitted to introduce "new" HCCs in the course of the RADV audit process if the HCCs were not previously assigned to the enrollee being audited, and if the diagnoses supporting the HCCs do not appear on the One Best Medical Record reviewed by CMS.[10] Because random discrepancies between a clinical record and a claim form can result in either undercoding or overcoding on the claim form, a fair audit would allow for correction of all coding discrepancies. By rejecting the assignment of new HCCs that are supported by additional medical records, CMS's audit will not determine whether all of the correct HCCs were assigned to Medicare members, even if the HCCs should be supported by medical records). Instead, CMS's proposed audits will merely eliminate HCCs not validated by the One Best Medical Record. This approach unfairly skews the audit results.

The One Best Medical Record rule therefore undermines the stated purpose of the agency's risk adjustment methodology, to "strengthe[n] the Medicare program by ensuring that accurate payments are made to MA organizations based on the *health status*

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[10] In the 2007 pilot audit, CMS permitted MA organizations to support HCCs within hierarchies (both higher and lower) if the medical documentation supported such an HCC, but not a different HCC than initially assigned. CMS did allow additional HCCs in the very limited circumstances where an additional HCC was coincidentally also included on the same One Best Medical Record. This limited allowance does not resolve the more significant issue of whether to credit a new HCC supported by other medical records.

plus demographic characteristics of their enrolled beneficiaries."[11] Indeed, the agency has justified its RADV audits by arguing that the audits ensure "accurate payment" to MA organizations and "improve the accuracy of the risk adjustment data."[12] However, the current design of CMS's RADV audits actually ensures inaccurate payments to MA organizations, and is therefore inconsistent with the Medicare Act. The One Best Medical Record rule tests a novel recordkeeping system rather than verifying the actual "health status" of MA enrollees.[13]

The One Best Medical Record requirement is also inconsistent with Congress's mandate that the Secretary of HHS obtain an evaluation by an outside actuary of the actuarial soundness of the risk adjustment system.[14] The required report was developed by the Risk Adjustor Work Group of the American Academy of Actuaries and delivered to CMS on January 14, 1999. The Academy report considered using diagnostic data from administrative sources (typically from claim records or encounter files), from clinical records (such as medical charts), and from surveys.[15] The Academy report concluded that the administrative sources should be used:

> At this point in time, it is our experience as actuaries that clinical information from sources such as medical records

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[11] Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 74 Fed. Reg. 54,634, 54,673 (Oct. 22, 2009) ("2009 Proposed Rule") (emphasis added).

[12] Id. at 54,674; April 2010 Regulations, 75 Fed. Reg. at 19,745, 19,747; see also 74 Fed. Reg. at 54,675 (citing § 1853(a)(3) of the Social Security Act (42 U.S.C. § 1395w-23(a)(3)) as authority for issuing RADV audit regulations).

[13] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

[14] 42 U.S.C. § 1395w-23(a)(3)(A).

[15] AMERICAN ACADEMY OF ACTUARIES, RISK ADJUSTOR WORK GROUP, ACTUARIAL REVIEW OF THE HEALTH STATUS RISK ADJUSTOR METHODOLOGY 30 (Jan. 14, 1999), available at http://www.actuary.org/pdf/medicare/hcfariskadj.pdf ("Based on our experience, there appear to be at least three main classes of models that meet the BBA requirement for health status-based payment," namely "[d]iagnostic-based models with data gained from administrative sources (typically from claim records or encounter files)," "[d]iagnostic information from clinical records, such as medical charts," and "[s]urvey-based health status information.").

> and patient charts is nearly impossible to gather, except in the most manpower-intensive manner through actual chart audits, etc. As a result, models in this category are of great theoretical interest but of little practical help for the [MA] program.[16]

CMS, contrary to congressional mandate, has now chosen to ignore the Academy's judgment of the actuarial soundness of risk adjustment using administrative sources, by considering only clinical records and ignoring administrative sources under the agency's One Best Medical Record rule in RADV audits. CMS has not obtained a new independent actuarial report to justify its new rule and its decision to ignore the Academy report. Rather, CMS simply imposed the rule, contravening the clear opinion of the American Academy of Actuaries and the statutory mandate to pay MA plans based on an enrollee's health status.

b) The One Best Medical Record Rule Is Inconsistent With Physician Recordkeeping Practices.

The One Best Medical Record rule is also inconsistent with the real-world medical recordkeeping practices of providers and CMS's own rules on claims. Providers do not prepare their medical records to support a diagnostic condition as set forth in CMS's One Best Medical Record rule. Rather, providers write down information in the medical record that they believe is necessary for treatment. The medical record may not even include a diagnosis, much less the "magic words" that a CMS coder may look for as part of the RADV audit process. CMS has not cited any statute, rule, or regulation requiring a physician to maintain clinical records in a way that can later be interpreted by a coder to support an HCC. Instead, providers report diagnoses based on their medical determinations on CMS 1500 Health Insurance Claim Forms that the providers submit for

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[16] Id.

payment. Yet, under the One Best Medical Record rule, CMS rejects clear diagnoses that are recorded only on claim forms, even if the medical record reports symptoms and conditions consistent with the diagnoses.

Provider recordkeeping practices vary widely, and CMS's rules fail to account for this reality. Providers may not use the narrative description of a diagnosis set forth in the ICD-9 in their medical records. For example, a podiatrist may note that a patient has diabetes and is being treated for foot problems. The medical record may not state that the patient had "[d]iabetes with peripheral circulatory disorders," the specific ICD-9 language, but the claim form will code the patient's condition as ICD-9 250.7, that very diagnosis. Any ambiguity regarding the diagnosis would be removed by considering the diagnosis on the claim form submitted by the provider.

Physicians also may record a diagnosis in a medical record by stating that a patient has a "history of" cancer or has symptoms "consistent with" a heart condition. These diagnoses can be confirmed by other medical records showing treatment for the conditions, or by claim forms. Pharmacy records and prescription drug data can also verify many chronic conditions, such as diabetes. In addition, hospital records may shed light on the member's condition whenever the medical record itself is not sufficiently clear. CMS precludes consideration of all these records in its RADV audits.

The One Best Medical Record rule is also inconsistent with CMS's own instructions. For example, CMS recognizes that a provider may misuse the "history of" description in a way that can cause an error in the diagnosis:

> A physician can make errors in one of two ways with respect to these codes. One error is to code a past condition as active. The opposite error is to code as "history of" a

> condition when that condition is still active. Both of these errors can impact risk adjustment.[17]

Yet, in its RADV audits, CMS will reject a physician's diagnosis set out on the claim form stating that the patient presently has the condition if the medical record states the patient has a "history of" the condition, without allowing for additional documentation that would help to verify the proper diagnosis.

Similarly, CMS recognizes the use of "alternative data sources (ADS)" by MA organizations to verify diagnoses for risk adjustment purposes, even though CMS arbitrarily refuses to consider ADS in its RADV audits.[18] CMS's 2008 Participant Guide specifically provided that "MA organizations may use ADS as a ***check*** to ensure that all required diagnoses have been submitted to CMS for risk adjustment purposes, such as pharmacy records and information provided to national or state cancer registries."[19] While these records alone are not sufficient to verify a diagnosis under CMS's rules, they should be allowed to supplement the record to verify a physician's diagnosis.

Moreover, the ICD Official Guidelines for Coding and Reporting, an authority for coding practices specified by CMS, state that "[t]he entire record should be reviewed to determine the specific reasons for the encounter and the conditions treated."[20] Contrary

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[17] CENTERS FOR MEDICARE & MEDICAID SERVICES, 2007 RISK ADJUSTMENT DATA TRAINING FOR MEDICARE ADVANTAGE ORGANIZATIONS, PARTICIPANT GUIDE § 6.4.3.

[18] CENTERS FOR MEDICARE & MEDICAID SERVICES, 2008 RISK ADJUSTMENT DATA TECHNICAL ASSISTANCE FOR MEDICARE ADVANTAGE ORGANIZATIONS, PARTICIPANT GUIDE § 3.2.4 ("2008 Participant Guide").

[19] Id. (emphasis in original).

[20] ICD-10-CM OFFICIAL GUIDELINES FOR CODING AND REPORTING 1 (2010), available at https://www.cms.gov/ICD10/Downloads/7_Guidelines10cm2010.pdf; see also ICD-9-CM OFFICIAL GUIDELINES FOR CODING AND REPORTING 1 (2006), available at http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.

to these instructions, CMS mandates a single best medical record be used to verify a diagnosis, rather than the "entire record."

The One Best Medical Record rule is also inconsistent with CMS's requirements in conducting audits under other Medicare programs. There is no such rule for FFS providers. To the contrary, a Medicare Part B physician can fill in gaps in his documentation by offering testimony to explain a beneficiary's condition when appealing a payment determination.[21] The One Best Medical Record requirement is simply an arbitrary rule that is inconsistent with current practices and requirements, and will not lead to accurate assignments of HCCs.

c) Notice-And-Comment Rulemaking Is Required To Institute The One Best Medical Record Rule.

CMS's One Best Medical Record rule is also invalid because the agency has failed to undertake appropriate notice-and-comment rulemaking before implementing the rule. This rulemaking process is required by statute, and would allow the agency to engage in a proper consideration of statutory requirements, as well as the substantial burdens imposed by the recordkeeping and coding requirements incorporated in the One Best Medical Record rule.

Moreover, allowing for notice and comment would permit all stakeholders to assess and comment fully on CMS's proposed rules. As President Obama instructed in his recent executive order, "[r]egulations shall be adopted through a process that involves public participation," and "an open exchange of information and perspectives among . . .

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[21] See April 2010 Regulations, 75 Fed. Reg. at 19,748; see also CENTERS FOR MEDICARE & MEDICAID SERVICES, MEDICARE PROGRAM INTEGRITY MANUAL, Chapter 3, Verifying Potential Errors and Taking Corrective Action, § 3.4.1.1 (Dec. 2010) (stating that auditors of fee-for-service providers may use "any information they deem necessary," including "soliciting documentation from the provider or other entity," and "documentation related to the patient's condition before and after a service in order to get a more complete picture of the patient's clinical condition"); see also id. § 3.4.1.2.

experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole."[22] Here, CMS has failed to allow for "an open exchange of ideas," has created substantial uncertainty, and has threatened to undermine the innovation and competiveness that the Medicare Advantage program provides to enrollees who are most in need of flexible coverage.[23]

Both the Medicare Act and the APA require CMS to issue substantive rules through notice-and-comment rulemaking. The Medicare Act provides that "[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the payment for services . . . under this subchapter shall take effect unless it is promulgated by the Secretary by regulation."[24] The APA also requires notice-and-comment rulemaking for substantive rules.[25] As the D.C. Circuit has held, notice-and-comment rulemaking is necessary when a rule carries "'the force and effect of law,'" as opposed to "spell[ing]

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[22] Exec. Order No. __, 76 Fed. Reg. __, § 2(a) (Jan. 18, 2011), available at http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order; see also id. § 2(b) ("To promote that open exchange, each agency, consistent with Executive Order 12866 and other applicable legal requirements, shall endeavor to provide the public with an opportunity to participate in the regulatory process. To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days. To the extent feasible and permitted by law, each agency shall also provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov, including relevant scientific and technical findings, in an open format that can be easily searched and downloaded. For proposed rules, such access shall include, to the extent feasible and permitted by law, an opportunity for public comment on all pertinent parts of the rulemaking docket, including relevant scientific and technical findings.").

[23] Id. § 1(a).

[24] 42 U.S.C. § 1395hh(a)(2).

[25] 5 U.S.C. § 553(d); Lincoln v. Vigil, 508 U.S. 182, 196 (1993); see also Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (lamenting that the problem with broad regulations by agencies is that "[l]aw is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations"); id. at 1024-26.

out a duty fairly encompassed" within an existing statute or regulation.[26] That is, a rule is substantive if the rule itself "impose[s] duties and obligations on those who are regulated."[27] Moreover, the D.C. Circuit has held that an agency cannot "make a fundamental change in its interpretation of a substantive regulation without notice and comment."[28]

CMS's application of the One Best Medical Record rule without notice-and-comment rulemaking is improper because that rule is substantive. The rule is more than just a part of an audit policy or procedure. Rather, the rule constitutes a "substantive legal standard,"[29] and "carries the force and effect of law" in imposing a duty that did not previously exist under statute or regulation.[30] The One Best Medical Record rule purports to impose a substantive limitation on the HCCs that an MA organization may assign to its members, based on the documentation an MA organization can use to support those HCCs. Under the rule, as applied through the proposed payment error methodology, MA organizations that submit HCCs risk substantial clawbacks by CMS with respect to payments for patients with complex conditions that can be validated only by considering multiple medical records. The rule also requires dramatic changes in the recordkeeping practices of providers, as it necessitates the documentation of every possible diagnosis code for every patient in every medical record.

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26 Paralyzed Veterans of Am. v. D.C. Arena L.P., 117 F.3d 579, 588 (D.C. Cir. 1997) (quoting Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1109 (D.C. Cir. 1993)).

27 Appalachian Power Co., 208 F.3d at 1027.

28 Paralyzed Veterans, 117 F.3d at 586.

29 42 U.S.C. § 1395hh(a)(2).

30 Paralyzed Veterans, 117 F.3d at 588.

The D.C. Circuit has recognized that "changing the method of measuring compliance" with a statutory or regulatory limitation constitutes a substantive change if it "affect[s] the stringency of the limitation itself."[31] CMS's One Best Medical Record rule does just that. The rule, and its implementation through extrapolation, is a substantial departure from prior practice, and it changes CMS's method for measuring compliance with the risk-adjustment system in a manner that changes the substance of the system. In previous audits, MA plans were allowed to submit new and clarifying documentation. The HCC for a given MA member could be verified by multiple documents prepared by various physicians, which verified the HCC when considered together. In the pilot RADV audit for contract year 2005, for example, MA plans were allowed to submit new and clarifying documentation in disputing CMS's audit findings, and HCCs could be verified by multiple records.[32] Indeed, in the 2007 pilot audit, CMS has not even provided the coder's basis for rejecting a physician's diagnosis to allow the MA organization and the treating physician to address the coder's concerns.

The purpose of rulemaking is to allow an agency to obtain and consider all the potential information and data necessary to make a determination as to the propriety of any rule or regulation.[33] "This articulation of the agency's duty is consistent with the repeated recognition in the case law that the agency must use 'the most reliable data

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[31] Appalachian Power Co., 208 F.3d at 1027.

[32] 2009 Proposed Rule, 74 Fed. Reg. at 54,674.

[33] Tripoli Rocketry Ass'n v. BATFE, 437 F.3d 75, 81 (D.C. Cir. 2006); Saint James Hosp. v. Heckler, 760 F.2d 1460, 1468-72 (7th Cir. 1985) (holding that a rule was arbitrary and capricious because the Secretary of HHS relied on a statistically flawed study, refused to investigate "several" important, but ancillary, factors that affected payments and costs related to malpractice lawsuits, and failed to respond to comments adequately).

available' to produce figures that can be considered sufficiently 'accurate.'"[34] An agency action is unlawful if it is implemented "without observance of procedures required by law."[35] At a minimum this requires publication of the new rule or guideline for comment.[36] Under this process, an individual would have the right to challenge the rule, based on the administrative record, both administratively and judicially if the rule became finalized.[37] Here, CMS has not allowed an administrative record to be developed.[38]

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[34] Baystate Med. Ctr. v. Leavitt, 545 F. Supp. 2d 20, 41 (D.D.C. 2008) (quoting Methodist Hosp. of Sacramento v. Shalala, 38 F.3d 1225, 1230 (D.C. Cir. 1994)); Cnty. of Los Angeles v. Shalala, 192 F.3d 1005, 1021-23 (D.C. Cir. 1999); Alvarado Cmty. Hosp. v. Shalala, 155 F.3d 1115, 1125 (9th Cir. 1998).

[35] See 5 U.S.C. § 706(2)(D); accord FLRA v. U.S. Dep't of the Treasury, Fin. Mgmt. Serv., 884 F.2d 1446, 1454 (D.C. Cir. 1989) (an agency's interpretation of its own regulations is not controlling if it is "plainly erroneous or inconsistent" with the language of the regulation); The Honorable David Pryor Chairman, Subcommittee on Federal Services, Post Office, and Civil Service Committee on Governmental Affairs, United States Senate, 1989 WL 240606, at *2 (Comp. Gen.) (letter, dated Feb. 23, 1989, of the Comptroller General, concluding "that OPM's determination is inconsistent with its current FEHBP regulations"); Roman v. CIA, 297 F.3d 1363, 1368-69 (Fed. Cir. 2002) (holding that where the OPM relied on its CSRS and FERS Handbook for Personnel and Payroll Offices and not a regulation, such reliance was not entitled "to the same weight as its reliance on a regulation that was promulgated pursuant to statutory authority and following formal notice and comment proceedings").

[36] Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives, No. 00CV0273 (RBW), 2002 WL 33253171, at *10 (D.D.C. June 24, 2002) ("Whether an agency characterizes its own actions as rulemaking is not determinative . . . . [I]t is the substance of what the agency has purported to do and has done which is decisive." (internal quotation and alteration omitted)).

[37] 5 U.S.C. §§ 553, 706.

[38] See 5 C.F.R. § 553(d); Brandt v. Hickel, 427 F.2d 53, 56-57 (9th Cir. 1970) (holding that an agency violated due process by giving an appellant erroneous and ambiguous instructions as to her procedural rights and responsibilities in complying with agency regulations). The importance of providing the opportunity for review and comment was recognized by the Office of Management and Budget ("OMB") in its recent "Final Bulletin for Agency Good Guidance Practices." OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES (Jan. 18, 2007), available at http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-07.pdf. That report noted that "OMB has been particularly concerned that agency guidance practices should be more transparent, consistent and accountable." Id. at 2. OMB recommended that any changes in procedures include "public participation, including notice-and-comment under the [APA]; . . . justification for the rule, including a statement of basis and purpose under the APA; . . . and judicial review." Id. at 3; see also id. at 13-16, 22. The report recognized that rules "which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they are initially labeled." Id. at 3; see also Appalachian Power Co., 208 F.3d at 1020-24 (same).

CMS's application of its proposed payment error calculation methodology, and the RADV audit requirements incorporated in that methodology, also will result in a denial of MA organizations' constitutional rights to due process. U.S. Const. amend. V.

2. The Proposed Error Calculation Methodology Violates The Principles Of Actuarial Soundness And Equivalence.

CMS's proposed error calculation methodology also changes the actuarial assumptions of risk adjustments to MA payments in a way that is inconsistent with the Medicare Act. To calibrate its system of risk adjustments based on health status, CMS relied on FFS claims to measure the relative costs of providing benefits to Medicare beneficiaries with various medical conditions. Under a proper actuarial analysis, it is therefore impossible to know whether MA organizations are being "overpaid" based on a methodology that relies on medical records simply by reviewing the medical records supporting the HCCs assigned by MA organizations. Rather, a similar review of the medical records supporting the FFS claims that were used to calibrate the MA payments should be conducted.[39]

As the Medicare Act emphasizes, in applying risk adjustments based on "health status," CMS is ultimately required to "ensure actuarial equivalence."[40] Because the statute does not define "actuarial equivalence," that phrase takes its ordinary meaning.[41] "Actuarial equivalence" ordinarily refers to the principle that two types of payments or benefits with different nominal values may have the same real value when factors such as interest rates and risk are taken into account.[42] Thus, the statute requires the Secretary to

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[39] 42 U.S.C. § 1395w-23(a)(1)(C)(i)-(ii); see also April 2010 Regulations, 75 Fed. Reg. at 19,749 ("We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue [of the FFS coding].")

[40] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

[41] See Ransom v. FIA Card Servs., N.A., 562 U.S. __, slip op. at 7 (2011).

[42] See, e.g., Summers v. State St. Bank & Trust Co., 453 F.3d 404, 409 (7th Cir. 2006) ("$10,000 certain [and] a 1 percent chance of obtaining $1 million . . . are actuarial equivalents."); see also AMERICAN ACADEMY OF ACTUARIES, CRITICAL ISSUES IN HEALTH REFORM: ACTUARIAL EQUIVALENCE 1 (May 2009), available at http://www.actuary.org/pdf/health/equivalence_may09.pdf ("Actuarial equivalence is a general term used to describe two or more benefit plan designs that have approximately the same value.").

make adjustments based on "health status" so that the monthly payment to each MA organization accounts for the risk associated with health status.

CMS's RADV audits are inconsistent with this statutory requirement because those audits cannot be reconciled with the agency's own risk adjustment methodology. MA payments are based upon the Medicare payments made to FFS providers under Medicare Parts A and B.[43] CMS used FFS payment data to estimate the costs of providing treatment to a Medicare beneficiary with a condition falling within a given HCC.[44] Using the ICD-9 codes supplied by FFS providers on 1500 Health Insurance Claim Forms—not medical records—CMS calculated the cost incurred for FFS beneficiaries with a given condition.[45] The ICD-9 codes were then used to create an HCC and to identify a "risk factor," or relative increase in cost, associated with that HCC.

In order to pay MA organizations accurately under CMS's methodology, there must be consistency in coding between the FFS population (which is used to establish the risk factors) and the MA population (to which the risk factors will be applied to determine payments). Indeed, given that FFS data were used to develop the risk adjustments to MA payments, Congress recognized that it was essential to "establish[] risk scores that

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[43] 42 U.S.C. §§ 1395w-23(a)(1)(C)(i)-(ii); 1395w-23(a)(1)(G); 1395w-23(a)(3)(A); 1395w-23(b)(i)(II); 1395w-23(b)(4); 1395w-23(k)(2)(B)(iv).

[44] See Gregory C. Pope et al., Risk Adjustment for Medicare Capitation Payments Using the CMS-HCC Model, 25 HEALTH CARE FINANCING REVIEW 119, 129 (Summer 2004), https://www.cms.gov/HealthCareFinancingReview/Downloads/04Summerpg119.pdf; 2009 Proposed Rule, 74 Fed. Reg. at 54,674; CTRS. FOR MEDICARE & MEDICAID SERVS., ANNOUNCEMENT OF CALENDAR YEAR (CY) 2010 MEDICARE ADVANTAGE CAPITATION RATES AND MEDICARE ADVANTAGE AND PART D PAYMENT POLICIES 20 (Apr. 6, 2009), https://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2010.pdf ("CY 2010 Rate Notice"); April 2010 Regulations, 75 Fed. Reg. at 19,748.

[45] CMS has contradictory definitions of what constitutes a valid basis for assigning an HCC. The diagnostic codes identified in the CMS 1500 Health Insurance Claim Forms by the treating physician in the FFS program are used to set the risk adjustment scores for HCCs used in the Medicare Advantage program. But CMS ignores those forms when auditing the HCCs assigned by MA organizations. Nowhere has CMS provided a single definition of what validates an assigned HCC.

are consistent across both fee-for-service and Medicare Advantage settings."[46] Accordingly, the Medicare Act mandates that, in performing risk adjustments based on health status in MA payments, the Secretary must "ensure that such adjustment reflects changes in treatment coding practices in the fee-for-service sector and reflects differences in the coding patterns between Medicare advantage plans and providers under Part A and B," and must "annually conduct an analysis of th[ose] differences."[47] CMS has similarly recognized:

> Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustment to be valid. This means that MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.[48]

Because "MA organizations are coding 'accurately' when they are coding in a manner similar to fee-for-service coding,"[49] it is impossible to determine whether MA organizations are being overpaid by auditing only the medical records supporting MA claims. A proper actuarial analysis requires a comparison of MA and FFS documentation.

For example, assume Medicare paid FFS providers a total of $15,000 per month above the average rate for Medicare enrollees with a certain risk condition. If the FFS

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[46] 152 Cong. Rec. S438 (daily ed. Feb. 1, 2006) (statement of Sen. Charles Grassley); see also id. at H46 (statement of Rep. Joseph Barton) (similar); id. at H54 (statement of Rep. William Thomas) (similar).

[47] 42 U.S.C. §1395w-23(a)(1)(C)(ii)(I)-(II).

[48] CY 2010 Rate Notice at 20.

[49] Id.

providers identified ten beneficiaries with that condition, the average monthly cost per beneficiary associated with that condition would be $1,500. That average cost would be used to pay an MA organization for any of its members that had the same condition. If, however, the FFS providers mistakenly included two beneficiaries who did not have that condition and thus incurred no costs associated with the condition, then the increase in monthly cost associated with the condition would be spread over eight enrollees, which would increase the average cost for the condition to $1,875 per month. But if CMS did not audit the underlying FFS medical records, the agency would continue to pay MA organizations only $1,500 per month per enrollee. As a result, if an MA organization assigned HCCs with 100% accuracy based on a review of medical records, the organization would be *underpaid* by $375 for every Medicare enrollee with the condition, compared to actual costs in the FFS program. Until an audit of FFS claims is performed, therefore, the presence of invalid HCCs in MA claims does not demonstrate that MA organizations are being overpaid in the aggregate.

CMS's proposed sampling and error-calculation methodology does not take this reality into account. CMS is effectively assuming that FFS coding is 100% accurate, but the agency has no basis for that assumption. Indeed, CMS has not, and could not, demonstrate that FFS coding contains no errors (as CMS has defined "errors" in the RADV audit process). Many FFS providers also provide services to Medicare members enrolled in MA organizations. It defies logic to believe those providers would list ICD-9 codes with 100% accuracy on the 1500 Health Insurance Claim Forms sent to CMS under the FFS program, but not on the 1500 Health Insurance Claim Forms sent to MA organizations. CMS has presented no reason to believe this is the case.

The sampling and error calculation methodology proposed by CMS does not allow for any evaluation of, or proper comparison with, the FFS program.[50] Accordingly, CMS's RADV audits fail to "ensure actuarial equivalence" in adjusting payments based on "health status," and therefore violate the Medicare Act.

3. CMS's Proposed Sampling And Extrapolation Methodology Is Invalid And Statistically Flawed.

CMS's proposed methodology for calculating payment error also violates the Medicare Act and is arbitrary and capricious because it suffers from numerous statistical flaws. As an initial matter, CMS's methodology suffers from the same procedural flaw as the agency's One Best Medical Record rule—CMS failed to follow the proper notice-and-comment rulemaking procedures with respect to its payment error calculation methodology. Unlike a full notice-and-comment rulemaking under the APA, CMS's notice of its proposed methodology allows for only a brief thirty-day comment period, was not published in the Federal Register, and does not contain a discussion of economic analyses or regulatory alternatives. Because the payment error calculation methodology is a substantive rule that will impose obligations on MA organizations in the form of substantial payment adjustments, the Medicare Act and the APA require CMS to submit the methodology to full notice and comment before it is applied in CMS's RADV audits.[51]

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[50] If CMS were to audit the medical records supporting FFS claims, the agency would need to apply the same rules in that audit as in its audits of MA organizations to allow for a meaningful comparison. It would be improper, for example, to apply the One Best Medical Record rule only with respect to the MA program.

[51] See 42 U.S.C. § 1395hh(a)(2); 5 U.S.C. § 553(d); see also Exec. Order No. __, 76 Fed. Reg. __ (Jan. 18, 2011), available at http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order (requiring, among other things, "a comment period that should generally be at least 60 days").

Moreover, the proposed extrapolation methodology for RADV audits is prohibited because Congress has limited the use of extrapolation to specific circumstances: Medicare contractors may only use extrapolation when the Secretary has found that "there is a sustained or high level of payment error; or . . . documented educational intervention has failed to correct the payment error."[52] The Secretary has not made such a finding with respect to RADV audits, has no basis to do so, nor is there any basis to do so, and has not undertaken rulemaking to determine these issues.

The need for rulemaking is apparent from the flaws in the proposed sampling and error calculation methodology. The methodology CMS proposed will not ensure that risk adjustments have "been applied correctly, and [an] MA organization has received the amount to which it was entitled."[53] As explained below, the sampling and error calculation methodology fails to ensure a statistically valid result because of various design flaws.

a) The Proposed Stratification Can Produce Inaccurate Results.

CMS's stratification design flaws generate arbitrary results. CMS proposes to stratify its sample of MA enrollees based on the enrollees' community risk scores.[54] CMS's notice explains that the enrollees will be divided "into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle

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52 42 U.S.C. § 1395ddd(f)(3).

53 April 2010 Regulations, 75 Fed. Reg. at 19,745.

54 December 2010 Proposed Methodology at 2.

stratum."[55] CMS will then randomly select up to 67 enrollees from each group for a maximum of 201 enrollees in the sample.[56] For example, CMS's notice of its proposed methodology stated that:

> [I]f a contract has 3,000 enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be selected from each group. The weight for each enrollee will equal 14.925 (i.e., 1,000/67).[57]

This stratification raises significant issues. First, CMS's notice provides no record to support the stratification proposed. Stratification is employed to deal with variations in the data that need to be taken into account to avoid an unintended bias or that would otherwise skew the results. CMS has not identified any need for stratification or how the proposed three tier stratification will resolve any data issues. The failure to include an explanation of the need for the stratification, as required by the Medicare Act and the APA, denies interested parties the opportunity to comment meaningfully on the proposal. Absent such an analysis, the proposed stratification is arbitrary.[58]

Second, CMS's notice of its proposed methodology provides no discussion of the effects of "stratification cluster," even though the agency's proposal effectively uses a cluster sampling technique. Although CMS suggests that it will randomly select enrollees from three strata of equal size, divided by rank-ordering enrollees by their community risk scores, CMS does not evaluate documentation error only once for each

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55 Id.

56 Id.

57 Id.

58 Appalachian Power Co. v. EPA, 251 F.3d 1026, 1035 (D.C. Cir. 2001).

enrollee. Rather, CMS will audit all the sample enrollees' HCCs. The result is a cluster sampling with uneven cluster sizes in each of the strata.

Because community risk scores are devised based on an enrollee's combination of HCCs, the sample selected from the stratum with the higher risk scores is also sampling larger clusters of HCCs that may not be representative of the overall sample enrollee population. This presents problems that need to be addressed as part of the sampling methodology.[59] For example, the sample of clusters may not reflect the diversity of all clusters across the community. The more the population clusters differ, the less the precision of the results based on the sample.[60]

The sampling methodology and the stratification exacerbate the problems arising from sampling enrollees but then testing the assigned HCCs, which adds a non-random element to the sample. Under CMS's proposed stratification technique, the enrollees in the high stratum are likely to have more HCCs assigned than enrollees in the middle or lower strata. This may result in the higher stratum having a disproportionate impact on the audit, which in turn may skew the audit results. In essence, CMS will sample based on observations of HCCs clustered by enrollee within each stratum, thereby adding a potential correlation among the elements of each cluster to its sampling procedure. The

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[59] "[P]eople within a cluster may have very similar survey characteristics to each other, but different from those within different clusters. Here, not only is one less likely to capture the full sample variation when using a clustered design, but there is likely to be a great deal of uncertainty about what results the non-sampled clusters would have yielded." Andrew Zelin & Roger Stubbs, Cluster Sampling: A False Economy?, 47 INTERNATIONAL JOURNAL OF MARKET RESEARCH 501-22 (2005), http://www.ijmr.com/MedalWinners/PDF/80562.pdf; HENRY, supra note 6, at 107-109. "Selecting unequal clusters creates several problems. First, the size of the sample is not fixed; it becomes a random variable, depending upon the chance selection of larger or smaller clusters. This augments the uncertainties in planning the cost and variance of the sample. Second, the ratio mean, though typically a good and practical estimate, is not an unbiased estimate of the population mean. Third, practical variance formulas are not unbiased estimates of the true variances, but they are good approximations in well designed samples. Fourth, the variance formulas appear complicated, although this problem is considerably eased with the development of simpler computing forms." LESLIE KISH, SURVEY SAMPLING 183-184 (1995).

[60] HENRY, supra note 6, at 107.

selection of each enrollee is independent, but the selection of each HCC is not independent. This sampling design might introduce some unmeasured factor that affects the records for the enrollee in a systematic way.[61]

Yet, CMS does not provide any discussion of statistical problems due to cluster sampling. Nor does CMS propose any diagnostic review of the sample to ensure it is representative of the MA organization's enrollment. At a minimum, CMS should analyze whether the sample is fair and representative. This would include assessing the average number of HCCs in the sample versus the average number of HCCs per enrollee, and the number of specific HCCs in the sample as compared to the number in the enrollment. Oversampling a particular HCC could create a disproportionate discrepancy that would be magnified though the proposed extrapolation. In fact, the 2007 RADV pilot audit suggests that the sampling approach may not produce a representative sample of HCCs in a composition that reflects the sample population. For example, the percentage of enrollees assigned HCC 15 (diabetes with renal or peripheral circulatory manifestation) in the 2007 pilot audit sample is approximately two times the percentage of enrollees assigned HCC 15 in the population of enrollees who were eligible for the sample. The same is true for HCC 80 (congestive heart failure). Since there is a basis to expect that certain HCCs are more likely to give rise to discrepancies, this representation problem will have implications for the estimated payment errors and their extrapolation.

Similarly, CMS does not present any plan to test for, or deal with, outliers in the data. But outliers can distort the outcome.[62] A few extreme values larger than expected

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61 Id.

62 "[A]n outlier is generally considered to be a data point that is far outside the norm for a variable or population . . . . [Commentators have] described an outlier as an observation that deviates so much from

from a normal distribution will have a greater influence on the mean and the confidence interval than other members of the sample.[63] With an overstated mean, the lower bound of the confidence interval used to estimate total payment error would be overstated. Given this distinct possibility, CMS should consider other measures of central tendency such as the geometric mean, the median, or the mode before selecting its methodology, or a non-parametric approach to selecting a lower bound for error. This issue is significant given the relatively small sample and the potential impact outliers could have on the extrapolation outcome.

In addition, like CMS's stratification methodology, CMS's proposed payment error extrapolation methodology is likely to generate arbitrary results. The confidence interval proposed by CMS to estimate the extrapolated payment recovery amount assumes that the enrollee payment discrepancies are normally distributed. If the data are not normally distributed, then the use of the formulas for variance and confidence interval set forth in the proposed methodology will produce invalid results. But there is no basis in the record for assuming a normal distribution of payment errors, and CMS has not explained what methodology it will apply if the distributions are non-normal or unknown.

Accordingly, CMS's proposed sampling and error calculation methodology has design flaws that may preclude the sample from providing meaningful data to ensure that

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other observations as to arouse suspicions that is was generated by a different mechanism . . . ." J.W. Osborne & Amy Overbay, The Power of Outliers (and Why Researchers Should Always Check for Them), PRACTICAL ASSESSMENT, RESEARCH & EVALUATION 9(6) (Jan. 20, 2011), http://pareonline.net/getvn.asp?v=9&n=6 (citations and quotations omitted). "Outliers can have deleterious effects on statistical analyses. First, they generally serve to increase error variance and reduce the power of statistical tests. Second, if non-randomly distributed they can decrease normality . . . . Third, they can seriously bias or influence estimates that may be of substantive interest . . . ." Id.

[63] "An outlier is an observation that appears to deviate markedly from other observations in the same sample. Many statistical techniques – such as regression, analysis of variance, factor analysis – are very sensitive to outliers: the value of these statistics can change drastically due to just one or two errant points." J.L. Rasmussen, Evaluating Outlier Identification Tests: Mahalanobis D Squared and Comrey Dk, MULTIVARIATE BEHAVIORAL RESEARCH, 23(2), 189-202 (1988).

an MA organization is paid correctly based on the health status of its enrollees, as Congress mandated in the Medicare Act. Courts refuse "to excuse [an agency's] reliance upon a methodology that generates apparently arbitrary results."[64]

b) The Sample Includes Only Enrollees With HCCs.

It is well-established that an "agency must use 'the most reliable data available' to produce figures that can be considered sufficiently 'accurate.'"[65] Here, CMS is not using the most reliable data available to produce sufficiently accurate results. The proposed sampling methodology samples only enrollees with "[a]t least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection period that led to at least one CMS-HCC assignment."[66] Random discrepancies in assigning HCCs, however, are likely to result in both overstating and understating risk factors. By excluding from the sample all the Medicare members to whom MA organizations did not assign a high risk factor, the audit will overlook any discrepancies resulting in the understatement of enrollees' health status.[67] The results of the audit, therefore, will have little relation to the HCC coding errors in the population, even assuming that the audit methodology identifies "discrepancies." CMS's failure to use the most reliable data likely will produce inaccurate results.

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64 Appalachian Power Co., 251 F.3d at 1034-35.

65 Baystate Med. Ctr. v. Leavitt, 545 F. Supp. 2d 20, 41 (D.D.C. 2008) (quoting Methodist Hosp. of Sacramento v. Shalala, 38 F.3d 1225, 1230 (D.C. Cir. 1994)); see also Cnty. of Los Angeles v. Shalala, 192 F.3d 1005, 1020-23 (D.C. Cir. 1999) (holding that agency must explain why a more recent database it had considered "reliable" for certain purposes was not used in calculating other Medicare payments where "accurately forecasting" payments depended on use of updated hospital stay data).

66 December 2010 Proposed Methodology at 2.

67 April 2010 Regulations, 75 Fed. Reg. at 19,746-47 (stating that CMS "intended [the audit] to validate the CMS-HCCs that were submitted in order to determine whether the *additional* payment amounts associated with these diagnosis codes were properly made" (emphasis added)).

Courts are "particularly" unlikely to "excuse [an agency's] reliance upon a methodology that generates apparently arbitrary results . . . where, as here, the agency has failed to justify its choice."[68] Here, the administrative record does not support CMS's decision to exclude from the audit sample enrollees who do not have an HCC assignment. To the contrary, if discrepancies in establishing risk scores are random, MA organizations are also likely to have failed to assign HCCs when such an assignment was warranted. Specifically, the record does not contain any evidence that supports the view that MA plans are likely only to overcode their enrollees with undeserved HCCs.[69] MA organizations primarily rely on physicians' and providers' claims to assign HCCs. The physicians and providers identify diagnoses by assigning ICD-9 codes. These codes are then tracked to HCCs as determined by CMS. There is no indication that providers will only make mistakes in coding conditions that will result in an HCC assignment on the claim. The audit is based on a review of medical records. Potentially, the medical record review during an audit process that included enrollees with no HCC assignment could provide a source of information to indicate that those enrollees should have been assigned HCCs. The sample, to be valid, must include all enrollees, with and without HCC assignments.

The audit sampling methodology is not only inaccurate, but is also inconsistent with CMS practice with respect to prior Medicare audits. In auditing providers for Medicare Parts A and B in the Medicare Integrity Program, CMS specifically tasked recovery audit contractors to "review claims, using automated or complex reviews, to

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[68] Appalachian Power Co., 251 F.3d at 1035; see also Cnty. of Los Angeles, 192 F.3d at 1020-23 (rejecting agency's use of improper data set and remanding for reasonable explanation or recalculation).

[69] CMS claims that MA plans have an incentive to do so, see 2009 Proposed Rule, 74 Fed. Reg. at 54,674, but has produced no evidence justifying that speculation.

identify potential Medicare underpayments."[70] Here, CMS has deviated from that practice, without explanation.

In addition to being inconsistent with the Medicare Act and past practice, an audit that only allows a downward adjustment is "unconscionable"[71] and will not pay MA organizations based on their enrollees' health status as mandated by the Medicare Act. An adjustment clause must be "a two-way, not a one-way street," allowing for both "an increase in the contract price," and "a decrease in the contract price."[72] Yet, by including only enrollees with "at least one CMS-HCC assignment," CMS excludes from each audit enrollees for whom an MA organization was underpaid because it mistakenly did not assign an appropriate HCC or risk score. There can be no overcoding with these enrollees. These enrollees were either properly coded, so there is no overpayment, or they should be assigned an HCC, in which case the MA organization is underpaid. As a result, the proposed sampling methodology cannot determine whether an MA organization was properly paid, but only whether the organization can validate with a single medical record the HCCs that were assigned.

c) CMS's Proposed Methodology Fails To Account For Sources Of "Error" Other Than Incorrect Assignments Of Health Status.

CMS's proposed methodology for calculating payment error also fails to account for the fact that the agency's audits may find "errors" that are unrelated to the health status of an enrollee. A basic principle in any sampling plan is to define clearly the item

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70 CTRS. FOR MEDICARE & MEDICAID SERVS., STATEMENT OF WORK FOR THE RECOVERY AUDIT CONTRACTOR PROGRAM 27-29, http://www.cms.gov/RAC/Downloads/RACFinSOW.pdf; see also 42 U.S.C. § 1395ddd(h) (authorizing use of RACs).

71 GloPak Corp. v. United States, 851 F.2d 334, 338 (Fed. Cir. 1998).

72 Id.

to be investigated.[73] It is essential to identify potential causes of "errors" or "discrepancies," and whether these potential causes might influence the sampling design and estimation. Different causes of the observed discrepancies might require different sampling approaches. Discrepancies might be caused by simple random omissions (*e.g.*, the required signature) not associated with any particular HCC. Alternatively, discrepancies might be due to the presence of certain systematic behavioral traits of providers working with particular types of enrollee conditions. These different potential causes of discrepancies should be considered not only in developing an investigation of the relevant actuarial equivalence, but also in the design of sampling and estimation methodologies seeking to make reliable inferences about the observed discrepancies.

For example, many supposed discrepancies identified in the RADV audit process result not from improper coding of medical conditions, but from the arbitrary limitations imposed by the One Best Medical Record rule—as the record of the 2007 RADV pilot audit already indicates. In a number of cases in that audit, the HCC assigned was not allowed because the one best medical record was not signed by the physician. In other cases, additional medical records verified the HCC, but were not considered by CMS. These technical discrepancies do not support a conclusion that the patient did not have the condition diagnosed, that an incorrect HCC was assigned, or that the MA organization was improperly paid.

Additional variables unrelated to "health status" also may impact the audit results, such as geographic variations in coding by providers. Indeed, in CMS's report on the results of its 2004 pilot RADV audit, the agency recognized numerous sources of discrepancies in addition to an incorrect determination by an MA organization of enrollee

[73] HENRY, supra note 6, at 15-16.

health status, including providers' failure to document a known medical condition, documentation in the medical record that was insufficiently specific, and coding that was incomplete, or "truncated."[74] CMS's methodology for calculating payment error should recognize and account for the statistical effects of these discrepancies, which do not result from the erroneous submission of HCCs by MA organizations.

4. The Proposed Methodology Would Interfere With Current Contracts.

The proposed sampling and error calculation methodology does not take into account that MA organizations have already submitted their bids and have preexisting contracts with CMS to provide benefits to Medicare beneficiaries who are enrolled in the organizations' plans. CMS's proposed methodology would impose retroactive, contract-wide adjustments that would be improper because such adjustments (1) would be inconsistent with the actuarial assumptions and data used by MA organizations to determine their annual bids; (2) would violate the Medicare Act and CMS regulations; and (3) would be inconsistent with existing MA contracts. At most, CMS may be able to use its audit results in its prospective evaluation of risk adjustment factors.

a) CMS's Proposed Methodology Undermines The Actuarial Basis Of MA Payments.

Inherent in the actuarial processes and assumptions underlying annual bids submitted to CMS by MA organizations is the principle that risk adjustment will be based on a comparison to the Medicare FFS population. CMS provides this comparison in the form of a risk-adjusted benchmark payment and risk factors in its annual announcement of MA payment rates. MA organizations compare their bids to the benchmark to

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[74] CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE ADVANTAGE RISK ADJUSTMENT DATA VALIDATION CMS-HCC PILOT STUDY, REPORT TO MEDICARE ADVANTAGE ORGANIZATIONS 12 (2004), available at http://www.hccblog.com/files/CMS_HCC_validation.pdf.

determine member premiums, co-pays, and supplemental benefits.[75] These determinations are inextricably linked to the estimates and assumptions supporting the bid, including the projected risk scores and benchmark.

Failing to maintain consistency with Medicare FFS would undermine the actuarial basis of the MA organizations' bids and resulting payments. The bid process is complex, and MA organizations must project the cost of providing benefits to an enrolled population in an actuarially sound manner. To submit a bid, MA organizations must know the applicable rates and actuarial assumptions. A valid and consistent measurement of the projected risk of a given population is critical to this actuarial analysis.

CMS's methodology for calculating payment discrepancies will have a direct impact on an MA plan's bid submissions, including its premium rates and benefits packages. It is therefore inappropriate to implement retrospectively a wholesale change in risk adjustment methodology and payments that was unknown at the time bids were developed. Changing projected risk scores, often based on missing or incomplete records under the One Best Medical Record rule and without reference to FFS error rates, will undermine the actuarial soundness of the original bids. The bids for years 2007, 2008, 2009, 2010, and 2011 were all developed and submitted prior to CMS's announcement of its proposed methodology for calculating payment error. Moreover, the bids for 2007 through 2009 were made prior to CMS even announcing its 2007 pilot RADV audit program. Yet, the proposed RADV audit sampling and error calculation methodology

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[75] See 42 U.S.C. § 1395w-24(b).

includes factors that were not provided to MA organizations before they submitted their bids.

As a result, MA organizations were unable to anticipate these audits and actuarially include these factors in their bids. Retroactive contract-level payment adjustments based on previously unknown RADV audit procedures will create a fundamental disconnect between MA organizations' payments and the benefits they offered. Moreover, CMS reviews the bids submitted by MA organizations to determine whether "(1) [t]he bid amount and proportions are supported by the actuarial bases provided by MA organizations [and] (2) [t]he bid amount and proportions reasonably and equitably reflect[] the plan's estimated revenue requirements for providing the benefits under that plan."[76] If CMS intended to make contract-level adjustments based on RADV audits, it had both the obligation and the opportunity to advise MA organizations that they needed to make adjustments in their bids based on anticipated RADV audits. CMS cannot now impose such a retroactive adjustment.

b) CMS's Proposed Methodology Violates The Medicare Act And CMS Regulations.

The Medicare Act requires the Secretary of HHS to provide advance notice of changes in methodologies and assumptions used to calculate MA payment rates.[77] Congress also mandated that CMS publish annually "[t]he average risk factor for the covered population based on diagnoses reported for Medicare inpatient services, using the same methodology as is expected to be applied in making [monthly risk-adjusted

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[76] 42 C.F.R. § 422.256(b).

[77] 42 U.S.C. § 1395w-23(b)(2) ("At least 45 days before" announcing capitation rates for the following year, "the Secretary shall provide for notice to [MA] organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.").

payments]."[78] CMS's regulations also require advance notice of changes in methodology and assumptions.[79] CMS's regulations further provide that the agency "will not implement, other than at the beginning of a calendar year, requirements . . . that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute."[80] CMS's application of contract-wide payment adjustments based on RADV audit procedures and methodologies, without advance notice that those procedures and methodologies would be applied, violates these provisions of the Medicare Act and CMS's regulations.

c) CMS's Proposed Methodology Violates Preexisting Contracts.

Although contracts between MA organizations and CMS provide for the submission of risk adjustment data to determine the risk adjustment factors, no provision provides for retroactive payment adjustments.

The MA contract specifically addresses CMS's right and authority to implement changes during the contract year. Only statutory changes that Congress requires to be applied during the term of existing contracts (and changes in regulation and policies implementing such statutory changes) are deemed to be incorporated into the contract.[81] There have been no statutory changes made during the term of any existing contracts that could be incorporated into those contracts that allow for retroactive contract-level

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[78] 42 U.S.C. § 1395w-23(b)(4)(C).

[79] 42 C.F.R. § 422.312(b)(1) ("No later than 45 days before making the announcement [of capitation rates for the following contract year], CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.").

[80] 42 C.F.R. § 422.521.

[81] Id.; 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), Articles II.B, II.C.

payment adjustments. Therefore, CMS cannot retroactively change payments to MA organizations based on the agency's new rules and methodologies.

CONCLUSION

Aetna respectfully requests that CMS:

1. Withdraw the proposed sampling and error calculation methodology and conduct full notice-and-comment rulemaking with respect to that methodology;

2. Institute notice-and-comment rulemaking for the One Best Medical Record rule;

3. Institute notice-and-comment rulemaking regarding the need for FFS auditing; and

4. Cease any ongoing RADV audit activities until these rulemaking processes are complete.

Only once such rulemaking is undertaken will MA organizations and other interested stakeholders have a meaningful opportunity to protect their rights and the rights of their members.

Exhibit 2

HUMANA
Guidance when you need it most

VIA EMAIL TO **RADV**@CMS.HHS.GOV AND **FEDERAL EXPRESS**

Ms. Cheri Rice
Acting Director, Medicare Plan Payment Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comment on RADV Sampling and Error Calculation Methodology

Dear Ms. Rice:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services's ("CMS") draft *Medicare Advantage Risk Adjustment Data Validation ("RADV") Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits*, released by CMS on December 20, 2010. Our comments incorporate the attached Exhibits, including the Actuarial Report attached as Exhibit A ("Actuarial Report").

As one of the largest sponsors of Medicare Advantage plans serving Medicare beneficiaries in the United States, Humana understands the trust that the government has placed with Medicare Advantage contractors as they serve many of the country's most vulnerable beneficiaries, and we are committed to continuing to work with CMS to ensure that Medicare Advantage organizations ("MAOs") are paid accurately. However, we have serious concerns about the draft sampling and payment error calculation methodology ("Proposed Methodology") because it will result in inaccurate payments to MAOs and also would have a real and direct impact on Medicare Advantage members and the health care benefits they receive.

The Proposed Methodology substantially deviates from the assumptions and methodology that CMS used to set payment rates and that MAOs relied on to submit bids. As a result, it improperly and retroactively changes how MAOs are reimbursed. It is mathematically certain that payments calculated using the Proposed Methodology would not accurately reflect the costs of providing benefits to Medicare Advantage members. In fact, the Proposed Methodology would fundamentally undermine the risk adjustment payment model by significantly underpaying MAOs for the risks they assume.

I. INTRODUCTION OF KEY ISSUES

The Proposed Methodology seems to reflect an assumption that MAOs are overpaid whenever a diagnosis relating to a risk adjustment payment is not supported by a medical record. Our comments below and the Actuarial Report describe in more detail why – given the existing actuarial method used to make risk adjustment payments – this assumption is incorrect and why the Proposed Methodology is fundamentally flawed:

- **The Proposed Methodology disregards the FFS Claims Data used to establish payment rates.** RADV audits review only medical records for MA claims data received by MAOs from providers and submitted to CMS ("MA Claims Data"), but do not review medical records for FFS claims data used to develop the risk adjustment payment model ("FFS Claims Data"). These two sets of data are inextricably linked. CMS cannot adjust one set of data without considering the relationship with the other set of data when both are part of the comprehensive payment model. Using the Proposed Methodology, CMS's payment model will be actuarially unsound for audited organizations because it would simultaneously use two very different sets of data to measure diagnoses – non-validated FFS Claims Data on the front end (the development of payment rates), and validated MA Claims Data on the back end of a risk adjustment data validation ("RADV") audits. Unless CMS modifies the Proposed Methodology to appropriately adjust for this inconsistency, it will undermine the basic fairness of the underlying risk adjustment payment model.

- **The Proposed Methodology improperly deviates from the assumptions and methodology upon which MAOs relied in submitting bids**. MAOs correctly relied on the assumptions and methodology released by CMS to develop the risk scores used in bids, and reasonably assumed that FFS Claims Data and MA Claims Data would be consistently compared. MAOs could not have anticipated that CMS would implement the Proposed Methodology to retroactively recalculate risk scores used to set MAO payment rates by introducing different assumptions and a different methodology from what was employed during the bid process.

We understand that some may argue that the Proposed Methodology is not a change in payment methodology. This is simply not the case as the Proposed Methodology (i) has a direct and substantial impact on the actuarial calculations under the payment model, and (ii) substantially affects the risk scores and payment amounts in a manner that is different from the assumptions and methodology used prior to the bids. As such, it is a substantive change that is subject to the notice-and-comment requirements under the Social Security Act (the "Act") and the Administrative Procedure Act ("APA").

- **The Proposed Methodology would not withstand legal scrutiny.** The Proposed Methodology is arbitrary and capricious and inconsistent with the actuarial equivalence requirement and other requirements of the Act. In addition, implementation of the Proposed Methodology would be inconsistent with advance notice requirements of the Act, and other applicable laws governing the development and implementation of this substantive rule. CMS must respond in a reasoned manner to the legal and actuarial principles discussed herein and previously presented to CMS, and it must propose a solution subject to public comment before implementing any payment error calculation methodology.

- **The Proposed Methodology suffers from additional defects**. The fundamental flaws noted above are compounded and exacerbated by defects in the statistical sampling and extrapolation approach, and by CMS's use of a "one best medical record" requirement to review MA Claims Data.

II. THE PROPOSED METHODOLOGY IMPROPERLY DISREGARDS THE FFS CLAIMS DATA USED TO SET MAO PAYMENT RATES

A. CMS Must Address the Data Inconsistency Issue

CMS relies on two interdependent sets of data to set payment rates for MAOs: (1) FFS Claims Data; and (2) MA Claims Data. The Proposed Methodology would review medical records for only one set of data (MA Claims Data), while not performing the same exercise on the other set (FFS Claims Data). However, because these two sets of data are inextricably linked, CMS must audit and validate *both* of them before extrapolating any potential RADV audit results. If it does not, CMS will dramatically underpay MAOs for the benefits they provided to Medicare beneficiaries.

Consider the following simplified example[1] (also set out in a chart below) that illustrates the impact of failing to validate the FFS Claims Data used on the front end:

- Suppose that in XYZ county, FFS Claims Data shows CMS spent an aggregate of $60,000 on treating cancer ("Treatment Costs") in Year 1.

- CMS expects to spend an aggregate of $60,000 on Treatment Costs again in Year 2. This is an anticipated based on FFS Claims Data and not tied to underlying diagnosis records.

- There are 100 people in the county enrolled in the original FFS program ("FFS Program"), and FFS Claims Data indicates that 60 of them have cancer. Assume if CMS were to audit the FFS Claims Data, which it did not, it would find that only 40 people have medical record documentation to validate those diagnoses.

- CMS nevertheless accepts the accuracy of the FFS Claims Data as submitted and calculates the increased risk for cancer patients to be $1,000 per patient, effectively the "Unit Cost." This Unit Cost is analogous to the risk coefficient in the CMS risk adjustment payment model.

- In Year 2, 30 people with cancer in XYZ county enroll in a Medicare Advantage plan. In this scenario, CMS pays the MAO $1,000 in extra revenue per cancer patient to cover the risk for covering the Treatment Costs for the 30 people.

[1] This example is simplified in order to illustrate the mathematical of failing to validate FFS Claims Data on the front end. The CMS risk adjustment methodology has additional complexities, and is described more fully in the Actuarial Report at § III.

- Two years later, CMS audits the MA Claims Data used to determine the MAO's payments in Year 2 and discovers that only 20 (not 30) of the members had adequate medical record documentation to validate cancer for all periods in question.

- CMS then seeks to recoup $10,000 from the MAO since only 20 members had a cancer diagnosis validated by a medical record. But this recoupment would result in an actuarially unsound and inaccurate payment.

- CMS should have calculated the Unit Cost to be $1,500 per patient ($60,000 / 40), not $1,000. This is because the $60,000 of Treatment Costs paid in Year 1 was accounted for by 40 patients whose medical records support the diagnosis, not 60 patients whose claims reflected that they had cancer. Using the corrected Unit Cost, the aggregate amount if correctly paid to the MAO for assuming the Treatment Costs would be $30,000 ($1,500 x 20).

	Year 1		Year 2	
	FFS Claims Data (Unaudited)	FFS Claims Data (if Audited)	MAO Payments (Unaudited)	MAO Payments (Audited)
Beneficiaries with Cancer	60	40	30	20
Payments for Beneficiaries with Cancer	$60,000	$60,000	$30,000	$20,000
Unit Cost per Cancer Patient	$1,000	**$1,500***	$1,000	**$1,000***

* Note that $1,000 would be the incorrect Unit Cost for audited MAO payments, which should be $1,500 in order to make a valid comparison.

The above example illustrates that in order to ensure an actuarially sound and accurate payment, both the front end (the development of payment rates) and back end (RADV audit results) must have a mechanism for ensuring comparability. The absence of such a mechanism in the Proposed Methodology will have severe repercussions for beneficiaries, MAOs, and the Medicare Advantage program, as the payment model will not do what CMS actuaries designed it to do – pay MAOs for the benefits they administer under Medicare Advantage. This problem is referred to herein as the "Data Inconsistency Issue." The Actuarial Report provides a more complete discussion and an actuarial analysis of this Data Inconsistency Issue, and should be reviewed as an integral part of these comments.

In other (similar) contexts, CMS has recognized the need to correct for the inconsistencies between FFS Claims Data and MA Claims Data when calculating payments to

MAOs.[2] Additionally, Congress's requirement that CMS "adjust the risk scores for differences in coding patterns between Medicare Advantage plans and providers under the original Medicare fee-for-service program under parts A and B" requires the consistent use of data in determining risk adjusted payments to MAOs.[3] The Proposed Methodology disregards the comparative nature of the risk adjustment payment model and the basic idea that valid comparisons cannot be made when risk scores for the FFS population are developed using unaudited FFS Claims Data, but risk scores for MAO enrollees are developed using MA Claims Data substantiated by medical records. In short, to ensure a valid comparison, the same type of data must be compared.

B. Recommendations for Adjusting for Data Inconsistency

The actuarial principles outlined above do not mean that CMS cannot implement an actuarially sound RADV methodology. We respectfully suggest, however, that if CMS intends to modify payments based on medical record review, then it must also correct for the Data Inconsistency Issue in an appropriate manner. To do so, CMS could audit FFS Claims Data and correct the risk (and demographic) coefficients used to establish payment amounts (which are analogous to the "Unit Cost" in the above illustration) using only those diagnoses substantiated in medical records, using the very same methodology that CMS has employed in the RADV audits. CMS would then apply the corrected coefficients to determine the final risk scores of audited MAO members. These corrected coefficients, as adjusted for unsubstantiated diagnoses

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[2] Advance Notice of Methodological Changes for Calendar Year 2008 Medicare Advantage (MA) Payment Rates at 8 (Feb. 16, 2007):

> Because the CMS-HCC model is calibrated on fee-for-service data and the resulting risk scores are adjusted for fee-for-service normalization, MA coding patterns that differ from patterns in fee-for-service may result in risk scores that are not equivalent to the risk scores of the FFS beneficiaries used to calculate the county rates.

Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies at 20 (Apr. 6, 2009) (emphasis added):

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

Id. at 26 (emphasis added):

> [T]he risk adjustment methodology is designed *to compare* the risk scores of MA plan enrollees to . . . beneficiaries not enrolled in MA plans.

[3] *See* Social Security Act § 1853(k)(2)(B)(iv)(III), 42 U.S.C. § 1395w-23(k)(2)(B)(iv)(III).

in FFS Claims Data, would be higher than those previously calculated by CMS. The post-audit risk scores for all sampled members would be recalculated using the corrected coefficients, and a statistically appropriate extrapolation methodology would then be applied. The problem with the coefficients and this potential solution are discussed further in the attached Actuarial Report at § VI.

Alternatively, CMS could apply payment adjustments following a comparison of the extent to which diagnoses are not substantiated by medical records in FFS Claims Data, and the extent to which diagnoses are not reflected in medical records in MA Claims Data. This approach would not, as has been suggested, reimburse MAOs for members whose diagnoses do not validate, or excuse a certain level of payment errors. To the contrary, it is an alternate mechanism for CMS to correctly calculate the payment impact of its audit and apply an appropriate conversion factor to account for the different sources of diagnostic data used to establish payment rates. As discussed in the Actuarial Report at § VI, this approach would be another way of achieving the same corrective result as the coefficient recalculation approach.

III. The Proposed Methodology Improperly Deviates from the Assumptions and Methodology Upon Which MAOs Relied in Submitting Bids

In addition to the actuarial issues described above, there would be other fundamental problems if CMS implemented the Proposed Methodology without appropriately addressing the Data Inconsistency Issue. In particular, the Proposed Methodology improperly deviates from the assumptions and methodology considered for calculating the risk scores that MAOs used in submitting bids and by CMS in approving those bids. The impact on the bidding process is explained in detail in the Actuarial Report at § V, which should be reviewed as an integral part of these comments but the main principles are set forth below.

A. CMS Must Publish the Methodology and Assumptions for Bids Before the Bids are Submitted, and Must Adhere to Those Assumptions and Methodology when Making Payment

The assumptions and methodology provided in advance of bid submission by CMS are critical to MAOs' bids and to the proper functioning of the Medicare Advantage program. The Act reflects the significance of these assumptions and methodology by requiring advance notice of payment rates and risk coefficients that will apply in the upcoming year. In addition to notice of payment rates and risk coefficients, the annual notice must also include an "explanation of the *assumptions and changes in* methodology used in such announcement."[4] Any such changes may be implemented only after CMS publishes and provides an opportunity for MAOs to comment on proposed changes from the "methodology and assumptions used in the previous announcement."[5]

[4] Social Security Act § 1853(b)(3), 42 U.S.C. § 1395w-23(b)(3) (emphasis added).

[5] Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2).

These provisions implement a core principle that CMS must give MAOs the assumptions and methodology needed to develop their bids *before* those bids are submitted. Furthermore, all MAOs must submit their bids using the same assumptions and methodology in order to achieve the level playing field that the Medicare Advantage competitive model requires.

B. The Proposed Methodology Deviates From the Assumptions and Methodology CMS and MAOs Relied on When Submitting and Approving Bids

The Proposed Methodology fundamentally changes the assumptions and methodology MAOs have used to develop risk scores[6] in bids that have already been approved. CMS requires MAOs to project the overall risk score of their enrolled population, which materially affects the MAOs' bid amount. MAOs projected risk scores in their bids using the same methodology that CMS used to develop the risk coefficients. Those coefficients were based on FFS Claims Data, not diagnoses substantiated by medical record review. These coefficients also define the beneficiary with a "national average risk profile."[7] MAOs must submit their bid amounts for providing the standard benefit package to a beneficiary with a "national average risk profile."[8] Similarly, CMS published risk scores for the FFS population based on FFS Claims Data, not diagnoses substantiated by medical record review.[9] MAOs applied the same methodology to project MAO risk scores and determine their bid amounts.

The Proposed Methodology recalculates the MAOs' risk score (and resulting payment) based "on the HCCs that are supported by RADV medical record review findings for the enrollee."[10] This is a different methodology for calculating risk scores from the methodology MAOs properly used in submitting their bids, with substantial and material payment implications.

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[6] A risk score is a description of the health and demographic status of the enrolled population. A brief summary is as follows: CMS assigns "coefficients" (otherwise known as "risk adjustment factors") for different demographic and health-status conditions. For example, in 2007, the coefficient for a 66 year old non-institutional male enrollee was 0.330. The coefficient for non-institutional diabetes without complications was 0.181. CMS adds the coefficients together to compute a "risk score" for each member; the plan's projected risk score is the anticipated average for a plan's membership. If a plan projects a risk score of 1.05, it is in effect projecting that its enrolled population will have medical costs 5% higher than the national average for a FFS beneficiary.

[7] CMS sets the coefficients in a statistical manner so that a FFS beneficiary with a "national average risk profile," Social Security Act § 1854(a)(6)(A)(i), 42 U.S.C. § 1395w-24(a)(6)(A)(i), is 1.0.

[8] The "bid" amount is "the monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements . . . in the payment area for an enrollee with a national average risk profile for the factors described in section 1853(a)(1)(C) (as specified by the Secretary)." Social Security Act § 1854(a)(6)(i), 42 U.S.C. § 1395w-24(a)(6)(i).

[9] CMS is required to publish the "average risk factor" [another term for "risk score"] for the FFS program covered population based on diagnoses reported for inpatient and other sites of services. Social Security Act § 1853(b)(4)(D), 42 U.S.C. § 1395w-23(b)(4)(D). In doing so, CMS is required to use "the same methodology as is expected to be applied in making payments" to MAOs. *Id.*

[10] Proposed Methodology, at 2.

We understand that CMS may have questioned why actuaries did not anticipate that medical record reviews might be conducted or that some MA Claims Data is not accurate. However, even if MAOs and certifying actuaries could have anticipated that CMS would conduct RADV audits, they had no reason to believe that CMS would not address the Data Inconsistency Issue as part of its calculation of any extrapolated payment errors. Indeed, even today it is uncertain how CMS will determine payment error from the RADV audits. It its final rule published in the Federal Register April 15, 2010 regarding RADV, CMS indicated, CMS indicated it is reviewing public comments on the Data Inconsistency Issue, but the Proposed Methodology does not address it.[11] As a result, the ultimate effect of RADV extrapolation on MAO risk scores remains unknown. Actuaries could not reasonably have known of or accounted for the Proposed Methodology in preparing bids. Indeed this challenge persists today, as CMS has not issued any notice seeking comments on a proposed change to the methodology for projecting risk scores for future contract years.

C. Actuaries Would Not Have Certified the Actuarial Soundness of MAO Bids, and CMS Should Not Have Accepted the Soundness of Those Bids, Using the Proposed Methodology's Approach to Calculating Risk Scores

MAOs calculated bid amounts using projected risk scores based on the methodology discussed above. MAOs and their actuaries certified that those bid amounts were actuarially sound, meaning that the required revenue stated in the bid was reasonable in relation to the benefits to be provided. If risk scores were instead based on the approach resulting from the Proposed Methodology, those same bids would not have provided the required revenue. As such, the bids would not have been actuarially sound, and actuaries would not have certified them. Instead, bid amounts would have been substantially higher, resulting in higher member premiums and or fewer supplemental benefits offered to members.

By accepting MAOs' bids, CMS verified the assumptions and methodology the MAOs used. This is because CMS

> may only accept such a bid amount . . .if the Secretary determines that such amount. . .[is] supported by the actuarial bases provided. . .and reasonably and equitably reflects the revenue requirements. . .of benefits provided under that plan.[12]

If the MAOs' assumptions and methodology for projecting risk scores were incorrect, CMS could not lawfully have accepted the bids.

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[11] Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,745 (Apr. 15, 2010).
[12] Social Security Act § 1854(a)(6)(B)(iii), 42 U.S.C. § 1395w-24(a)(6)(B)(iii); *see also* 42 C.F.R. § 422.258(b).

IV. THE PROPOSED METHODOLOGY WOULD NOT WITHSTAND LEGAL SCRUTINY

A. The Proposed Methodology Effects an Impermissible Retroactive Change to the Assumptions and Methodologies in the Bids and is Contrary to the Contract

If applied to contract years for which bids have already been submitted, the Proposed Methodology would violate the Act. As noted above in Section III, the Act requires the Secretary to provide, in advance, the assumptions and methodology to be used in each annual announcement. The Act further requires the Secretary to provide advance notice of, and an opportunity to comment on, "proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement" in the prior contract year.[13] Similarly, CMS committed itself not to "implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute."[14]

Also as described in Section III, CMS obtained bids from MAOs (and approved the soundness of those bids) based on the published methodology for projecting risk scores and estimating bid amounts. The Proposed Methodology would make payments using wholly different methodology. MAOs performed their end of the contract and provided healthcare benefits to their enrollees. The Proposed Methodology changes the assumptions on which the CMS pricing was established based on the MAO bids.

By changing a critical assumption and introducing a new methodology, the Proposed Methodology violates the advance notice requirements in the Act, and breaches the contract between MAOs and CMS. CMS did not provide (and has not otherwise provided)[15] advance notice of this change in assumptions and methodology.[16]

B. The Proposed Methodology Must Be Promulgated Through Notice-and-Comment Rulemaking

In addition to the specific advance notice requirements discussed in Section IV.A above, the Proposed Methodology may not be applied retroactively because it "takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or

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[13] Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2); *see also* Social Security Act § 1853(b)(3), 42 U.S.C. § 1395w-23(b)(3) (requiring an explanation of assumptions and changes in methodology).

[14] 42 C.F.R. § 422.521.

[15] The Proposed Methodology does not satisfy the notice-and-comment requirement for changes in assumptions and methodology for future contract years, as set forth in the Act. Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2). Rather, the Proposed Methodology is framed as an audit tool with respect to contracts already entered into. We believe that CMS must carefully consider and provide clear indications if it wishes to change the assumptions and methodology for projecting risk scores and other aspects of the bid process for CY 2012.

[16] Social Security Act § 1853(b)(2), 42 U.S.C. § 1395w-23(b)(2).

attaches a new disability in respect to transactions or considerations already past."[17] The Proposed Methodology would alter the legal landscape that existed when MAOs submitted bids, as described above in Sections II and III, and in Section V below. Most notably, MAOs had no notice that CMS would attempt to implement the Proposed Methodology, which had not been used or announced. Nor would the Proposed Methodology be, as CMS has asserted, just "a means for ensuring that payments made to MA organizations comply with substantive rules governing MA payments that are set forth in the statute."[18] RADV audits that rely on medical record validation alter the risk adjustment payment model because payment rates that were developed using Medicare FFS Claims Data would be retroactively adjusted using a different methodology – MA Claims Data supported by a medical record.

Moreover, the Act requires that any:

> rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . [shall be] promulgated by the Secretary by regulation.[19]

The APA similarly requires notice-and-comment rulemaking before the Proposed Methodology is implemented because it is a substantive "rule" within the meaning of the APA.[20] As it has not proceeded through this process, it is invalid and void.[21]

Although Humana appreciates that CMS has provided this opportunity for comment on the Proposed Methodology, this procedure would not satisfy the requirements of notice-and-comment rulemaking even for prospective application. CMS itself has already identified the Data Inconsistency Issue as a significant issue requiring further study, but has not yet proposed how it intends to address it. As part of the formal rulemaking process that established appeals rights for RADV audits in April 2010, commenters raised the Data Inconsistency Issue and, as CMS described it, argued that CMS must "account for any error rates inherent in [FFS Claims Data] that affect MA error rates" before CMS can extrapolate alleged overpayments resulting

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[17] *Nat'l Mining Ass'n v. Dep't of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002).

[18] Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,745 (Apr. 15, 2010). There is no statutory provision that requires risk adjustment payments to be made based solely on validation of diagnoses in medical records. In fact, the Act requires that CMS address the Data Inconsistency issue as discussed elsewhere in these comments.

[19] Social Security Act § 1871(a)(2), 42 U.S.C. § 1395hh(a)(2); H.R. REP. NO. 100-391, at 430 (1987) ("Policies meeting the definition [of covered policies] that were not issued in compliance with those procedures would be invalid.").

[20] 5 U.S.C. § 551(4); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 102627 (D.C. Cir. 2000) (recognizing that test methods for compliance are substantive rule because "changing the method of measuring compliance with an emission limitation can affect the stringency of the limitation itself").

[21] *Heartland Reg'l Med. Ctr. v. Sebelius,* 566 F.3d 193, 199 (D.C. Cir. 2009) (holding that lack of notice and comment is "fundamental flaw that 'normally' requires vacatur of the rule").

from an RADV audit.[22] CMS acknowledged the importance of the Data Inconsistency Issue, stating: "We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue."[23] However, CMS has not proposed any mechanism for resolving the issue. CMS must "respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments, and to show how that resolution led the agency to the ultimate rule."[24] CMS must therefore address the Data Inconsistency Issue detailed in the Actuarial Report before implementing the Proposed Methodology, or any other methodology that computes extrapolated payment error amounts based on RADV audit findings. As a result, we respectfully submit that CMS may not simply "post a final version of the RADV sampling and payment error calculation methodology" on its website, as CMS indicated it intends to do.[25] Rather, CMS must address the substance of the public comments on the Data Inconsistency Issue that have already been presented and that have been further presented here. It must publish its analysis and proposed resolution, with a statement of the basis for the proposed resolution. That must be published for public comment prior to implementation.

The United States Court of Appeals for the District of Columbia Circuit earlier this month reemphasized the need for the Department of Health and Human Services to follow the relevant rulemaking procedures, and consider and provide a reasoned response to comments submitted to the Agency arguing that the Agency's mathematical computations for implementing payment rates to hospitals were incorrect.[26] Additionally, the President's recent Executive Order instructs agencies that the public has the right to comment on "all pertinent parts" of rulemaking, including "relevant . . . technical findings," before they are implemented.[27] Here, CMS has already acknowledged the potential merit of refining the error rate calculation, highlighting the procedural flaw if CMS does not publish an analysis and propose a solution for comment.

Simply asserting that the Proposed Methodology is designed to assure proper payments[28] does not suffice to meet the substance of the public comments or address the Data Inconsistency. Nor are these simple assertions a legally sufficient response to the detailed analyses and arguments presented in this letter and the attached Exhibits, which are incorporated by reference.

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[22] Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,749 (Apr. 15, 2010).

[23] *Id.*

[24] *Action on Smoking & Health v. C.A.B.*, 699 F.2d 1209, 1216 (D.C. Cir. 1983) (quoting *Rodway v. U.S. Dep't of Agriculture*, 514 F.2d 809, 817 (D.C. Cir. 1975)).

[25] Proposed Methodology, at 3.

[26] *Cape Cod Hosp. v. Sebelius,* No. 1:08-cv-1751, slip op. (D.C. Cir. Jan. 14, 2011).

[27] Exec. Order No. 13,563, 76 Fed. Reg. 3,821, 3,822 (Jan. 21, 2011).

[28] *See, e.g.,* Preamble discussion to Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,677, 19,746–47 ("[T]he RADV is an audit process that is intended to validate the HCCs that were submitted by MAOs in order to determine whether the additional payment amounts associated with these diagnosis codes were properly made.").

CMS's failure to conduct an analysis of and to address public comments, and publish for public comment a proposed resolution of, the Data Inconsistency Issue would render invalid any extrapolated overpayment amounts calculated through the Proposed Methodology.

C. Arbitrary and Capricious and Contrary to Law

By failing to address the Data Inconsistency Issue and other issues identified in these comments, the Proposed Methodology is so internally inconsistent and illogical as to be arbitrary and capricious under the APA.[29] That is, it fails to consider and address important factors,[30] and lacks a "rational connection between the facts found and the choice made."[31]

The Proposed Methodology is also "not in accordance with law,"[32] because it fails to implement various statutory provisions governing the Medicare Advantage program. In addition to the important provisions discussed above in Sections III and IV.A relating to the bid process and advance notice requirements, the Proposed Methodology fails to implement the statutory provisions relating to risk adjustment. Congress required CMS to adjust Medicare Advantage payments for health status "so as to ensure actuarial equivalence,"[33] and to ensure that risk adjusted payments reflect "differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences."[34] Congress further required that CMS's method "account for variations in per capita costs based on health status."[35] By failing to address the Data Inconsistency Issue, the Proposed Methodology would violate these provisions governing risk adjustment. As discussed in these comments, by failing to address the Data Inconsistency Issue, risk adjustment payments will no longer be comparative with FFS, and would not properly compensate MAOs for the health status of their membership.

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[29] 5 U.S.C. § 706(2)(a); *see also ABF Freight Sys., Inc. v. NLRB*, 510 U.S. 317, 324 (1994).

[30] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) ("court must consider whether the decision was based on a consideration of the relevant factors"); *Woods Petroleum Corp. v. Dep't of Interior*, 47 F.3d 1032, 1037 (10th Cir. 1995).

[31] *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins.*, 463 U.S. 29, 42–43 (1983).

[32] 5 U.S.C. § 706(2)(A).

[33] Social Security Act § 1853(a)(1)(C)(i); 42 U.S.C. § 1395w-23(a)(1)(C)(i). Adoption of the Proposed Methodology would also place CMS in conflict with various other provisions of the Act, including various aspects of the bid process including assuring the actuarial soundness of bids based on the cost of providing benefits to an enrollee with a "national average risk profile" (as defined by the Secretary). Social Security Act § 1854(a)(6)(A)(i); 42 Social Security Act § 1854(a)(6)(A)(i); 42 U.S.C. § 1395w-24(a)(6)(A)(i).

[34] Social Security Act § 1853(a)(1)(C)(ii)(I); 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I).

[35] Social Security Act § 1853(a)(3); 42 U.S.C. § 1395w-23(a)(3).

V. OTHER ISSUES

A. CMS's Proposed Methodology is Statistically Unsound

In addition to the Data Inconsistency described above, CMS's Proposed Methodology fails basic requirements for sampling and extrapolation. Any authority to recover overpayments through an extrapolation methodology must be exercised consistent with a rigor that is missing in the Proposed Methodology. Courts routinely scrutinize extrapolation, where it is authorized, to assess whether the extrapolation is statistically sound.[36] Exhibit B includes a more detailed explanation of the statistical issues raised by the Proposed Methodology.

B. The One Best Medical Record

The above issues and concerns related to the Proposed Methodology are further exacerbated by CMS's use of the "one best medical record" requirement in conducting the audits. The "one best medical record" requirement distorts the RADV audit results, highlights the Data Inconsistency Issue described above, and further undermines the actuarial and statistical validity of the Proposed Methodology. It excludes relevant and probative evidence of members' conditions for reasons unrelated to probativity – *i.e.*, the ability of the evidence to show a member's "health status" in support of a risk adjustment payment. In doing so, it effectively changes the statutory inquiry from "health status" to health status as established by only one best medical record. In addition, it imposes documentation standards not enforced with respect to FFS Claims Data, and thus ensures a lack of both actuarial equivalence and actuarial soundness, as well as a lack of logical consistency. CMS must also follow proper rulemaking procedures with respect to the "one best medical record" requirement because it is a substantive standard that may be accomplished, if at all, only by rulemaking.[37] Finally, CMS may not retroactively apply the "one best medical record" requirement to contract years prior to adoption of such a rule.[38]

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The above comments and the attached Actuarial Report highlight the economic and legal concerns associated with the Proposed Methodology. As stated previously, CMS indicated that it would study the issue of FFS Claims Data adjustments, but there is no evidence that it has

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[36] *See, e.g., John v. Sebelius*, 2010 U.S. Dist. LEXIS 107584, at *14 (E.D. Ark. Oct. 6, 2010) (FFS Medicare case) ("[W]hen dealing with probability sampling, if a particular probability sample design is properly executed (i.e., defining the universe, the frame, the sampling unit, using proper randomization, accurately measuring the variables of interest, and using the correct formula for estimation) then assertions that the sample and its resulting estimates are not statistically valid, cannot be legitimately made.").

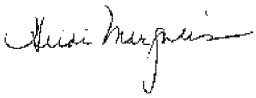
[37] *See* 5 U.S.C. § 551(4); Social Security Act § 1871(a)(2), 42 U.S.C. § 1395hh(a)(2); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 102627 (D.C. Cir. 2000) (test methods for compliance are substantive rule because "changing the method of measuring compliance with an emission limitation can affect the stringency of the limitation itself").

[38] *See Nat'l Mining Ass'n v. Dep't of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002).

done so. While we fully support CMS' interest in ensuring that risk adjustment payments are made accurately, we believe that the Proposed Methodology threatens to fundamentally undermine the risk adjustment payment model. In doing so, the Proposed Methodology jeopardizes the MAO's ability to provide Medicare beneficiaries with the health care coverage and benefits on which they depend by potentially limiting benefits, increasing premiums, and reducing plan choices. In allowing comments, we believe that CMS recognizes the potential to significantly disrupt or even displace Medicare Advantage coverage for millions of seniors across the nation. Accordingly, we respectfully request that CMS reconsider its proposed approach to payment validation and thoughtfully review these comments as well as the detailed discussion and recommendations contained in the Actuarial Report.

Thank you for your consideration of these comments. Humana would welcome the opportunity to engage in further dialogue with CMS in order to ensure that efforts to accurately reimburse MAOs are actuarially sound, and will not result in any disruption to Medicare Advantage members and the benefits they receive. Please contact me if I can provide any further information that would assist you in the evaluation of the issues detailed above.

Sincerely,



Heidi Margulis
Senior Vice President, Public Affairs

EXHIBIT A

WAKELY CONSULTING GROUP
CONSULTING ACTUARIES & HEALTHCARE SPECIALISTS
BOSTON · CLEARWATER · DENVER · LOUISVILLE

Actuarial Report on the Notice of Payment Error Calculation Methodology for Part C Organizations

This report addresses actuarial principles related to making contract-level adjustments that retrospectively reduce risk scores for Medicare Advantage Organizations (MAOs) by removing diagnoses that are not substantiated by the providers' medical records. This report is being submitted to CMS in response to the request for comment on the *Notice of Payment Error Calculation Methodology for Part C Organizations* (the "Notice") dated December 20, 2010.

Wakely Consulting Group, Inc. ("Wakely") was retained by Humana, Inc. to provide an independent review and report regarding the Notice. Wakely has no employment or other related party affiliation with Humana outside of this retainer, nor does it have a relationship with the authors of the Notice. The report concentrates on the payment error calculation methodology and does not include any report regarding the sampling approach or the impact to the MA program if implemented. This report is intended for CMS to use in response to the request for comment. In the event that it is distributed more broadly, it should be distributed in its entirety.

I certify that I am a Member of the American Academy of Actuaries, and am in good standing as an FSA with the Society of Actuaries. I am familiar with the codes of conduct and standards of practice set forth by the professional organizations, and I am familiar with the actuarial concepts integral to MAO payment.

I. Executive Summary

The Notice is characterized as simply implementing an audit function and validating data. However, examination of the proposed changes indicates that it has broad actuarial implications. The Payment Error Calculation Methodology ("Proposed Payment Adjustment") in the Notice would result in a significant change in the risk score system and MAO payment.

Risk adjustment and MAO payment are complex topics which require actuarial review. The statute, CMS and the American Academy of Actuaries (AAA) all indicate the importance of actuarial principles in various MA matters, including bid development, risk adjustment and payment. References include:

- Within the last year, the AAA has commissioned a task force to draft an Actuarial Standard of Practice (ASOP) on risk adjustment methodologies. It has not yet been released.
- The bid submissions, which determine benefits and payment, are required to be certified by actuaries.

EXHIBIT A

005118

- The Social Security Act specifies that "The Secretary shall adjust the payment amount….including adjustment for health status… so as to ensure actuarial equivalence."

In addition to requiring the risk adjustment methodology to be developed, the BBA required an evaluation of the actuarial soundness of the methodology by an independent actuary. In response, a work group of the AAA commented on the actuarial soundness of the risk adjustment methodology in 1999.

In the same manner as the 1999 AAA comments, this report addresses how the Proposed Payment Adjustment impacts the actuarial soundness of the risk adjustment methodology, bid submission and payment process.

The Proposed Payment Adjustment is contrary to the following two actuarial principles:

1. The application of a risk model should be consistent with its development.
2. The bid submission process requires that actuaries have advance notice of assumptions and methodology of the MA payment process when calculating the values in the bids.

II. Description of the Proposed Payment Adjustment Methodology

Described below is the methodology outlined in the Notice regarding how risk scores and payments will be adjusted.

1. Obtain a statistically significant, stratified sample of enrollees who were continuously enrolled in the MAO during the prior year and had at least one risk adjustment diagnosis.
2. Require the MAO to produce qualifying medical records to substantiate the HCCs in the sample.
3. Evaluate the records and determine the HCCs that are supported by medical record review findings for the enrollee.
4. Revise the risk score based on the HCCs substantiated through the above process and recalculate the risk score and payment for each sampled enrollee.
5. Determine the payment error for each enrollee in the sample as the difference between the original payment and the recalculated payment.
6. Extrapolate the error rate from each stratum to determine an estimated payment error for the MA contract.

III. Development of HCC Methodology

The Hierarchical Condition Categories (HCC) model is developed using Medicare FFS (FFS) claims data. It is a prospective risk adjustment system where the base year's (Year 1) diagnoses are used as predictors of the next year's (Year 2) FFS costs. Diagnoses are mapped to groupings that CMS has determined to be predictors of medical costs for the subsequent year. Over 15,000 ICD-9 codes are mapped to one and only one of the 804 diagnostic groups. Diagnostic groups are further collapsed to about 70 condition categories, HCCs.

After the categories (i.e. HCCs) are determined, a value of each HCC (a coefficient) is calculated by performing the following major steps:

- First each FFS beneficiary's HCC markers and demographic characteristics (e.g. age/sex) are determined from the enrollment information and diagnoses in Year 1 FFS claims data.
- CMS determines the Year 2 marginal cost of each of these respective HCC and age/sex components. CMS does so by using a statistical regression analysis to assign the FFS costs of the FFS beneficiaries in Year 2 to the beneficiaries' Year 1 HCCs and demographic characteristics .
- CMS converts the Year 2 marginal costs to relative costs (risk coefficients) for each HCC and demographic cell by dividing the marginal costs for each component by the mean predicted Year 2 expenditure across all FFS beneficiaries.
- A Year 2 risk score for each FFS beneficiary can then be determined by adding the risk coefficients for the beneficiary's demographic characteristics and Year 1 HCCs applicable to that beneficiary. The average risk score calculated in this manner across all FFS beneficiaries will be 1.0 for Year 2.
- Lastly CMS multiplies the coefficients by factors that adjust the coefficients for 1) expected FFS coding improvements and 2) differences in coding between the FFS and the MA program.
    - The first adjustment is to account for more complete coding in FFS between the Year 1 data and the diagnosis year used to determine MAO payment. There is typically a lag of 2-3 years between the data used to calibrate the risk coefficients and the MAO payment year. The first adjustment is intended to ensure that the average risk score across all FFS beneficiaries remains 1.0 as a result of improvements in coding since the model was calibrated.
    - The second adjustment is to account for more complete coding in MA than in FFS.
    - Neither of these adjustments directly considers the accuracy of the data underlying either the FFS data used to determine the risk coefficients or the MA data used to determine payment.

I am not aware of any audit, medical record review, or adjustment of the diagnoses in the FFS claims data used to establish the HCCs. My understanding is that the diagnoses are used as submitted on the FFS claims by the providers. Therefore, some diagnoses in the FFS data used to develop the risk adjustment system would not be substantiated in medical records.

Once the risk coefficients are determined, the risk score for a given individual is equal to the sum of their demographic and any HCC condition markers multiplied by the associated risk coefficients (i.e. a 'sum product').

The HCC model was developed for and is applied as part of the MA payment program. The underlying premise is that the relative risk of the enrolled MA population can be measured and payment to MAOs can be adjusted to reflect expected costs using the HCC model, even though the factors were developed based on FFS data. For example, suppose a subset of the population in FFS has an average risk score of 0.95; this means they are healthier than the average FFS individual and have health conditions with anticipated medical expenses that are 5% less than the average FFS individual. When this same group of

members is enrolled in an MAO, the application of the risk model indicates the MAO should be paid 5% less than average to cover the costs of the healthier population.

IV. Principle I: The application of a risk model should be consistent with its development.

The documentation of any risk adjustment methodology is generally focused on the concept that – 'the application of the model should be consistent with its development'. Common topics associated with implementing risk adjustment systems reflect this principle. These topics include claims runout, exposure periods, inclusion of diagnoses from encounter data when capitations are present, the time period between the experience period and application period, population carve-outs, reinsurance provisions, etc. The point is always the same – to make the model's application consistent with its development.

In the MA risk adjustment system, the FFS claims data used to develop the HCC model has diagnoses that are not substantiated by medical records. Therefore, the coefficient values depend on diagnoses that were not always supported in underlying medical record documentation. The statistical regression technique determining the value of the coefficients and the relative value of the condition incorporates each marker indicated in the FFS data. Having more or fewer markers in the FFS data would change the relative value (i.e. the coefficient) of each condition.

Because the number of markers are central to the coefficient development process, *as long as the coefficients are applied to similar data (with inherent unsubstantiated diagnoses), the methodology is sound.* Various CMS documents and the statute confirm that accurate MAO payment depends on the similar coding between the FFS claims data and the MA claims data:

- The most compelling reference is the Social Security Act Section 1853 following the reference to actuarial equivalence which states: "In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences." In response to questions about the risk score adjustment implementation resulting from this statute, The *Final 2010 Rate Announcement* elaborated on this concept by stating: "MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means 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."

- The *2008 Advance Notice* states: "because the CMS-HCC model is calibrated on [FFS] data and the resulting risk scores are adjusted for [FFS] normalization, MA coding patterns that differ

> from patterns in [FFS] may result in risk scores that are not equivalent to the risk scores of the FFS beneficiaries used to calculate the county rates."

The Proposed Payment Adjustment methodology adjusts the MA organization's payment by determining revised risk scores that reflect only HCCs substantiated by the medical records.[1] The proposed methodology in effect removes unsubstantiated HCCs from the risk score determination. The Proposed Payment Adjustment methodology adjusts the MA organization's payment by estimating revised risk scores that reflect only HCCs substantiated by the medical records. The Proposed Payment Adjustment in effect removes unsubstantiated HCCs from the risk score determination[i] that were not removed in the initial development of the risk adjustment model. Therefore, the data used to develop the risk adjustment model may be fundamentally and materially different from the data used in the RADV audits to calculate the MAO's revised risk score and payment.

Without adjustment to other components of the payment system, the data inconsistency inherent in the Proposed Payment Adjustment causes a systematic reduction to MA risk scores resulting in a risk adjustment payment methodology that underpays MAOs. Consider an extreme hypothetical example where the entire FFS population moves to an MA environment. In theory, the average risk score for the MAOs should be the same as the average FFS beneficiary (i.e. a "1.0"). However, the Proposed Payment Adjustment reduces the MAO risk score to something less than 1.0, an illogical outcome. The entire FFS population, which by definition characterizes a 1.0 average, should not have a lower risk score when enrolled in an MA environment. Because MAO payment is based on this lower risk score under the Proposed Payment Adjustment, CMS underpays the MAO for the enrolled populations' risk.

V. Principle II: The bid submission process requires that actuaries have advance notice of assumptions and methodology of the MA payment process when calculating the values in the bids.

Any change to assumptions and methodology after the bid submission jeopardizes the actuarial soundness of bids. The Social Security Act Section 1853 endorses the need for advance notice to the MAOs by requiring that CMS provide notice of assumptions and methodology, in the annual rate letter, and notice of changes at least 45 days in advance of the annual rate letter.

MAO payment rates, benefit plans and member premiums are not predetermined by CMS. They are the result of a bid submission process in which MAOs must project the cost of providing the proposed benefits to an enrolled population in an actuarially sound manner. Critical to this process is a valid and

[1] The proposed methodology includes both the potential removal of HCCs and a recognition of HCCs that were documented but not submitted by the plan for payment. We focus on unsubstantiated HCCs in this report and believe this is not a misrepresentation of the overall result of the proposed method. This belief is based on the indication in the Notice that CMS is seeking "payment recovery", which one would logically conclude means that there are fewer instances of documented but not submitted codes than codes that were submitted but not substantiated.

consistent definition of a beneficiary with a "national average risk profile" and a consistent method for computing risk scores. MAOs' correct understanding of the national average risk profile and method for computing risk scores is essential to determining a benefit design, member premiums, and payment rates that are financially viable.

"The Required Revenue for the National Average Risk Profile" is an amount in the MAO's bid and directly affects the payment to the MAO. The MAO's estimate of the Required Revenue for the National Average Risk Profile is derived in part from projected risk scores.

CMS pays MAOs for an enrolled member using the formula:

(Risk Score of the member) times (the 1.0 bid) plus (the rebate.)

This formula shows that payment to MAOs is not only dependent on the member risk score, but also the amount of the 1.0 bid and rebate, which are both determined via the bid submission process. The "1.0 bid" is the MAO's estimate of the "Required Revenue for the National Average Risk Profile".

The 1.0 bid is a critical determinant of what MAOs get paid. To the extent the bid submission under/overestimates the required revenue for a national average risk profile, the MAO will be under/overpaid. CMS recognizes the significance of the 1.0 bid by requiring an actuarial certification stating that in accordance with Federal law, the bid(s) are based on the "average revenue requirements in the payment area for a Medicare Advantage/Prescription Drug enrollee with a national average risk profile."

Projecting an accurate 1.0 bid through bid submission depends on a thorough understanding of the MAO payment process, including how risk scores will be determined. Table A at the end of the report demonstrates the relationship between the 1.0 bid and the projected risk score. The 1.0 bid is the quotient of the "Plan A/B bid" (the projected costs for the expected population) and the projected risk score for the expected population. An appropriate 1.0 bid requires projecting risk scores in the BPT in the same manner that MAO payment is made. MAOs and actuaries have been aware that the risk coefficients were determined without medical record substantiation of diagnoses, and CMS has published risk scores for the FFS population that do not incorporate any review of medical record substantiation of diagnoses.

Because the advance and final rate notices for the payment methodologies did not contain any information regarding the Proposed Payment Adjustment, MAOs were not able to raise the issues discussed in this document, project the risk scores in the bids in conformance with the Proposed Payment Adjustment, or appropriately project the required revenue for an enrollee with a national average risk profile. MAOs did not anticipate in their bid submissions potential changes to risk scores resulting from the Proposed Payment Adjustment.

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The Proposed Payment Adjustment changes the how risk scores are calculated, changes the definition of the required revenue for a national average risk profile enrollee, and renders the original actuarial certification invalid.

Had actuaries known that the MAO risk scores would be adjusted by the Proposed Payment Adjustment via RADV audits at the time of bidding, 1) the actuarial community would have likely raised concerns similar to those outlined in this document, and 2) the bids would have been completed differently. Specifically, the projected risk scores would have been lower. This would have resulted in a higher bid amount (a higher projected expenditure for a beneficiary with a national average risk profile. For bids below the benchmarks, there would have been reduced savings, less rebate dollars, and either less benefits or higher premiums for members. (Table A at the end of this report illustrates the bid changes if MAOs had known that risk scores were going to be calculated on 100% substantiated diagnoses.)

In fact, it is unclear whether actuaries will be able to provide certifications of the 2012 bid submissions without qualifications (exceptions) if CMS adopts the Proposed Payment Adjustment. ASOP 8, which provides guidance to actuaries submitting regulatory rate filings, states "the actuary should adjust past experience for any known or expected changes that, in the actuary's professional judgment, are likely to materially affect expected future results." The Proposed Payment Adjustment methodology has very material impact on future results, depending on whether the MAO undergoes a RADV audit. In the bid submission, the actuary will need to project risk scores and define the revenue requirements for an enrollee with a national average risk profile. Yet the actuary will not know in advance whether the MAO will be subject to audit. Depending on whether or not the MAO will undergo a RADV audit, the final risk score could vary significantly. In short, actuaries will not know which methodology for determining risk scores will apply to the particular MAO – a RADV-adjusted risk score based on medical record substantiation, or the risk score methodology CMS used to calculate the coefficients and report FFS risk scores. Even if CMS were to specify the plans to be audited, there would still be a mismatch between the coefficients published by CMS and the post-audit MAO risk scores, which could result in plan actuaries being unable to certify bids.

VI. Considerations for Appropriately Adjusting Payment for RADV Audits

If CMS is resolute in extrapolating a payment adjustment related to the amount of unsubstantiated diagnoses, it is only possible to remedy Principle I. Because we cannot now go back and change our historical bids to reflect risk scores that are projected in the same manner as payment is being made, any retrospective change in risk score determination or payment methodology will result in a violation of Principle II.

However, it is possible to consider and propose a payment extrapolation approach that is more compliant with Principle I and may not be a significant violation of Principle II. Two concepts that CMS could consider:

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1) Correct the risk coefficients.
2) Adjust the Proposed Payment Adjustment to reflect the difference in diagnoses substantiation rates of the MAOs versus the FFS program.

Correct the Risk Coefficients

Removing unsubstantiated diagnoses from the FFS data set used to develop the HCC model and developing a modified model to correct the coefficients would solve the data inconsistency in Principle I. The revised coefficients would be used when recalculating the risk scores and payments for all members in the sample (including members for whom there were no changes in HCCs). As explained above, risk coefficients include both demographic and HCC components.

If unsubstantiated diagnoses were removed from the FFS data set used to develop the HCC model, the modified model would result in HCCs with higher coefficients. Because the coefficients are determined through regression, this result is somewhat obscure. The explanation for the increase in coefficients depends on whether the diagnoses are truly identified conditions and just not substantiated or if they are errant diagnoses that have no predictive value of cost.

- Assuming that at least some of the unsubstantiated diagnoses are valid indicators of health status, the age/gender coefficients would increase as less variation in cost would be explained by identifiable conditions, and a higher proportion of costs would be assigned to a random component (a flat amount added to all age/gender coefficients) or differences in age and gender (a change in the slope of the age/gender coefficients). The accuracy of the risk adjustment model would decrease, and the HCC risk adjustment model would do a poorer job of fairly compensating MAOs based on differences in morbidity.
- To the extent that the unsubstantiated diagnoses are not valid indicators of health status, the HCC coefficients would increase as more variation in cost would be explained by the substantiated HCCs. The accuracy of the risk adjustment model would increase, and the HCC risk adjustment model would do a better job of fairly compensating MAOs based on differences in morbidity.

Either way, removing unsupported diagnoses from the FFS data used for setting the HCC coefficients would cause the risk coefficients on average to increase.

To illustrate this point, consider a simplified model where a base risk score is allocated to each member unless the member had diabetes, in which case they would get the base risk score plus an additional increase for the additional diabetes risk. Suppose the historical raw data used to set the risk scores looks as follows with 10 identified people with diabetes:

Member Type	Members	Ave Monthly Costs	PMPM
Non-Diabetes	90	$90,000	$1,000
Diabetes	10	$15,000	$1,500
Total Members	100	$105,000	$1,050

Each person would be assigned the appropriate number of markers, indicating their condition(s). Non-diabetes members would each be assigned one marker, to indicate they would only receive the base component of the payment. Each diabetes member would receive two markers, one for the base component and one for the diabetes component:

Member Type	Base Marker	Diabetes Markers	Total Markers
Non-Diabetes	90	0	90
Diabetes	10	10	20
Total Markers	100	10	110

To calculate the average marginal value of the markers, the total cost is divided by the total markers ($105,000/110=$955). The average marginal value is divided by the average expenditure of $1,050 to find the average coefficient value of 0.909 ($955/$1,050=0.909). Note, that 0.909 is the average coefficient value, and that on average members have 1.1 markers for an average risk score of 1.0.

Description	Amt
a. Total Costs	$105,000
b. Total Markers	110
c. Average marginal value of each marker (a/b)	$955
d. Average Expenditure	$1,050
e. Average Coefficient Value (c/d)	0.909

Now consider recalculating the average coefficient value assuming some of the diabetes diagnoses were not substantiated and are not valid indicators of diabetes. Suppose two members were found to not have appropriate substantiated claim records. The historical costs are still $105,000, but number of markers would be reduced to 108:

Member Type	Base Marker	Diabetes Markers	Total Markers
Non-Diabetes	92	0	92
Diabetes	8	8	16
Total Markers	100	8	108

Using the same method to calculate the average coefficient as before, the average coefficient value is now 0.926:

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Description	Amt
a. Total Costs	$105,000
b. Total Markers	108
c. Average marginal value of each marker (a/b)	$972
d. Average Expenditure	$1,050
e. Average Coefficient Value (c/d)	0.926

Removing the two unsupported diagnosis resulted in an average HCC coefficient increase from 0.909 to 0.926. In general, removing the unsupported diagnosis in HCC development results in higher risk coefficients.

In summary, the point of this illustration is the following:

- Today's risk coefficients have been developed assuming unsubstantiated diagnoses are valid markers.
- The RADV audits are premised on the fact that unsubstantiated diagnoses are not valid markers and should not result in payment. This is appropriate only if the HCC developed coefficients were developed on data that also did not include unsubstantiated diagnoses.
- Correcting the HCC development to remove the unsubstantiated diagnoses would result in higher risk coefficients. In order to maintain appropriate payment, the Proposed Payment Adjustment must use these higher coefficients in calculating the revised payment if the unsubstantiated diagnoses are removed from the MAO data. Without correcting the coefficients (or making potential other changes like FFS comparisons), the Proposed Payment Adjustment results in understated risk scores.

Comparison to FFS

Adjusting the Proposed Payment Adjustment to include a comparison of the MAO substantiation rate to the FFS substantiation rates is an attractive solution for a few reasons:

1) An adjustment reflecting the comparison of the diagnoses substantiation between MA to FFS is similar to the coding intensity adjustment that has already been implemented by CMS.
2) CMS has already established a sampling methodology through the RADV audit that would allow them to assess the substantiation rate in the FFS program. Because of this, the comparison of the substantiation rates, using the same standards and methodology, would be the easiest method to implement.
3) Compared to correcting the risk coefficients approach above, this approach avoids any concerns that different coefficients may have resulted in revised benchmarks and other changes to the projected risk scores in the BPTs depending on the mix of membership enrolled.

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Wakely appreciates the opportunity to comment on this significant change in the MAO payment methodology. If you have any questions regarding this report, please feel free to contact me.

Respectfully,

Julia Lambert, FSA, MAAA
Principal and Consulting Actuary
Wakely Consulting Group, Inc.
727-507-9858 x115

January 21, 2011

EXHIBIT A

Table A

Bid Amounts and Payment Results Under Current Methodology
Versus Assuming Retrospective Payment Adjustment

Description (Column A)	PMPM Amounts: Current Methodology (Column B)	PMPM Amounts: Retrospective Pmt Adj[1] (Column C)
Bid Development of 1.0 Bid		
a. Standardized A/B Benchmark	$1,000.00	$1,000.00
b. Projected Average Risk Score for Plan Population[2]	1.000	0.950
c. Plan A/B Benchmark (a*b)	$1,000.00	$950.00
d. Plan A/B Bid for 2007 (for expected plan population)	$800.00	$800.00
e. Standardized A/B Bid (1.0 Bid) (d/b)	$800.00	$842.11
f. Savings	$200.00	$150.00
g. Rebate/Amt Available for Supp Benefits (.75*f)	$150.00	$112.50
h. Expected payment/required revenue for benefits provided	$950.00	$912.50
Actual Payment (assuming population as expected)		
i. Initial Risk score of population (including unsupported diagnoses)	1.000	1.000
j. Initial Payment based on all diagnoses (e*i+g)	$950.00	$954.61
Adjustment for Payment for Unsupported Diagnosis		
k. Revised Risk Score	0.950	0.950
l. Payment adjustment (k-i)*e	-$40.00	-$42.11
m. PMPM Payment	$910.00	$912.50
n. Difference from expected payment/required revenue (m-h)	-$40.00 paid $40 less than benefits provided	$0.00 paid appropriately for benefits provided

[1] Retrospective Payment Adjustment assumes risk scores in bids projected based on only supported diagnoses, but no other adjustments to risk coefficients or benchmarks are made.

[2] Average Risk Scores based on only supported diagnosis are assumed to reduce risk scores by 5%.

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EXHIBIT B

Exhibit B

Statistical Issues Related to the RADV Audit Proposed Methodology

CMS's Proposed Methodology fails several elementary requirements for sampling and extrapolation. There are a number of problems with the Proposed Methodology that could result in biased samples and call into question whether certain aspects of the Proposed Methodology are statistically valid, including the following:

- CMS provides no statistical analysis to support basing its audit adjustments on reviews of 201 members, irrespective of an MAO's plan size.

- The Proposed Methodology fails to facilitate comparisons between MAO plans and, in particular, to facilitate correction of the Data Inconsistency Issue. There are alternate statistical models that would be more appropriate for comparing plans, for example "Best Linear Unbiased Estimators,"[1] in order to evaluate the impact of non-validation between plans (including Medicare FFS). (We note that while this may be an appropriate vehicle for doing a comparison of plans, however it would not solve the Data Consistency Issue on its own).

- MAO members in the sample will have varying exposure periods during the payment year. While it is required that members be enrolled for all 12 months of the data collection year, the same is not true for the payment year. Accordingly, the sampling must be adjusted to ensure proportionate representation of exposure periods in the sampled population compared to the eligible population.

- Different contracts and plan benefit packages with varying base premium amounts will be represented in the sample. The sampling must be adjusted to ensure proportionate representation of different base premium amounts. Bias in the sampling could exist if differences in base premium between the sampled population and eligible population are not recognized.

- The Proposed Methodology improperly computes the alleged overpayment payment based on the average of differences for the sample member's changes in total paid premiums ("Average Dollar Differences"). This convolutes the sample's exposure periods and base premiums into the assessment, although these values are determined for the entire population and do not require auditing.

- The sample also fails to assure proportional representation of all HCCs in the population, and does not represent the variety of providers whose data is being reviewed.

In addition, as a procedural matter, CMS should provide plans with a list of the enrollees eligible for RADV sampling, and the enrollees stratum, for each audit and allow plans to review and comment on the list to ensure that it meets the criteria identified by CMS for the eligible population.

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[1] Rao, Poduri. *Sampling Methodologies with Applications,* 2000, Chapter 9, §§ 9.7-9.12.

Exhibit 3

AMERICAN ACADEMY of ACTUARIES

January 21, 2011

Ms. Cheri Rice
Acting Director, Medicare Plan Payment Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comment on RADV Sampling and Error Calculation Methodology

Dear Ms. Rice:

On behalf of the American Academy of Actuaries'[1] Health Practice Council, I appreciate this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to its recent request for comments on the Medicare Advantage (MA) risk adjustment data validation (RADV) payment error calculation methodology. We are concerned that the audit process as currently proposed would apply the risk-adjustment model in a way that is inconsistent with the way it was developed. This letter outlines our concerns.

The Importance of Risk Adjustment

In general, risk adjustment is intended to capture differences in morbidity from one cohort of individuals to another. As such, the CMS hierarchical condition categories (HCC) risk adjustment system is an important component of the MA program. Risk-adjusting plan payments can reduce incentives for plans to avoid high-cost enrollees and can help ensure that plan payments are adequate.

Throughout the development and refinement of the MA risk-adjustment model, CMS has sought to ensure that the risk-adjustment system properly reflects the differences in the risk profile of enrollees in a consistent manner. In addition, CMS has sought to recognize appropriate changes in fee-for-service (FFS) coding over time and differences in coding across programs.

Periodically auditing the data is appropriate to ensure that conditions are coded correctly and that risk scores and the resulting risk-adjusted payments properly reflect the underlying health status of MA enrollees. Because improper coding can result in inaccurate payments to MA plans, RADV audits can help improve plan payment accuracy.

Concerns with Proposed Audit Process

Our primary concern with the proposed audit process is that it creates an inconsistency between how the risk-adjustment factors were developed and how they now would be applied. An underlying principle of risk-adjustment systems is that there needs to be consistency in the way the model was developed and how it is used. The CMS-HCC risk-adjustment factors were developed with FFS data that, to the best of our knowledge, were not validated or audited for accuracy. The proposed audit process, however,

[1] The American Academy of Actuaries is a 17,000-member professional association whose mission is to serve the public on behalf of the U.S. actuarial profession. The Academy assists public policymakers on all levels by providing leadership, objective expertise, and actuarial advice on risk and financial security issues. The Academy also sets qualification, practice, and professionalism standards for actuaries in the United States.

effectively would apply those factors only to MA data that are validated. In other words, the data used in the RADV audit to determine a plan's payment error are fundamentally and materially different from the data used to develop the risk-adjustment model.

If, as a result of the RADV audit, for example, certain lower-cost enrollees no longer are considered diabetic but would have been considered diabetic in the FFS data used to develop the risk scores, then the payment for diabetic members in the payment year could be inadequate. In this example, the risk score factor associated with diabetes would be understated relative to the factor that would have resulted from using only substantiated diagnoses, because the lower-cost patients would have lowered the average spending amounts among those identified as diabetics in the FFS data. When that factor is applied to similarly non-validated data, the total payments for those with diabetes would be adequate. When that same factor is applied only to those with substantiated data, however, the total payments could be too low.

This type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities. In addition, the uncertainty related to a plan's ultimate post-audit risk score could make it difficult for actuaries to estimate the plan's risk score and certify the plan bid.

Extrapolating RADV payment-error calculations to adjust premium payments to MA plans represents a significant change in the risk-adjustment methodology. The Health Practice Council is concerned that the resulting modified payment methodology may not appropriately reflect the relative risk profile of enrollees in the affected MA plans.

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As you may be aware, per a request from CMS (then the Health Care Financing Administration), the Academy reviewed the risk-adjustment methodology that was developed in response to requirements in the Balanced Budget Act of 1997.[2] We welcome the opportunity to serve as a similar resource to CMS. We would be happy to study more closely the current risk-adjustment and proposed audit processes and to consider potential options for addressing the above concerns. If you have any questions or would like to discuss these comments further, please contact Heather Jerbi, the Academy's senior health policy analyst (202.785.7869; Jerbi@actuary.org).

Sincerely,

Thomas F. Wildsmith, MAAA, FSA
Vice President, Health Practice Council
American Academy of Actuaries

cc: Richard Foster, Chief Actuary, Centers for Medicare & Medicaid Services (CMS)
Paul Spitalnic, Director, Parts C and D Actuarial Group, CMS
Timothy Hill, Deputy Director, Center for Medicare, CMS
Jennifer Harlow, Director, Division of Payment Validation, Medicare Plan Payment Group, CMS

[2] American Academy of Actuaries' Risk Adjustor Work Group, *Actuarial Review of the Health Status Risk Adjustor Methodology*, Jan. 14, 1999: http://www.actuary.org/pdf/medicare/hcfariskadj.pdf.

Exhibit 4

December 8, 2009

Charlene M. Frizzera, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

File Code: CMS-4085-P, Document ID CMS-2009-0088-0002

Dear Ms Frizzera:
Aetna Inc. appreciates the opportunity to present comments on the proposed rule regarding Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. The following outlines our specific concerns and suggested recommendations.

Section A. Changes to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers	FR Page #	Comments
II. Provisions of the Proposed Regulations	54639	Related to the eight specific goals on which these proposed regulations are based, we would like to ensure that tangible measures are in place and these measures are communicated in advance to Plan Sponsors so that processes can be instituted to guard against the potential for non-compliance. As an example, for the goal that reads "Strengthen our ability to distinguish for approval strong applicants for MMA participation and remove consistently poor performers", we request that specific, clear criteria be outlined that will ensure that a level playing field is in place and ask CMS to identify how 'poor performance' will be measured.
3. Deny Contract Qualification applications Based on Past Contract Performance (§422.750 & §423.750)	54641	We support CMS' effort to develop a performance evaluation process; however we recommended a 12 month, not 14 month look back at performance data. We strongly recommend the development of a consistent process that will applied across all contractors "nationally" regardless of their size or geographic location. The performance measurement criteria developed needs to clearly establish what are considered "open issue" outliers and should be based upon significant proven non-compliance actions, sanctions and/or fines. Open corrective actions for which an organization is in process of responding and working through with CMS or notices of non-compliance for which an organization has responded and resolved should not included in the criteria. MAOs and Part D

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		sponsors begin planning for expansions and filings in late Spring each year, therefore receiving guidance regarding this new evaluation process to be utilized is critical information for organizations to understand. In regards to notifying organizations who CMS has determined do not meet the qualifications to file an application, we recommend CMS provide this notification within 15 calendar days of receipt of a written notice of intent, so organizations do not spend resources preparing and submitting applications. We do not support that a decision to withdraw from a service area would be viewed as an indication of poor performance by an organization, since this type of decision could be result of other factors that are unrelated to performance.
4. Use of Data to Evaluate Continued Ability to Act as a Qualified Sponsoring Organization Under Parts C and D (§422.504 & §423.505)	54642	We support the development of a consistent performance data evaluation process. However, we strongly recommend CMS conduct data analysis at the contract verses the PBP level (which could result in diluted data), where as contact level data analysis would provide the performance data required to evaluate contract comparability. Additionally, we request CMS provide adequate lead time for the implementation of future data collection requirements so that organizations can plan and secure IT resources and funding required for implementation.
5. Compliance Programs under Parts C and D (§422.503(b)(4)(vi) & §423.504(b)(4)(vi))	54643	We supports the to change to section § 422.503(b)(4)(vi)(C) regarding the deeming of FWA training for medical providers as this is consistent with the recommendation made when we met with CMS staff to discuss this regulation earlier in the year. We do not support the proposal to leave the current regulation "as is" for § 423.504(b)(4)(vi)(C), as it is our opinion based on feedback received that the FWA training requirement is just as burdensome for contractors and Part D providers as it is for medical providers. We recommend rather than CMS expecting contractors to develop and provide FWA training (which results in inconsistent messaging) that CMS take accountability to develop standardized FWA training that addresses Original Medicare, Medicare Advantage and Part D fraud. The availability of standardized training material from CMS would be the most effective solution and it would ensure consistency while satisfying CMS requirements as to the topics and level of detail expected. The standardized training could be made available on CMS' website for all providers and contractors to access. Recommend CMS engage pharmacy associations such as the NACDS and Independent pharmacy associations to establish a registry of pharmacies that have completed training. Sponsors could search the registry by NCPDP number and get the latest dates of training completion which would relieve the current administrative burdens associated to this existing regulation. Sponsors should not be responsible for implementing or monitoring FWA activities of other contracted entities. Plan sponsors should be allowed to rely on contractual commitments by subcontractors that they will implement reasonable FWA activities related to their delegated activities and appropriate to their size and organization structure. . Additionally, recommend organizations have the flexibility to identify and provide the appropriate level of compliance training for internal constituents.
6. Network Adequacy of Coordinated Care and	54644	We supports CMS' approach to develop a consistent review process to determine network adequacy

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Network-Based Private Fee-for-Service Plans Under Part C (§422.112)		which should help to reduce the inconsistency and subjectivity previously encountered with Regional CMS reviewers. MAOs and Part D sponsors begin planning for expansion filings in late Spring each year; therefore it is critical for CMS to provide network adequacy guidance by late Spring to allow plans adequate time to conduct required market analysis. It would be beneficial for CMS to share the type of software mapping program that will be utilized to allow organizations the option of purchasing and utilizing this same software in their internal annual analysis of network development. We recommend CMS provide their application training in early Fall, rather than the current January timeframe which is not beneficial given that applications are due in February. Suggest that CMS move back the application due date from February to late March as in prior years or allow for a longer period than 10 days for MAOs to provide additional network data to cure identified deficiencies during the application review process. We appreciate the recent Network Adequacy guidance CMS provided, but there is still the need for additional clarification required for the prevailing patterns of care and when 30 minute verses 30 mile criteria will be applied. There is also the need for additional information regarding the minimum number requirement and specialty codes for the hospital based providers that will now be required in the HSD tables. It is important to point out that organizations may not have direct contacts with some of these provider types, therefore given that a minimum number requirement has not been established for hospital based providers; we need to understand the implications for not including these types of providers on the HSD tables. Recommend CMS establish a quarterly schedule for refreshing provider data on Medicare.gov since it is CMS' recommendation that organizations use this tool in their network analysis and development; however MAOs have expressed concerns with the inaccuracy and inconsistency of the data in this tool. Additionally, CMS needs to consider that while county data may reflect an adequate number of available providers, there are several factors that could prevent an organization from securing a contract agreement, such as exclusive arrangements, unreasonable payment rates, etc. CMS needs to also re-evaluate and further clarify some of the required documentation listed on the Exceptions Criteria list such as "claims data and local provider interviews" because as noted above the current 10 day timeframe allowed to cure network deficiencies will create a challenge for MAOs to provide such documentation. Recommend CMS pilot the use of the automated system with some of the CY2011 applications to work through identified discrepancies and further develop network adequacy guidance to be applied with for use with the CY2012 applications that can be released in Spring of 2010.
7. Deemable Program Requirements under Parts C and D (§422.156(b)(7), §422.156(f), §423.165(b) & §423.165	54645	We support consistency of deemable requirements where permissible. We also encourage the agency to look at additional deemable requirements based on differences in the Part D program.
8. Modify the Corrective Action Plan (CAP) Process as it Relates to Procedures for Termination and Nonrenewal of a Part C or D Contract by CMS (§422.506(b)(3), §422.510(c)(1), §423.507(b)(3), &	54646	We support CMS' goal to shift to an outcome-oriented, rather than process-oriented, approach for CAPs. However, in some situations 30 days would not be sufficient time to demonstrate a cure for deficiencies especially if corrective actions will require system changes and testing. We would support the development of a CAP within 30 day, provided that CMS and the organization can come to an agreement on realistic implementation timeframes based on the nature and extent of the

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§423.509(c)(1))		deficiencies requiring correction. We do not support a CMS applying a 30 day CAP timeframe or routine or ad-hoc audits.
9. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§422.756 & §423.756)	54647	Request further clarification regarding the types of immediate sanctions situations that will require the use of an independent auditor. Also recommend that CMS recognize that many organizations have available internal resources and expertise available to validate if deficiencies have been corrected. Recommend it be at the discretion of the MAO to hire an outside auditor, not make it a requirement. We are supportive of the proposed approach of a test period for marketing and/or enrollment activities.
10. Termination of Contracts Under Parts C and D (§422.510(a) & §423.509(a)	54648	We support CMS' authority to take immediate action to terminate a contract if there is the potential for beneficiary harm or if an organization has substantially failed to carry out it contract obligations, however we do not support the inclusion of "failure to meet performance standards" given that CMS in still in the process of developing policies and performance data metrics to be used for program-wide evaluations and assessments and additional guidance is still expected. CMS states an organization could be out of compliance with a Medicare requirement based on their analysis of data related to that sponsoring organization's performance indicating it is an outlier relative to that of other organizations. Under the proposed language, CMS could terminate on the basis of a single instance in which a particular requirement is not met. The proposed grounds for termination and/or imposition of intermediate sanctions are overly broad and allow too much authority and discretion to CMS. We recognize and support the importance of protecting the Medicare program against fraudulent or abusive activities, but have concerns with the proposal to amend the regulation to include false, fraudulent, or abusive activities affecting Medicaid, or other State or Federal health care programs. Our concerns have to do with the potential for a specific vendor of one program being at risk when that vendor is not involved with the other program (e.g., contracted vendor for a carrier's Medicaid program that is found to have some employees committing fraudulent acts when these employees have no involvement with the administration of the carrier's Medicare program). This type of situation should not result in contract termination.
12. Burden of Proof, Standard of Proof, Standards of Review, and conduct of Hearing (§422.660, §423.650, §422.676, & §423.658)	54650	Request that CMS provide a definition for "preponderance of evidence standard". We are supportive of the extending the appeal determination deadline from July 15th to September 1st and request that CMS consider moving back the application filing deadline to late March to allow organizations more time to adequately prepare applications which could reduce the number of appeals.
14. Time and Place of Hearing Under parts C and D (§422.670 & §423.655)	54652	We do not support the 5 day change proposed because this could have a serious impact to travel arrangements scheduled for hearing attendance. The need for a postponement to allow for additional preparation time is something both parties should be able to identify early in the process and should request within 2-3 business days of receiving the hearing notice to ensure all parties are notified timely of a request for postponement.
15. Discovery Under Parts C and D (§422.682 & §423.661)	54652	We do not support the deletion of the formal discovery process; recommend the right for discovery be retained.

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18. Prohibition of MA and Part D Applications for 2 Years After a Mutual Termination (§422.503(b)(6) & §423.504(b)(5)	54653	We do not support the proposal for a 2 year ban. Current market conditions with have necessitated the need for contract terminations and service area reductions. We request CMS allow flexibility on market re-entry based on environmental conditions and appropriate negotiations and approval with the agency.
Section B. Changes to Strengthen Beneficiary Protections	**FR Page #**	**Comments**
General Comment		With the drop in reimbursement this year and over the next few years MAPD organizations budgets are going to become strained. We believe that CMS has an obligation to calculate the implementation costs of proposed regulations and balance these costs against the benefits for the regulation. We believe that these cost benefit analysis should be included in all proposed regulations.
1. Broker and Agent Requirements Under Parts C and D	54654	We do not support the proposal to limit the use of brokers to certain times of the year and to a subset of beneficiaries; as there is clearly no values added with this approach. This would not be an effective approach and will only create additional confusion for beneficiaries. We believe that brokers and agents are critical consultants to beneficiaries throughout the year. Beneficiaries who age into Medicare or in special election periods rely on their established relationships with brokers for one on one consultation, advice and recommendations about the best plan based on the beneficiary's specific needs. This approach will also be very problematic for individuals with limited mobility or who cannot easily travel to receive plan information and education. In 2008, over 8,000 beneficiaries purchased an product from brokers of our plan during the off-cycle (non AEP/OE periods). This represents 23% of total sales during off cycle which highlights beneficiaries need and preference for this option. CMS and the SHIPs should continue to explore methods to effectively educate beneficiaries on the plan options available, however there is concern that the individuals who work for the SHIPs are not licensed agents and the use of SHIPs beyond educational efforts could result in steerage. Recommend CMS review the best practices and oversight processes that organizations have implemented to monitor agent/broker activities, education, complaint tracking, terminations, etc. to develop an oversight module for all organizations to follow for consistency.
2. Beneficiary Communications Materials Under Parts C and D (§422.2260, §422.2262, §423.2260, & §423.2262)	54655	We support the new definition of marketing materials for individual plan communication materials, but recommend it expressly exclude forms of communication from marketing materials and CMS should more explicitly define marketing material and enrollee communications. We recommend CMS apply the operational material definition more broadly to include enrollment/disenrollment, appeals, and other materials for which CMS has provided model documents. Organizations utilizing model documents should be able to attest to this fact, but not have to submit materials via HPMS. Organizations and Sponsors could be expected to make materials readily available for random CMS audits to validate compliance. This recommendation would provide resource and cost savings for CMS, MAOs and Part D Sponsors. Request CMS continue to apply a waiver for employer group materials as well as expanding the employer waiver more broadly with employer enrollment materials. We would be willingly to work closely with the agency to provide issues employers experience w/CMS requirement documents. We also ask at this

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		opportunity for the agency to exclude employer groups from the ANOC/EOC requirements during annual enrollment. We recommend Group members receive their EOC post plan election.
3. Required Use of Standardized Model Materials Under Parts C and D (§422.2262 & §423.2262)	54656	We do not support this proposal; it is very broad and does not define which materials would fall into this category. Organizations need to have flexibility in material development to ensure plan benefits and guidelines are accurately explained to prospective enrollees and existing members. We continue to receive commentary from CMS model documents that lead to member confusion today. Standardized materials are not effective for Dual Eligible SNPs which need to have flexibility to incorporate state specific information into standardized materials such as the Summary of Benefits. Group materials need to continue to be waived from standardization requirements particularly on pre-enrollment because plan sponsors prefer to incorporate the MA plans information in other materials used through-out OE and we receive many requests for customization. There has been inconsistency with the terms used in CMS' model materials and with the checklists plans area expected to complete. The continued release of untimely or multiple versions of model documents continues to severely impacts MAO and PDP plan material development and compliance with CMS designated mailing dates.
4. Involuntary Disenrollment for Failure to Pay Premiums Under Parts C and D (§422.74 & §423.44)	54656	We recommend the 30 day grace period be retained as the minimum, with contractors being permitted to extend timeframe if desired. This would be in order to maintain the current administrative processes and would limit impact on overall plan costs by having to modify policies and procedures and make systems enhancements to support any proposed changes. We currently extend beyond a 30 day grace period, and exclude low income subsidy eligible members from the non-payment termination process.
5.Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services (§422.100)	54657	While we recognize CMS' duty to insure benefit plans are non-discriminatory, it objects to this method of insuring non-discrimination for three main reasons: (1) It creates a discriminatory situation with Original Medicare. Since original Medicare does not have an out-of-pocket Maximum, then by the arguments made by CMS original Medicare would be considered a discriminatory benefit, (2) CMS is not funding this new benefit. Because CMS is proposing to mandate that all plans have an out-pocket-max they are obligated to adjust the underlying FFS prices and (3) Medicare Parts A/B do not have a comparable limit on OOP costs. Imposing this requirement on MA plans creates an incentive for high utilizing members to join MA plans and discriminates against MA plans. The resulting adverse selection would jeopardize the MA program's viability. We generally support this proposal if CMS provides adequate funding to support the benefit enhancement. Specific concerns about potential impacts of the requirement are: (1) Inadequate Funding: Requiring an OOP max as low as $3,400 is a significant enhancement compared to A/B benefits that is not funded as capitations currently paid to MA plans are based on costs incurred to deliver A/B benefits. While certain MA plans have chosen to enhance their plans by implementing an OOP max, this should not be a requirement unless CMS provides adequate funding to all plans. Table C2 of Milliman's Over 65 Health Care Cost Guidelines estimates that a $3,400 OOP max adds approximately $38 pmpm to the 2008 OOP costs for a 65+ population. The added costs in 2010 for the overall Medicare population (including <65) would be ~$50 pmpm.

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		(2) Increase in MA Premium/Loss of MA and Part D coverage: As is noted in the proposed regulations, imposing an OOP Max on all MA plans would result in premium increases in some plans. This could have the unintended consequence of making the monthly premium for MA plans unaffordable to beneficiaries with modest incomes. The Kaiser Family Foundation publication, *Examining Sources of Supplemental Insurance and Prescription Drug Coverage Among Medicare Beneficiaries: Findings from the Medicare Current Beneficiary Survey 2007,* includes a chart showing supplemental coverage by income level. Individuals with incomes between $10,001 and $30,000 had the highest rates of Medicare Advantage. (Income of $10,001 to $20,000, N=9.1 million and 26% have MA including with Part D). (Income of $20,001 to $30,000, N=6.6 million and 24% have MA including with Part D). (3) Creates Non-Level Playing Field vs. Government's A/B Plan: Medicare Parts A/B do not have a comparable limit on OOP costs. Imposing this requirement on MA plans creates an incentive for high utilizing members to join MA plans and discriminates against MA plans. The resulting adverse selection would jeopardize the MA program's viability. Minimum requirements for MA plans should be on a level playing field with A/B benefits. (4) Employer Group Waiver: If implemented, it is essential that CMS provide a waiver for employer group MA plans. Employers frequently try to mirror benefits within the pre and post 65 retiree offerings. Likewise, they also try to mirror overall benefits within their active populations to minimize disruption. Implementing an OOP max would introduce variability that would impair a plan sponsor's ability to maintain consistency. CMS has alternative methods to achieve its duty with respect to benefits. For example they could continue with their review process as outlined in the proposed rule. Implementing an OOP max would introduce variability that would impair a plan sponsor's ability to maintain consistency. (5) SNP Waiver: If implemented, CMS should exempt Dual SNPs from the requirement so that no monthly premium has to be charged related to the OOP Maximum. An unintended consequence of imposing a mandatory OOP Max could be to reduce the number of beneficiaries with Medicare Advantage moving them to having "just" FFS Medicare with no supplemental medical and no Part D coverage. In many markets, beneficiaries can purchase MA-PD plans and obtain Part D coverage at premiums that are less than stand alone PDP. This makes Part D coverage affordable to some beneficiaries who may not qualify for Part D LIS. Recommendation: We supports implementing a Maximum OOP Max as long as CMS funds the enhancement through increases to the capitation rates paid to MA plans (i.e. more than A/B funding should be provided if more than A/B benefits will be required). If CMS does not explicitly fund an OOP Max, then we feel a Maximum OOP Max requirement should not be implemented. If an unfunded Maximum OOP Max is required, it should be at least $7,500 so as to limit the impact on the sustainability of the MA program. Recommend that employer group plans and Dual SNPs be exempt from any OOP max requirement.
6. Maximum Allowable Cost sharing Amount for Medicare Parts A and B Services and Prescription Drugs	54657	We recommend that CMS establish cost sharing thresholds for discriminatory benefits prior to the June bid, for example in the Call Letter. This will prevent having to refile plans with relatively minor adjustments after the June filing. It is time consuming to resubmit bids after the June filing and

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		delays organizations from producing accurate final member and marketing material. The proposal is not clear on whether CMS would set cost sharing thresholds for all Medicare A, B and D benefits or only certain benefits identified as potentially discriminatory. We does not support having CMS set cost sharing thresholds for all Part A and B benefits but rather supports continuing to apply the logic in the BPT which assesses overall actuarial equivalence of each plan compared to FFS Medicare. If CMS sets cost sharing thresholds for discriminatory benefits and potentially additional A, B and Part D benefits, then an OOP Maximum is somewhat redundant. We recognize CMS' duty to insure non-discrimination. However the proposed procedure is not equitable with original Medicare. (1) It creates a discriminatory situation with Original Medicare. To the extent the cost sharing maximums are lower than original Medicare, then by the arguments made by CMS original Medicare would be considered a discriminatory benefit, (2) CMS is not funding this new benefit. Because CMS is proposing to mandate that all plans have an out-pocket-max they are obligated to adjust the underlying FFS prices We recommend this cost sharing guidance not be extended to MA group offering as it would impair a plan sponsor's ability to mirror coverage of benefits between their pre and post 65 offering and their current commercial offerings. Likewise, plan sponsors also try to mirror overall benefits within their active populations to minimize disruption. Implementing an OOP max would introduce variability that would impair a plan sponsor's ability to maintain consistency. CMS has alternative methods to achieve its duty with respect to benefits. For example they could continue with their review process as outlined in the proposed rule. Recommend referring to the Social Security Act, Section 1853 (7) as amended. Set maximum cost sharing amounts at Original Medicare levels with Employer sponsored plans being exempt from the requirement. The proposed rule indicates CMS would review annual Part D bid data to determine acceptable cost sharing tiers for other than defined standard plans, and that this would be based on review of prior year bids. We submit that any such review that excludes consideration of the breadth of formulary would result in an inappropriate maximum cost sharing threshold. The formulary composition is a critical component in developing overall expected plan costs as it takes into account the actual amount of member cost sharing along with the tier structure of the Part D plan design. A plan design that is associated with a robust formulary should be able to support higher member cost sharing, particular for non-preferred drugs, compared to a formulary that meets minimum requirements and, coupled with low premium may be attractive to those with minimal drug utilization who seek protection from potential future changes in health status. Formulary must be taken into account in assessing appropriate maximum cost threshold for the various cost sharing tiers.
7. Prohibition on Prior Notification by PPO, PFFS and MSA Plans Under Part C (§422.2, §422.4, & §422.105(b)	54658	We do not support this proposal, MAO use pre-notification of plan services to help identify those plan members who may qualify for plan disease management and case management programs. For OON PPO and PFFS, this may be the only vehicle to help us to make this identification in a timely manner so that the plan can help address member health needs and have impact on health care outcomes. Providing a lower cost sharing for this type of notification, without requiring notification, has helped us receive this timely notification and has promoted care coordination. Implementation of the provisions

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		suggested will significantly impede an MAO's ability to provide quality of care, one of the real value propositions of the MA Program. This process also helps to ensure that beneficiaries do not utilize costly OON services that do not meet medically necessity or Medicare coverage guidelines. We do not support limiting POS service to only HMO plans. We believe that it is appropriate for MA PPO plans to be able to offer incentives such as lower cost sharing for PCP selection, because this engagement with the member helps us to facilitate timely case management which can result in potential cost savings.
9.Enrollment of Full Subsidy Eligible Individuals and Other subsidy Eligible Individuals Under Part D (§423.34)	54659	We would like to provide additional comments at a later time. To that end, we remain concerned as well with the amount of members who are re-assigned each year. We support additional diminmus capability as well as waiving premium difference above bench mark in order to remain the member. We are concerned with significant changes would impact the integrity of the bidding process. We recommend an industry work group to strategize directly with the agency on this issue.
11. Transition Process Under Part D (§423.120(b)(3)	54660	Proposal is for Part D sponsors to provide for a transition for specified categories; request that CMS define "other coverage" related to the requirement to provide a transition period for 'newly eligible Medicare enrollees from other coverage'. Does this mean that newly eligible Medicare enrollees who don't have 'other coverage' should not qualify for a transition period? Request that CMS clarify that 'newly eligible Medicare enrollee' would not include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (i.e., 65). The proposal to provide a transition period to 'current enrollees remaining in the plan who are affected by formulary changes from one contract year to the next', appears to be eliminating the option to provide existing members the opportunity to request a "formulary exception" in advance of the beginning of the new plan year and implement only a transition fill. We strongly recommend maintaining the current process that allows members impacted by an annual formulary change the option for a formulary exception request to be submitted prior to the start of the subsequent plan year or a transition fill within 90 days of the start of the subsequent plan year. The cost to plans, and ultimately to enrollees, to implement a transition fill as a result of formulary changes from year to year would be expected to be greater than cost to process exception requests in advance of the beginning of a subsequent plan year. We do not support the proposal about making reasonable efforts to notify prescribers that members cannot get a prescription refill due to transition policy. We are not set up to handle this type of process and have concerns due to errors in physician identification at the pharmacy and potential for PHI issues. The existing exceptions process should be utilized if a prescription cannot be filled. Without CMS issuing a physician mandate, it is unlikely that physicians will take any action upon receiving this type of plan notification until they hear from their patient. This proposal would result in additional administrative costs required to make systems enhancements to capture prescriber information, ensure pharmacies collect accurate prescriber information and modify pharmacy contract language to support this undertaking and also to allow for auditing. As the proposal is to require plan sponsor make "reasonable" efforts to perform this notification, there may be disparity in handling amongst Plan Sponsors as to what could be construed as "reasonable".

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12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D(§422.256 & §423.272)	54662	Related to electronic transaction standards & timeliness of payment when coordination between carrier is needed: We recommend that a new NCPDP electronic standard(s) needs to be created (a new type of N transaction(s), so it would allow the Medicare Part D Sponsor to trigger this new type of N transaction to the TrOOP Facilitator whenever a correction has been made to the member's Part D cost share. The information would contain the new copay from the primary Part D carrier (higher or lower than the original due to a correction). TrOOP Facilitator would trigger this N transaction to be sent to the secondary carrier. The secondary carrier can choose to update their claim as needed (does not need to be POS). After the secondary carrier makes a correction, they would trigger a different type of N transaction to be sent to the TrOOP facility which would then send the updated PPA (Patient Paid Amount) back to the Medicare Part D carrier to replace what they had on file.
13. Time Limits for Coordination of Benefits (§423.466)	54664	We recommend a 12-18 month time limit, not supportive of the proposed 3 year time limit; this would fall in line better with PDED reconciliation and decrease the need for dated re-opening periods.
14.Use of Standardized Technology under Part D (§423.120)	54665	We are opposed to the requirement for Part D sponsors to create and exclusively use RxBIN or a RX BIN/PCN combination for part D members as well as to assign an RX identifier to a part D individual. Pharmacies are currently able to identify plan enrollees based on the required Part D coverage indicators that must be contained on member ID cards (i.e., Medicare Program Mark), in addition to real time processing edits and messages received. The real time pharmacy point of sale processing systems currently in place allows pharmacies to process claims according to part D rules. The establishment of Part D specific 4RX data will be a costly operational and systematic undertaking as many of our processes are hard coded, impacting enrollment, on-line processing, member notification (letters), ID card generation etc., and ultimately this recommended proposal will not change the point of sale processing. This type of change would require Part D sponsors to make major system enhancements to their current systems, therefore the industry would need CMS to begin issuing specific technical guidance in early Spring 2010 to allow sponsors adequate lead time to begin planning, secure IT funding and develop the required system enhancements. If this requirement becomes final, plans should not be expected to implement until January 1, 2012. Additionally, it is strongly recommended that this type of system change only occur for a January 1 effective date so that it is alignment with the renewal for the bulk of the membership. We request clarification to the reference to "individual" Part D beneficiaries. Is this a reference to members of individual (vs. group) plans, or a reference to any person who might have Part D?
15. Absence from Service Area for More Than 12 Months under Part D (§423.44)	54666	We oppose extending the temporary absence from PDP plan service area to 12 months. Instead we suggest either continuing the current policy or institute a similar policy as for MA organizations and allow the Part D organization to have the option to offer "visitor" program for currently enrolled individuals who are consecutively out of the area for up to 12 months, provided that plan has same range of benefits as available to other members. To help contain costs, Part D organizations may vary Part D plans significantly by region, including varying the formulary, premium and cost share design. In particular, a member from one service area may have different coverage of drugs than in another service area; therefore, the benefits for the out of area member would not be the same as what is available to other members enrolled in the area. The extension to 12 months places additional risk to the PD organization for members that enroll in lower cost plan and but then reside in another higher cost area for up to a year.

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17. Nonrenewal Beneficiary Notification Requirement under Parts C and D (§422.506 & §423.507)	54667	We support proposal to change to 90 day non-renewal notification and eliminate the requirement for public notice. We continue to stress the importance of timely receipt of CMS' model non-renewal notice that is required as part of this process.
18. Notice of Alternative Medicare Plans Available to Replace Nonrenewing Plans Under Parts C and D (§422.506(a)(2)(ii) & §423.507(a)(2)(ii))	54668	We recommendation that organizations not be required to include alternative plan information in the non-renewal letter, rather the letter should contain language that directs impacted members to Medicare.gov Plan Finder for the most current plan information available in their service area. Plans should have the option to contact impacted members by phone, but it should not be a requirement.
23. Disclosure Requirements Under Parts C and D (§422.111(g) & §423.128(f))	54669	The disclosure requirement whereby CMS may require plans to disclose to enrollees or potential enrollees' compliance deficiencies is a burdensome requirement that should be eliminated. It is felt that this would cause unnecessary alarm for the existing beneficiaries, who will likely bombard CMS and the plan with calls and disenrollment requests that potentially could not be honored due to enrollment regulations. It is expected that plans will be focusing resources on correcting the deficiency and should not then refocus those resources to deal with the unnecessary panic caused by the notification to enrollees not understanding the compliance innuendos of a federally mandated provision. Additionally, we do not believe a satisfied enrollee is served by being provided this kind of notification, even if it would occur during and OEP or AEP, but rather only adds to the churn that CMS has worked diligently to avoid over the last several years.
Section C. Changes to Provide Plan Offerings with Meaningful Differences	**FR Page #**	**Comments**
Changes to Provide Plan Offerings with Meaningful Differences	54670	Related to the proposal to revise the nonrenewal regulations to expressly provide as grounds for nonrenewal that the plan has failed to attract more than a small number of enrollees over a sustained period of time: We request that these factors be well-defined so that we can ensure we understand what a "small number of enrollees over a sustained period of time" might consist of. This would assist in better managing our product development efforts in considering new service areas or plan revisions.
1.Bid Submissions—Ensuring Significant Differences (§422.254 & §423.265)	54671	We supports a requirement for meaningful differentiation between bids provided that CMS implements clear, concise guidance around what constitutes a meaningful difference and that CMS enforces these requirements consistently across all sponsors and service areas. We believe each organization should be allowed to offer a variety of plans that allow beneficiaries to balance provider access, premiums, and cost sharing levels with their individual needs. As such, we feel that HMO and Local PPO plans should be viewed as meaningfully different due to the coverage of OON services under Local PPO plans. MA-Only and MA-PD plans should also be viewed as meaningfully different. As noted we are supportive of this change, if CMS will provide sufficiently clear guidance regarding meaningful differences between bids since this could simplify an organization's offerings and enable beneficiaries to make better plan choice decisions. Related to ensuring significant differences in plan characteristics within a service area: This requirement would seem to offset the need to continue imposing an absolute limit on the number of plans offered (e.g., limit of 3 individual PDP standalone plans per CMS region). If meaningful differential in benefit offering is the guiding force, then that parameter on its own should be sufficient, rather than imposing an arbitrary limit on the number of plans. Requirements on variations in benefit

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		design in itself will control the number of plans offered. Related to the proposed requirement that plans be dropped that do not offer meaningful choices for beneficiaries: We request clear definition of "meaningful" difference be provided far enough in advance of the bid submission due date in order to assist in planning and to avoid submitting bids that would not be approved. We would like to ensure that this be evaluated in a consistent manner amongst all Plan Sponsors in order to maintain a level playing field, so that specified criteria are provided. It would be helpful to understand any steps that CMS might be taking to make the assessment of 'meaningful' differences so they can be built into our own processes in developing plan/product design.
2. Bid Review Process (§422.256 & §423.272)	54672	We will support this change if CMS clearly defines the meaning of "substantially different" before bids are due and the review process should be a collaborative effort between CMS and the sponsors in order to avoid unforeseen complications. Bid assumptions and calculations often consider all the plans offered in a given service area, so it is important that sponsors have the opportunity to revisit their assumptions if CMS does not accept all bids submitted by the organization. We recommend CMS provide explicit guidance on what will determine whether two bids are substantially different as part of the annual Call Letter. In the event CMS feels two bids are not substantially different, they should negotiate with the sponsor to come to a mutually acceptable resolution.
3. Transition in cases of Acquisitions and Mergers (§422.256 & §423.272)	54672	We are not opposed to this proposal but do recommend that CMS allow and consider for special exceptions to be requested.
4. Non-renewing Low-Enrollment Plans (§422.506(b)(1)(iv) & §423.507(b)(1)(iii))	54673	We recommend a defined member threshold that averages more to a 250-500 enrollment versus a 100 member threshold. To that end, we recommend special considerations as new market entry are taken into consideration and appropriately negotiated with the agency.
Section D. Changes to Improve Payment Rules and Processes	**FR Page #**	**Comments**
1. Proposed Risk Adjustment Data Validation Appeals Procedures (§§ 422.2 and 422.311)		**Please refer to our detailed RADV Appeals comments contained at the end of this comment chart.**
4. Calculation of Minimum Percentage Increase Under Part C	54679	CMS' interpretation of Section 1852(k) (1)(B); clearly says "Applicable Amount Defined: if such year is not specified under subsection (c)(1)(D)(ii), an amount equal to the amount determined under this paragraph for the area for the previous year (determined without regard to paragraphs (2) and (4)[344]), increased by the national per capita MA growth percentage, described in subsection (c)(6) for that succeeding year, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004" Subparagraph (C) contains the minimum 2% increase requirements. However 1852(k)(1)(B) only removes the minimum increase for years prior to 2004, we would like to understand the basis for CMS' interpretation. We recommend keeping the 2% minimum requirement and recalcaute any retroactive payment from prior year.
Section E. Changes to Improve Data Collection for Oversight and Quality Assessment	**FR Page #**	**Comments**

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1.Requirements for Quality Improvement Programs Under Part C (§422.152, §422.153, & §480.140)	54680	We support Chronic Care Improvement projects but do not support any CCIP/QIP project mandate from CMS as this will be a resource drain. MAOs need to have the ability and flexibility to plan ahead and select programs that will be the most effective for their membership, rather than a "one size fits all approach". MAOs have experience in this area and with deeming and accreditation in place; there is not a need for CMS to have to select the project. It will also be problematic for MAOs to have to shift projects every year based on CMS' annual selections. Additionally, Dual SNPs may already be required to conduct required state QI projects. We also have concerns about the timeliness of the analysis of the QIO data that CMS is proposing to use and if there will be additional burden placed on deemed plans that don't submit to the QIOs so that some sort of data could be all inclusive from the QIOs. We have the following questions that were not addressed in the proposal: 1) Will plans that have passed an NCQA Medicare Deeming review be required to conduct the CMS defined CCIP? 2) Will NCQA Medicare Deeming standards, related to CCIP, also be updated to require a plan to conduct the CMS defined CCIP versus a plan selected topic? 3) Will NCQA Medicare Deeming standards, related to CCIP, also be updated to require a plan to conduct the CMS defined CCIP versus a plan selected topic?
3. Validation of Part C and Part D Reporting Requirements (§422.516 & §423.514)	54682	We do not support placing provisions regarding the reporting requirement validation in regulation at this early stage in its development. There is concern that the validation mechanisms are very preliminary and should be vetted through the sub regulatory process. It is concerning that the validation approach being stipulated in regulation that is placing the full cost burden on the health plan, could be found to not meet CMS's needs related to data consistency/validity and the approach could change. It would be concerning to see this item be stipulated in regulation and these costs continue to be bore by plans, if the approach needs to evolve. Additionally, we have commented strongly that the level of reviews, the tools shared with plans, and the approach continues to require additional levels of revisions and clarity. These items have been shared with the administration through several avenues and commenting opportunities. Recommend CMS provide the audit requirements in sub regulatory guidance that is issued with adequate lead time to allow MAOs time for appropriate planning and funding that will need to be secured.
4. Collection of Additional Part D Claims' Elements for Nonpayment- Related Purposes	54683	We request clarification on this proposal. Is this a reference to fields that have already been added to the PDED layout or is this a request for additional data to be sent?
Section F. Changes to Implement New Policy	**FR Page #**	**Comments**
1. Protected Classes of Concern Under Part D (§423.120(b)(2)(v)	54685	Related to the clarification that MIPPA protections do not apply to non-Part D drugs: We appreciate the analysis and consideration that went into the definitions for application of the MIPPA requirements for the classes of clinical concern and support the language as stated in the section. We request that CMS will consider the impact on pricing and potential lost rebate opportunities which can result in lower costs to members when adding classes to those of clinical concern. Related to the clarification on exceptions to the inclusion of drugs meeting the criteria under section 176 of MIPPA: We do have concerns about the potential restrictions on utilization management for

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		the current classes and future classes of clinical concern. There are guidelines for therapy and treatment protocols for many of these drugs. Currently CMS has put restrictions on the ability to manage to these guidelines in the six protected classes and this has created inconsistencies as to when guidelines are applied and inconsistencies around "all or substantially all". We have concerns that if rules are not applied consistently or if appropriate utilization management cannot be allowed to apply across the board (such as with some HIV drugs), then expansion of this will create inequalities in the benefits. Proposal of determining which drug classes meet MIPPA criteria through "data driven" process, including analysis of certain reference materials (such as Part D compendia): This seems inconsistent w/ CMS guidance on how we can develop clinical criteria for use in coverage determination decisions. We recommend that the same resources be used for making the decisions for which drug classes meet the definition as those that Plan Sponsors must use for management of the formulary. Related to the options of announcing protected classes: We appreciate the fact that government physicians and pharmacists provide a more efficient and cost effective process for review. We recommend that input from the field may still needed in order to assess fully the actual impact of the decisions that are being considered. In addition, Option 1 using the Call Letter will result in a delay in timing of formulary development. We would support Option 2.
Section G. Changes to Clarify Various Program Participation Requirements	**FR Page #**	**Comments**
4. Visitor/Traveler Benefit Under Part C for the Purpose of Extending enrollment Up to 12 Months (§422.74)	54691	We support providing Medicare covered services under the visitor/travel program, but are opposed to having to include optional supplemental benefits. This change would require organizations to have to adjust plan premiums and could ultimately impact an organizations decision to offer optional supplemental benefits such as dental coverage, if a plan is not able to develop and meet network access requirements in all MA service areas.
5. Medication Therapy Management Programs Under Part D (§423.153(d)	54692	Related to the proposed requirement that MTMPs include interventions for both beneficiaries and prescribers: We recommend that Part D Sponsors have the flexibility to determine if an MTMP intervention should be for member, prescriber or both. The CMR should continue "to be offered" not "required to include" an interactive, person-to-person consultation. This requirement may also be more of a hardship for member/caregiver, even if they want to participate. In addition, there is the possibility that there will be a lack of success in reaching the member/caregiver during the outreach phase.
9. Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§423.568)	54695	Proposal states that there would be 14 days to make the determination with payment no later than 14 days of the receipt of the request. In the event that the determination is made after the 9th day, it would be very challenging to send a check and meet the 14 day timeframe. We recommend making modifications to the proposal as follows: "Make a coverage determination on a request for payment and notify the enrollee of its determination no later than 14 calendar days after receipt of a request for reimbursement, and (2) for favorable coverage determinations, make payment no later than 30 calendar days after receipt of the reimbursement request."

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12. Clarify Novation Agreements Under Part D (§423.551)		In general we support this change to match Medicare Advantage. We do recommend CMS allow special circumstances that may necessitate the need for novations of the Medicare PDP line of business.
Section H. Changes to Implement Corrections and Other Technical Changes	**FR Page #**	**Comments**
3. Revision to Definition of Gross Covered Prescription Drug Costs (§423.308)	54700	Related to proposal to change definition of gross covered prescription drug costs at an OON pharmacy: We recommend expanding the definition of gross covered prescription drug costs to reference covered Part D vaccines and their associated vaccine administration fees that can be obtained from non-pharmacy, out-of-network providers such as physicians and clinics. And while the "U&C" price is defined per § 423.124(a) as that which is charged by a pharmacy/provider to patients without insurance coverage, it is more appropriate to pay a vaccine administration fee subject to a scheduled amount, similar to how this would be handled for Part B vaccine administration fees. We believe that additional flexibility is needed in the definition of gross covered prescription drug costs to account for a scheduled vaccine administration fee rather than an implication of it being subject to U&C to guard against permitting coverage for an excessive amount charged by a provider under a percent copay cost sharing tier.

Comments on Proposed Risk Adjustment Data Validation Appeals Procedures

(§§ 422.2 and 422.311)

We welcome the opportunity to submit comments on the proposed rules governing administrative appeals for Risk Adjustment Data Validation ("RADV") audits that appeared in the October 22, 2009 Federal Register.[1] While we share CMS's recognition of the need for a dispute and appeal process for audit, it is concerned that the proposed rules are too narrow and do not provide for meaningful appeals beyond correcting clerical errors. Moreover, the proposed appeals procedures will effectively implement substantive requirements, such as the "One Best Medical Record" rule, that are contrary to Title XVIII of the Social Security Act (the "Medicare Act"), unsupported by the administrative record, and inconsistent with CMS's contractual obligations. These subsumed

[1] 74 Fed. Reg. 54634, II.D.1., at pp. 54673-678, 54716, 54719-720(October 22, 2009).

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rules and limits on appeals may result in RADV audits that distort, not facilitate, the accuracy of payments to Medicare Advantage ("MA") organizations.

The proposed appeals rules raise four major concerns. Specifically, the proposed rule: (1) creates a contract-level rate adjustment process for MA organizations that is contrary to the statutory mandate that their rates be comparable to fee-for-service rates and is actuarially unsound; (2) imposes requirements regarding acceptable documentation for data validation and provider recordkeeping rules under the "One Best Medical Record" rule without proper rulemaking or an administrative record supporting such rules; (3) provides no substantive appeal rights and allows only for the correction of clerical errors; and (4) conflicts with current MA contracts.

As explained more fully below, these issues can best be addressed by withdrawing the proposed rules and instituting new rulemaking to determine the appropriate documentation needed to verify the health status of members, the statistical analyses to be used, and a full and fair appeals process for RADV audits.

1. Proposed Appeals Rules Need to be Consistent with the Medicare Act

We are concerned that the underlying premise of CMS's proposed appeals rules is inconsistent with the Medicare Act. MA payments are based upon the Medicare payments made to the fee-for-service ("FFS") providers under Medicare Part A and B. The payments for the average FFS Medicare beneficiary provide the baseline for determining payments to MA organizations. The Medicare members of a MA organization may incur higher or lower medical costs than the average FFS beneficiary depending on the

members' health status.[2] As a result, the Medicare Act requires that the payments to the MA organizations be adjusted for the healthcare status of its members, "that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs."[3]

To identify the healthcare status of Medicare beneficiaries, CMS developed a hierarchical condition category ("HCC" or "risk score") based on "such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate ...."[4] HCCs reflect diagnosis codes that are clinically related and have similar cost implications.[5] The HCCs are based on ICD–9–CM guidelines. The ICD-9 is a complex system that identifies thousands of diagnoses.

There may not be a single ICD-9 that covers a specific chronic condition. There may be a combination ICD-9 code that identifies the full diagnosis, while other times multiple ICD–9 diagnosis codes will be needed. For example, an individual with diabetes will have a diagnosis of diabetes, but may also have other chronic conditions such as neurological or ophthalmic manifestations that also must be coded. The combinations of the ICD–9 codes are used to create the HCCs and reflect the cost of treatment for the diagnoses. All diagnosis will not necessarily be identified by the treating physician if a diagnosis will not impact the treatment to be provided.

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2 *Id.* at 54673.

3 *Id.*

4 *Id.; see also* 42 C.F.R. § 42.308(c)(1).

5 74 Fed. Reg. at 54674.

The adjustments to MA payments based on HCCs also have "to ensure actuarial equivalence" to the FFS payments.[6] The Medicare Act mandates that the payments be adjusted to:

> ensure that such adjustment reflects changes in treatment encoding practices in the fee-for-service sector and reflects differences in the coding patterns between Medicare advantage plans and providers under Part A and B to the extent that the Secretary identifies such differences."[7]

To ensure the "actuarial equivalence" that is mandated by the Medicare Act, each "MA enrollee's HCCs are assigned based on risk adjustment diagnoses from FFS claims and ... an enrollee's risk score ... is used to adjust a base payment rate" to the MA organization.[8] As CMS has recognized:

> Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustment to be valid. This means that MA organizations are coding "accurately" when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.[9]

6 42 U.S.C. § 1395w-23(a)(1)(C)(i).

7 *Id.* at §1395w-23(a)(1)(C)(ii)(I).

8 *Id.*

9 CY 2010 Rate Notice, April 6, 2009, at 20

Concomitantly, payments are accurate when the HCCs for MA organizations are adjusted to be comparable to the HCCs for the FFS sector. Thus, if an MA organization's Medicare members have lower HCC scores than the baseline FFS member, the MA organization is paid less, and if its Medicare members have higher HCC scores, the payment is higher.[10]

CMS's proposed administrative appeals regulations are inconsistent with the statute. Through the proposed RADV audit appeal process, CMS will impose a set of rules regarding physician record keeping that was not anticipated in the ICD-9 coding guidelines, not consistent with standard practices and not enforced on FFS claims. The result will be MA payment adjustments based on recordkeeping discrepancies without an adjustment to FFS risk scores for the same recordkeeping discrepancies.

Auditing only the MA organizations may determine how accurate MA organizations code, but without determining how MA risk scores compare to FFS coding, the audit will lack the appropriate baseline to determine if any payment adjustments should be made for the MA organizations. Even if the audits resulted in 100% accurate coding for the MA organizations, they still may be over- or underpaid. For example, if the FFS sector under-codes Medicare beneficiaries by 10%, then MA organizations that code 100% accurately would be overpaid by 10%. The converse would also be true, that is, if FFS providers over-code by 10% and an MA organization is coding 100% accurately, the MA organization would be underpaid by 10%.

Congress recognized that using the FFS payments as a baseline would hinge on the equivalency of the two sectors, and therefore provided that "[i]n order to ensure payment accuracy, the secretary shall conduct an analysis of the differences" between MA

[10] 74 Fed. Reg. at 54674.

organizations and FFS coding practices."[11] Congress understood that the MA payments are based upon the actual dollars paid to the FFS sector. Absent such an analysis, no meaningful adjustment to MA payments based on an audit of their HCCs can be undertaken. To require 100% accurate HCCs for the MA organizations when it is not required for the FFS sector will result in inaccurate payment adjustments. Yet the audit and appeals process proposed by CMS does not allow for any evaluation of or proper comparison with the FFS sector. The proposed appeals regulations fail to consider the other half of the equation–the risk coding accuracy of the FFS payments. Moreover, appeals under Medicare Part A and Part B, and PRRB determinations, allow the submission of additional evidence and testimony.

To justify auditing only MA organizations, CMS assert that "there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment."[12] Yet, MA organizations do not control the medical documentation. Rather, they rely on physicians and practitioners who may have no stake in payments to MA organizations and therefore have no "incentive ... [to] over-report diagnoses ...."[13] Even assuming this contention to be true, by failing to assess any "over-report[ing]" by the FFS sector, the MA payments must still be actuarially equivalent to the FFS payments. That cannot be achieved without also auditing the FFS sectors' compliance with the recordkeeping rules.[14] Moreover, there is no evidence that physicians providing

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11 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(II).

12 74 Fed. Reg. at 54674.

13 *Id.*

14 The Department of Health and Human Services has recognized in a recent report required by the Improper Payments Information Act that FFS providers do not consistently code diagnoses. "*Medicare Claim Review Programs: MR, NCCI Edits, MUEs, CERT, and RAC*," Centers for Medicare and Medicaid

services to MA organizations' members document diagnoses differently for their FFS patients. If providers document the diagnoses for all their patients the same, then there is no over-reporting for MA organizations' members as compared to FFS patients.

In addition, the sampling methodology used by CMS may be inconsistent with the Medicare Act. Although CMS has yet to announce its sampling or extrapolation methodologies, the sampling methodology it used in the 2007 pilot audits undercuts the Medicare Act's mandate that the MA organization rates reflect the actual expectations of losses and benefits to be paid by each organization.[15] In its 2007 pilot RADV audit, we understand that CMS sampled only enrollees with certain HCCs. Random errors in assigning HCCs, however, are likely to result in both overstating and understating the risk factors. By excluding from the sample all the Medicare members to whom MA organizations did not assign a high risk factor, the audit will overlook any errors resulting in the understatement of enrollees' health status.

Moreover, the proposed rule expressly prohibits MA organizations from introducing "new" HCCs in the course of the audit and appeal process if the HCCs were not previously assigned to enrollees.[16] Since random errors can result in either under- or over-coding, a fair audit would allow for correction of all coding errors. By precluding assigning a new HCC based on the medical records, CMS's audit will not determine whether correct HCCs were assigned to Medicare members. Rather, the audits will eliminate HCCs that are not supported by the One Best Medical Record, but not allow new HCCs that are supported by the

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Services, ICN # 006973 (Oct. 2008) The Department indicated that it plans to work with FFS practitioners to improve medical record documentation practices. *Id.* Yet, MA organizations will be required to comply with the recordkeeping rules when the FFS providers will not be held to the same standard.

15 42 U.S.C. § §1395w-23(a)(1)(C).

16 74 Fed. Reg. at 54676.

medical records. This will not lead to accurate coding, but under-coding. As a result, the appeals process is inconsistent with the statutory mandate that the MA rates accurately reflect expected losses and benefits paid and be comparable to the FFS payments. In addition to being inconsistent with the Medicare Act, an audit that only allows a downward adjustment is "unconscionable"[17] and will not achieve the "actuarial equivalence" mandated by the Medicare Act.[18]

II. The Administrative Appeals Rules Regarding the "One Best Medical Record" Create New Substantive Regulations

The proposed administrative appeals process incorporates certain underlying requirements that have not been subject to proper rulemaking. Specifically, MA organizations will be limited to submitting One Best Medical Record to validate the HCCs of the beneficiaries in the RADV audit sample. Incorporated within the One Best Medical Record rule are requirements on how physicians and providers must keep records, code conditions, and care for their patients. These rules have yet to be subject to rulemaking and, therefore, there is no administrative record that supports these requirements or provides the courts with a meaningful record to review the requirement. Indeed, in an appropriate rule-making process, we would be able to provide record evidence that the One Best

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17 *C.f. GloPak Corp v. United States*, 851 F.2d 334, 338 (Fed. Cir. 1998) (a market price adjustment clause must be a "a two-way, not one-way street," allowing for both "an increase in the contract price,"); *also see., United States v. Delta Dental Plan*, 943 F. Supp. 172, 190 (D. R.I. 1996); *accord* Consent to Judgment at *United States v. Delta Dental Plan*, 1997 U.S. Dist. LEXIS 11239 at *3 (D. R.I. July 27, 1997); *United States by and through Woods v. Delta Dental Plan,* 1995 U.S. Dist LEXIS 9752 at *3-4 (D. AZ May 19, 1995).

18 It is worth noting that CMS's proposed extrapolation of the RADV is inconsistent with the intent of the Medicare Act. Medicare contractors are allowed to extrapolation "to determine overpayment amounts" only in extraordinary circumstances where " there is a sustained or high level of payment error; or ... documented educational intervention has failed to correct the payment error. 42 U.S.C. § 1395ddd(f)(3).

Medical Record rule would improperly exclude hundreds of valid HCCs from its 2007 RADV pilot audit. The Administrative Procedures Act ("APA") mandates nothing less than such a formal rule-making process.

CMS applied the One Best Medical Record rule for the first time in its 2007 pilot RADV audits,[19] This rule significantly limits the documentation an MA organization can use to support the HCCs assigned its members and is not consistent with current physician recordkeeping and patient care practices. To verify an HCC of a Medicare member, CMS will only accept one medical record.[20] According to the audit criteria specified by CMS, the one medical record has to include a diagnosis supporting the HCC(s) of the member that was recorded at the time the physician or practitioner personally saw the member, for a date of service within the audit data collection period, that includes the physician or practitioner's credentials, and that is signed by the physician or practitioner.[21] A record that does not meet these requirements will not be considered as supporting an HCC for a MA organization's member. The sole accommodation in its proposed rulemaking is that an MA plan may submit an attestation from the physician in case the One Best Medical Record failed to include the physician's signature or credentials.[22]

This documentation restriction is a substantial departure from the prior practice. In previous audits, MA plans were allowed to submit new and clarifying documentation. The HCC for a given member could be verified by multiple documents prepared by various physicians, all of which added up to and supported the HCC.

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19 2006 Revised Risk Adjustment Data Training for Medicare Advantage Organizations Participation Guide at § 8.2.3.1.

20 74 Fed. Reg. at 54716

21 *Id.*

22 *Id.* at 54675.

1. The One Best Medical Record Rule

Notwithstanding that CMS has yet to announce the results of the RADV 2007 pilot audits, it has proposed appeal regulations that essentially incorporate the requirements of the pilot audits, including the One Best Medical record rule, as if they were already adopted as a regulation. Before CMS can impose its One Best Medical Record rule, it needs to follow the basic rulemaking requirements in the APA.[23] The Medicare Act specifically mandates that:

> No rule, requirement, or other statement of policy, (national coverage determination) that establishes or changes a substantive legal standard governing the...payment for services...under this title shall take effect unless it is promulgated by the Secretary by regulation ...."[24]

The One Best Medical Record rule will subject MA organizations to potentially significant payment adjustments.[25] The result will be payment adjustments that do not primarily correct for MA organizations' mistakes in coding HCCs, but for a MA organization's providers' recordkeeping and patient care practices that do not comply with CMS's One Best Medical Record rule.

Rather than implementing the One Best Medical Record rule through the proposed administrative appeals process, we suggest that CMS provide notice in the Federal Register of the One Best Medical Record requirement, allow interested parties to submit comments, publish a final rule with the statement of the basis of purpose, and grant the right to petition to modify or repeal the rule.[26]

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23 5 U.S.C. § 553(b)(e).

24 42 U.S.C. § 1395(hh)(a)(ii).

25 74 Fed. Reg. at 54674 (Applying contract level adjustments based on the RADV audits "would result in substantially larger payment error than the previous enrollee-level audits)

26 5 U.S.C. § 553(b)-(e).

The purpose of the rulemaking is to allow an agency to obtain and consider all the potential information and data necessary to make a determination as to the propriety of any rule or regulation. The absence of such underlying information and data invalidates the rule.[27]

The importance of providing an opportunity for review and comments was recently recognized by the Office of Management and Budgeting ("OMB"). In its "Final Bulletin for Agency Good Governance Practices" Report, OMB stated that it "has been particularly concerned that agency guidance practices should be more transparent, consistent and accountable."[28] OMB acknowledged that any changes in procedures should include "public participation, including notice-and-comment under the [APA]...justification for the rule, including a statement of basis and purpose under the APA" and "judicial review."[29] The report recognized that rules "which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they are initially labeled."[30]

The proposed administrative rule exemplifies why there is a need to submit the One Best Medical Record requirement to appropriate rulemaking. CMS asserts that allowing additional documents is "unlikely to result in any meaningful change in RADV audit results."[31] Yet, CMS in its proposed rule on administrative appeals never provides any of the data or cites to any studies or tests that support this contention.

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27 *Tripoli Rocketry Ass'n v. BATFC*, 437 F.3d 75, (DC Cir. 2006); *Saint James Hosp. Heckler*, 760 F.2d 1460 (7th Cir.) *cert denied*, 474 U.S. 902 (1985).

28 OMB Final Bulletin at 2.

29 *Id.* at 3, 13-16, 22.

30 *Id.* at 3 (*citing Appalachia Power Company v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (striking down admission to monitoring standards as legislative rules requiring notice-and-comment).

31 74 Fed. Reg. at 54677.

In fact, the proposal ignores the available information and data, all of which undercut the One Best Medical Record rule. In 2005, CMS acknowledged that it "allowed MA organizations to submit new medical record documentation and clarifying documentation" if MA organizations disputed the audit findings, and CMS would then provide a "revised payment error estimate" if the HCCs were supported by the additional documents.[32] These additional documents in fact verify the HCCs assigned to the MA organization's Medicare members. In addition, when responding to the RADV 2007 pilot audit, we submitted additional documentation beyond the One Best Medical Record. These documents demonstrated the validity of hundreds of the HCCs that CMS had challenged; yet, under the One Best Medical Record rule, they would not be considered by CMS.

The simple facts are that alternative sources of information are available to prove that a member has the condition diagnosed. HCCs identify chronic healthcare conditions that generally are not curable, such as diabetes, congenital heart decease, paralysis and genetic disorders. These chronic conditions are always present, but will not necessarily be diagnosed or even noted on every medical record. Yet, CMS's proposed appeals process precludes submission of anything but a single medical record, even when the balance of the medical record would validate the HCC coding.

The One Best Medical Record Rule is inconsistent with the real-world medical keeping practices of providers. In fact, multiple records are often needed to verify the accuracy of the HCCs of Medicare members. There may not be a single medical record that verifies every HCC. For example, the records of several specialists may be needed to validate the HCC, such as a diagnosis of diabetes with heart complications. Similarly, pharmacy records and prescription drug data can verify many conditions such as

[32] *Id.* at 54674

diabetes, high blood pressure and other chronic conditions. In addition, hospital records may shed light on the Member's condition whenever the medical record itself is not sufficiently clear.

In addition, Medicare beneficiaries with a valid HCC may not need to see a physician during the audit period, while others may only see a physician during the audit period for something not specifically related to the HCC diagnosis. The purpose of medical recordkeeping is to document the patient's condition and treatment as necessary for clinical purposes. Under standard record-keeping practices, there is no requirement that a patient's underlying diagnosis be "re-documented" in every record every year. In fact, in the case of chronic conditions, the diagnosis will often not be noted each and every year following the initial diagnosis. Whether such chronic conditions are recorded depends on the care sought and the treatment rendered during the period in question. The lack of re-documentation of the underlying medical condition does not mean that the condition has "gone away," nor does it affect the kind and level of care the doctor provides.

For example, after an initial diagnosis of diabetes, a provider might or might not have reason to re-document the patient's diabetes in a subsequent year for clinical purposes. In such circumstances, a MA organization would not be able to produce a record from the year being audited that included the diabetes diagnosis. Although diabetes is a chronic condition that does not go away, CMS would conclude that the associated HCC was "invalid" solely because the plan could not produce documentation of the diabetes diagnosis during the audit year. Under the One Best Medical Record Rule, the MA organization would be prohibited from submitting a record from the prior year with the diabetes diagnosis to substantiate the HCC, or a sworn statement from the physician stating that the

patient still had diabetes during the audit year. This makes no sense inasmuch as the stated purpose of the audit is to determine whether the individual actually had the condition identified by the HCC.[33]

The One Best Medical Record rule is also inconsistent with the mandate that MA payment adjustments be actuarially equivalent to the FFS sector. There is no One Best Medical Record rule for FFS providers. To the contrary, a Medicare Part B physician can fill in gaps in their own documentation by offering testimony to explain a beneficiary's condition when appealing a payment determination. MA organizations should also have the ability to supplement medical record documentation. The need for such additional documentation is even more compelling for MA organizations where the audit results may be extrapolated.

If rulemaking had been undertaken for the One Best Medical Record rule, a complete record could have been submitted to determine whether additional documentation or data would have a significant impact on audit results. This is significant because the purpose of the audit is to ensure that MA organizations are properly paid. An MA organization is properly paid if its members' HCCs are correctly validated and then compared to the FFS sector's validated HCC coding baseline. CMS's limitations on corrective documentation unfairly eliminate from consideration medical information that could verify the HCCs for members. As a result, CMS's One Best Medical Record rule fails to ensure the integrity and accuracy of the HCCs and could render the audits inaccurate.[34] In

[33] Moreover, given that the stated purpose of the validation audits is to ensure proper HCCs were coded, CMS should look to the "best data available" to see if the HCC is supported before invalidating any HCC. *C.f., Baystate Medical Center v Leavitt* No. 06-1263 (JDB) (D.D.C. Dec. 8, 2008). This should include data and records CMS maintains. For example, every time a Medicare beneficiary receives inpatient hospital treatment, a bill is generated and sent to CMS even if the hospital is not seeking payment. These bills will include diagnoses that CMS can use to verify these beneficiaries' HCCs.

[34] *Tripoli Rocketry Ass'n v. BATFC*, 437 F.3d 75, (DC Cir. 2006); *Saint James Hosp. Heckler*, 760 F.2d 1460 (7th Cir.) *cert denied*, 474 U.S. 902 (1985).

essence, the One Best Medical Record tests a recordkeeping system rather than verifying that the proper HCCs are assigned to MA organizations' members.

2. The Record Keeping and Coding Rules

Similarly, CMS should undertake appropriate rulemaking to consider the recordkeeping and coding requirements incorporated in the One Best Medical Record rule. These rules are the very bases by which CMS determines whether a health condition exists and whether the one record submitted by MA organizations validates the HCC coding. Given the potential impact, rulemaking under the APA is required.[35]

Through the proposed appeals process, CMS requires physicians and providers to prepare a single medical document when he or she saw the patient that includes the all diagnoses, and contains the physician's or practitioner's signature and credentials. Providers will be required to reproduce diagnosis information for chronic conditions every time they see a beneficiary even if the condition had been documented elsewhere in the member's medical records and there is no need to do so from a patient care perspective. This is different from the current practice and mistakes documenting HCCs are to be anticipated. Yet, physician diagnosis coding will determine the amount a MA organization is paid. CMS never solicited comments from the physicians and practitioners as to whether the recordkeeping requirements are consistent with standard medical recordkeeping practices. CMS never tested whether these requirements are reasonable or will impose undue and unnecessary burdens.

[35] 42 U.S.C. § 1395(hh)(a)(ii).

Moreover, the proposed appeals rules subsume the ICD–9–CM guidelines and impose record keeping practices that physicians and practitioners must use. Although these coding guidelines are complicated, CMS seeks to implement them without determining whether the guidelines are reasonable, will impose undue and unnecessary burdens, or are likely to generate coding mistakes. CMS nonetheless precludes a MA organization from correcting the submission or providing supplemental documents to verify the code on appeal. To impose such recordkeeping and coding requirements will create discrepancies based solely on the recordkeeping rules, not on whether the member had the condition identified in his or her HCC. The result will be less accurate payments in contradiction to the stated purpose in the Medicare Act.

Since the Medicare Act mandates that the MA payments be the "actuarial equivalence" of the FFS payments, the coding and document requirements must be equally applied.[36] It is therefore essential for CMS to create rules for all providers, and not just implement these requirements through the appeals process for RADV audits of MA organizations. Given the fact that the MA payments are based on FFS payments adjusted for how the risk scores of Medicare beneficiaries enrolled in MA organizations to Medicare beneficiaries serviced by the FFS sector, this comparison is valid only if the same coding and recordkeeping rules apply to both MA organizations FFS providers. CMS, however, has never tested whether FFS providers comply with these coding and recordkeeping requirements.

Moreover, MA organizations must rely on providers, who may have no stake in payment, to generate the medical records and HCC codes submitted to CMS and face contract-level payment adjustments if providers fail to comply with CMS's recordkeeping

[36] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

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requirements. Since MA organizations account for only about one quarter of the total Medicare beneficiaries, enforcing the coding and recordkeeping requirements only on MA organizations will not likely change the coding and recordkeeping behavior of Medicare providers. Rather, CMS must develop coding and recordkeeping rules through proper rulemaking and apply those rules to all Medicare providers.

Without an administrative record developed through rulemaking, CMS has no basis to determine whether these coding and recordkeeping requirements are reasonable or arbitrary and capricious, or whether they create actuarial variations between the FFS and MA payments. The impact of these rules on the audit results will be significant.[37] Failure by the physicians and providers to follow these requirements will subject MA organizations to potentially significant payment adjustments. These payment adjustments will not be the result of improper HCCs, but the result of the failure of providers to comply with CMS's record keeping requirements. Because these document requirements "establish ... a substantive legal standard governing the...payment for services," rulemaking is mandatory under the Medicare Act.[38]

As a result, the proposed administrative appeals process is premature. The first step is to determine whether the One Best Medical Record and its associated recordkeeping and coding requirements are reasonable by instituting appropriate rulemaking. Only then will CMS have an appropriate record upon which to determine whether or not these recordkeeping requirements are justified; only then will CMS be able to determine what should be included in an administrative appeal.

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[37] 74 Fed. Reg. at 54674.

[38] *Id.* at § 1395(hh)(a)(ii).

III. The Proposed Appeals Process is Too Limited

The proposed rules provide "three RADV-related dispute and appeal procedures that MA organizations could undertake to reduce their RADV payment error to include—[1] Physician/practitioner attestation(s); [2] Documentation dispute; and [3] RADV payment error calculation appeal."[39] Each of the three proposed appeal processes is so limited, as to preclude any meaningful appeal of a RADV audit findings. Rather, the three appeal procedures provide only a process to correct clerical and calculation errors.

1. "Physician/practitioner attestation(s)" (Section 422.311(c)(2))

The proposed administrative appeals rule limits MA organizations to providing the "One Best Medical Record," which includes a diagnosis made during the year under audit by a physician or practitioner personally seeing the patient, signed by the physician or practitioner and includes his or her credentials.[40] The first aspect of the proposed appeal process allows only for the submission of an attestation by a physician or practitioner where his or her signature or credentials was missing or incomplete on the One Best Medical Record that the MA organization submits in response to RADV audits.[41] The attestation is limited to the one record the MA organization has already submitted in response to the audit. The proposed rule specifically precludes an MA plan from providing any new or additional documentation supporting the HCCs of any member included in the RADV audit.[42] Moreover, the attestation cannot

39 *Id.* at 54675.

40 *Id.* at 54675-676, 54716.

41 *Id.* at 54675-76.

42 *Id.* at 54676.

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be used to identify other diagnostic information regarding a member of the MA organization's plan.[43] Simply put, this appeal process is limited to where the physician or practitioner failed to sign the medical record or to include their credentials in the record. By limiting the attestations to verifying a provider's signature and credentials, CMS's proposed appeals process simply and effectively establishes the One Best Medical Record rule and precludes an administrative appeal of any substantive issues regarding potential RADV audit findings.

CMS also limits the submission of attestations to outpatient care. CMS contends that "the percentage of payment error associated with signature and credentials for inpatient medical records is relatively small."[44] Yet, CMS acknowledged that its earlier audits were not extensive and exclusion of attestation for inpatient records based on non-extensive audits is unwarranted. CMS does not identify the "small percentage" of errors that would be corrected by allowing attestation of inpatient records. Even a small percentage can be significant if it is extrapolated to make contract wide adjustments as proposed by CMS. Furthermore, if the attestation corrections for inpatient records amount to a "small percentage," then the burden to submit and review such attestations will be minimal and excluding such corrections is inappropriate.

Finally, the proposed appeals rule limits attestations to those:

> [a]ttestations [that] accompany the medical record at the same time that the medical record is submitted to CMS for RADV audit. MA organizations may not submit attestations before or after submission of their RADV medical records.[45]

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43 *Id.*

44 *Id.* at 54675.

45 *Id.*

MA organizations will not be permitted to provide attestations as part of an appeal. Rather it is a requirement regarding the original submission of the medical record supporting an HCC.

This requirement is particularly troublesome since CMS will allow MA organizations only twelve weeks to produce the medical records validating HCCs.[46] The process for locating and producing the documents for CMS review is highly labor intensive. MA organizations must reach out to physicians, hospitals and other practitioners to obtain the medical records for members in the sample identified by CMS and review these records to identify the best record for submission to CMS. Problems can arise if a practitioner has retired, relocated, or died. The records may not be readily accessible and the MA organization may need to make additional requests. To develop a meaningful administrative appeals process for the attestations, therefore, CMS needs to allow submission of attestations after the initial response to the RADV audit and to allow attestations that verify the diagnoses rather than just the signature of the provider.

2. "Documentation dispute" (Section 422.311(c)(2))

Notwithstanding its claim to allow a "documentation dispute process," CMS limits the process to "errors that arise out of operational processing of medical records selected for RADV audit and submitted to CMS by established deadlines."[47] By way of example, CMS notes that if a two page medical record became unstapled, an MA organization could correct the record by showing

[46] *Id.* at 54676

[47] *Id.* at 54675

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that it was in fact a single One Best Medical Record that was submitted to support the HCC.[48] The proposed regulation does not allow the MA organization to dispute any coding discrepancy, to submit new medical records, to provide previously missing medical records or to establish new HCCs for payment consideration.[49] This documentation review will be final and not subject to further administrative review.[50]

CMS's proposed "documentation dispute" appeals process allows an MA organization nothing more than to correct a clerical error, such as a two page document becoming unstapled. The fact that CMS "conduct[s] two rounds of medical record review by two independent contractors" does not alleviate the inadequacies of the proposed RADV audit and appeals process.[51] The inadequacies are not in the number of reviews or the "vigor" of the reviews, but in the limits imposed on what information will be considered during the audit and any subsequent appeals.[52]

The coding guidelines imposed by CMS on physicians and practitioners are complex and mistakes are inevitable. The administrative appeals process needs to allow, not preclude, a MA organization to submit supplemental documents to verify the code.[53] By not allowing the correction of coding mistakes, the result can only result in less accurate MA payments.

48 *Id.*

49 *Id.*

50 *Id.*

51 *Id.*

52 *Id.*

53 *Id.*

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The proposed appeal rule does not provide for a document review process, but a clerical error review that provides no meaningful administrative review for an MA organization to contest the interpretation of the documents submitted or to supplement the record to validate an HCC for a Medicare member of the organization's plan. Moreover, like the attestation procedure, this limited appeal right effectively establishes the One Best Medical Record rule as a regulation.

3. "RADV payment error calculation appeal" (Section 422.311(c)(3))

While the proposed rule provides three "layers of appeal" for contesting the "payment error calculations,"[54] the process actually amounts to nothing more than whether CMS added, subtracted, multiplied and divided correctly in calculating its audit error rate. Specifically, the proposed rule provides:

> Under the proposed RADV payment error calculation appeal process, we are establishing a three-level appeal process whereby MA organizations may—
>
> - Seek reconsideration;
> - Appeal the reconsideration decision to an independent CMS hearing officer; and
> - Appeal the decision of the independent CMS hearing officer to the CMS Administrator.[55]

This elaborate procedure does not mask the fact that there is no meaningful opportunity to contest the calculations and the underlying premises.

CMS has specifically precluded any challenge to the medical record review errors or attestation rules.[56] MA organizations cannot submit any additional medical record for consideration in calculating the alleged HCC payment error.[57] "Furthermore, MA

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54 *Id.* at 54677

55 *Id.*

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organizations cannot appeal the CMS's payment error calculation methodology."[58] Accordingly, MA organizations will not be allowed to challenge the sampling methodology used in the audit nor will they be able to contest the statistical analyses or challenge the extrapolation methodology.

Instead, CMS asserts that it will annually publish its payment error calculation methodology and allow MA organizations to comment on them.[59] This procedure is inadequate. First, it amounts to CMS unilaterally imposing the payment error calculation methodology on MA organizations. Second, simply allowing the submission of comments without providing a meaningful appeal to contest disputed methodologies forecloses any ability to administratively appeal this essential aspect of the RADV audits. In fact, CMS specifically provided that, "MA organizations cannot appeal the CMS' payment error calculation methodology."[60]

Its only justification for precluding any appeal of the sampling and extrapolation methods is that "the methodology that we employ to calculate RADV payment errors is methodologically sound and academically defensible."[61] Simply claiming its methodology is "is methodologically sound and academically defensible" does not excuse CMS from precluding any appeal to challenge it.

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56 *Id.*

57 *Id.*

58 *Id.*

59 *Id.*

60 *Id.*

61 *Id.*

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First, CMS fails to provide any record of submitting its methodologies to an academic review. CMS should have included such studies with the proposed rule so that interested parties can review this claimed support and comment on any of these academic studies.

Second, the methodologies should still be subject to review through the administrative appeal process. The methodology that CMS uses to determine payment adjustments will impact MA Plan bids and premium rates. It is not clear when the annual notice will be provided to MA organizations, what level of detail will accompany the notice, and whether the notice will be sufficiently in advance of the bid submission process to allow plans to include it in developing bids. A pre-audit announcement will be inadequate since the bid, benefits and rates have already been actuarially determined by the MA organization. Post-audit explanations will be even less useful. Yet, CMS indicated that it will provide an "expanded explanation of methodology as part of each audit report of findings that we send to MA organizations that undergo RADV audit."[62] That is too late for MA organizations to include the potential results of the extrapolation in its annual bids. It is therefore critical that MA organizations be able to appeal the methodology and the potential retroactive impact on MA organizations.

Third, if the methodologies are sound, they should be certified by an accredited actuarial organization based on an independent review. When the risk adjustment system was established, the Medicare Act required the Secretary to submit an actuarial report to Congress[63]. A RADV audit process that will include an extrapolation to make contract-level payment

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62 *Id.*

63 Social Security Act §1853 (3) (A)

adjustments impacts the risk adjustment system and the original actuarial review. A new actuarial report, therefore, is needed. None of these steps, however, were done or are even allowed.

Even the "several layers of appeal available to MA organizations" in the proposed rules is an illusion. If a MA organization seeks to appeal the audit finding to "an independent CMS hearing officer," the second layer of appeal, "[t]he Hearing Officer does not recalculate the error and offer either party an alternative RADV payment error."[64] The hearing officer can only uphold or reverse the audit calculations.[65] The "third level" of appeal to the CMS Administrator is "discretionary" and the Administrator can simply refuse to accept the appeal.[66]

There is nothing left to the "payment error calculation appeal" other than to contend that CMS has made a mistake in their arithmetic. Accordingly, the proposed administrative appeals process provides no meaningful appeal. The proposed rules create an appeal process that appears to be nothing more than an attempt to satisfy CMS's obligations under the APA. It falls far short of those requirements.

IV. The Proposed Rules Should Not Be Retroactive

The proposed appeals process does not take into account that MA organizations have already submitted their bids and have pre-existing contracts with CMS to provide benefits to Medicare beneficiaries who are a part of the organization's plan. CMS's

64 *Id.* at 54678

65 *Id.*

66 *Id.*

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proposed appeal rules that implicate contract wide adjustments cannot be retroactively applied because: (1) a contract-level adjustment will be inconsistent with the actuarial assumptions and data used by MA organizations to determine their annual bids and how it would project risk scores; and (2) a contract-level adjustment will be inconsistent with the existing contracts.

1. Actuarial Basis of MA Payment

Inherent in the actuarial processes and assumptions underlying the bids are that the risk adjustment will be based on a comparison to the Medicare FFS population provided by CMS in its rate letters. MA organizations compare their bids to the corresponding risk-adjusted benchmark to determine member premiums, co-pays and supplemental benefits.[67] MA organizations' payment rates, benefit designs and member premiums are inextricably linked to the estimates and assumptions supporting the bid, including the projected risk scores and benchmark.

If consistency is not maintained with Medicare FFS, the actuarial basis of the MA organizations' bids and resulting payments are undermined. The bid process is complex and MA organizations must project the cost of providing benefits to an enrolled population in an actuarially sound manner. To be able to submit a bid, MA organizations must know the rates and actuarial assumptions. A valid and consistent measurement of the projected risk of a given population is critical to this actuarial analysis. The projected risk impacts the MA organizations' benefit design, member premiums, and payment rates. As a result, the Medicare Act

[67] 42 U.S.C. § 1395w-24(b).

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mandates that CMS provide "[a]dvance notice of changes to be made in the methodology from the methodology and assumptions" to MA organizations.[68]

The methodologies for calculating payment errors will have a direct impact on an MA Plan's bid submissions, including its premium rates and benefits packages. It is, therefore, inappropriate to implement retrospectively an adjustment that was unknown at the time the bids were developed to payment rates. To change the projected risk scores, often based on missing or incomplete records under the One Best Medical Record rule and without reference to fee-for-service error rates, will undermine the actuarial soundness of the original bids. The bids 2007, 2008, 2009 and 2010 were developed and submitted prior to the proposed regulations. Moreover, the bids for 2007 through 2009 were made prior to CMS even announcing its 2007 pilot RADV audit program. The proposed RADV audits appeals rules include factors that were never provided to MA organizations before they submitted their bids. No MA organization was aware that CMS would institute a One Best Medical Record that would limit the ability to validate HCCs; hold them responsible for the recordkeeping and risk coding of their providers; and adjust contract-level payment based on a yet to be identified extrapolation method.

As a result, none of the MA organizations were able to anticipate these audits and actuarially include these factors in their bids. Retroactive contract-level payment adjustments based on previously unknown RADV audits will create a fundamental disconnect between MA organizations' payments and the benefits offered. Moreover, CMS reviews the bids submitted by MA organizations' bids to determine whether "(1) The bid amount and proportions are supported by the actuarial bases provided by MA [organizations], [and]

[68] 42 U.S.C. § 1395w-23(b)(2); 42 C.F.R. § 422.312(b); *see also*, 42 C.F.R. § 422.521 (requirements that impose "a significant new cost or burden" may be implemented only at the beginning of a calendar year).

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(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan ... "[69] If CMS intended to make contract-level adjustments based on RADV audits, it had both the obligation and the opportunity to advise MA organizations that they needed to make adjustments in their bid based on anticipated RADV audits. CMS cannot now impose such a retroactive adjustment.

2. Preexisting Contracts

Although the MA organization contracts with CMS provide for the submission of risk adjustment data to determine the risk adjustment factors, no provision provides for retroactive payment adjustments. Moreover, the Medicare Act and the applicable regulations require advance notice of changes in assumptions that will impact payments.[70]

The MA contract specifically addresses CMS's right and authority to implement changes during the contract year. Only statutory changes that are made during the term of the contract (and changes in regulation and policies implementing such statutory changes) are deemed to be incorporated into the contract.[71] There have been no statutory changes made during the term of any of the existing contracts that could be incorporated into the MA contracts that allow for any retroactive contract-level adjustment.[72]

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69 42 C.F.R. § 423.256(b).

70 42 U.S.C. § 1395w-23(b)(2), 42 C.F.R. § 422.312(b); *see also*, 42 C.F.R. § 422.521 (requirements that impose "a significant new cost or burden" may be implemented only at the beginning of a calendar year).

71 42 C.F.R. § 422.521.

72 MA contracts at Articles II.B and II.C.

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The MA contract requires CMS to provide the FFS rates to be used to determine the MA rates. CMS did not announce these audit requirements, the One Best Medical Record, or the limited appeal rights at any time prior to announcing the rates for 2007 through 2010. Therefore, CMS cannot now retroactively change the payment.

CMS's proposed appeals process does not take these contractual obligations into account. It does not allow an MA organization to explain how it generated its bid based upon the information provided to it by CMS at the time of bid calculation. As a result, the process precludes any adjustment to the audit findings based upon contractual obligations. Hence, it is inconsistent with CMS's current contractual obligations.

V. Conclusion

The proposed administrative review process provides an inadequate review, allowing only for the correction of clerical and mathematical errors in the RADV audits. It provides no meaningful administrative review of the substantive issues that may be raised in these audits. Moreover, the appeals process is based upon RADV audit parameters such as the "One Best Medical Record" rule, sampling methodologies, and statistical and extrapolation methodologies, which themselves are invalid because they are inconsistent with the Medicare statute mandating "actuarial equivalence" to the FFS rates and have not been subject to proper rulemaking.

As a result, we respectfully requests that CMS:

1. Withdraw the Risk Adjustment Data Validation Appeals rule;
2. Institute rulemaking for the One Best Medical Record rule and the recordkeeping requirements;

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3. Institute rulemaking regarding the need for FFS auditing. Only once such rulemaking is undertaken can an appeal process be developed that offers a meaningful opportunity for MA organizations to protect their rights and the rights of their members.

Exhibit 5

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December 8, 2009

Centers for Medicare & Medicaid Services
Hubert Humphrey Building
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Washington, DC 20201

Re: CMS-4085-P

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) to comment on the notice of proposed rulemaking titled, "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on October 22, 2009 (74 FR 54633). AHIP is the national association representing 1,300 member companies providing health coverage to more than 200 million Americans. These regulations have a direct impact on AHIP's member organizations many of which participate in the Medicare Advantage, Medicare Part D prescription drug benefit (Part D), and Medicare Cost Plan programs.

Specific Comments

A. Changes to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers

1. **Require Notice of Intent to Apply Under Part C and D Within application Requirements (§422.501 & §423.502; Preamble, p. 54640)**

   Under §422.501(b) and §423.502(b), CMS is proposing to require a Notice of Intent to Apply by the date specified annually by CMS as a condition for a new or existing MA or Part D contractor to be permitted to submit an MA or a Part D application. We believe that the proposed codification of the requirement for submission of a Notice of Intent to Apply raises several concerns, because it eliminates flexibility currently exercised by CMS to respond to circumstances that may merit permitting submission after the established deadline, which in recent years has been three months prior to the due date for applications.

   On pages 54640 and 54641 of the preamble, CMS identifies the stated purpose for the Notice of Intent as allowing CMS to assign a pending contract number and complete CMS User ID connectivity. Because applications are only submitted electronically, AHIP understands the need for the applicant to establish connectivity as a condition of

submission of the application. However, it is unclear that a three month lead time is necessary to assure that timely connectivity can be established, particularly for existing contractors who already have access to CMS systems. In addition to ensuring that connectivity can be established, it is our understanding that the Notice to Intent has served as an indicator to CMS of the number of applications that may be submitted so that the agency can plan to allocate appropriate resources for their review. However, it appears that this concern will diminish over time.

In the preamble, CMS notes that submission of a Notice of Intent is not binding. While this policy relieves a potential applicant from making a final decision about whether to apply prior to submission of the Notice of Intent, it does not take into consideration the possibility that organizations may not have considered submitting an application at the time the Notices of Intent are due, 14 months prior to the contract period. This might be the case for a variety of reasons. For example, after extended discussions, a state may express interest in contracting with dual eligible SNPs for the contract year at issue subsequent to the submission deadline, or an organization may reach agreement with an integrated delivery system that makes a service area expansion feasible.

For these reasons, AHIP recommends that CMS modify the proposed rule to permit the agency to grant exceptions to the submission deadline for the Notice of Intent to Apply under appropriate circumstances (e.g., when new information becomes available to the potential applicant subsequent to the deadline). We also recommend that in establishing the annual submission deadline in guidance, the agency establish a date that is closer to the application submission deadline.

2. **Application Requirements (§422.501(c) & §423.502(c)) and Evaluation and Determination Procedures for Determining Whether Applicants are Qualified for a Contract Under Parts C and D (§422.502 & §423.503; Preamble, p. 54641)**

- CMS is proposing to modify the regulations at §422.502(c)(2) and §423.503(c)(2) by adding a new paragraph to clarify that applicants must adhere strictly to CMS deadlines for submission of additional or revised information in response to a notice of intent to deny an application. While clarity regarding CMS' intent to enforce the deadline is constructive, there are several important practical issues that we believe should be addressed in order to avoid inappropriate barriers for applicants who are prepared to meet program requirements to serve Medicare beneficiaries.

  + First, AHIP's understanding is that CMS' current policy is to deny an entire application if a single county fails to meet CMS' access requirements and that any decision by an applicant to drop a county from its application must be made prior to the end of the 10 day period following a notice of intent to deny that identifies

network deficiencies in the county. This result undermines the purpose of the intent to deny process. In a number of cases, we understand that applicants that have disagreed with CMS' network adequacy determinations have been reluctant to seek re-evaluation of their networks in specific counties because of the possibility that CMS will confirm its original finding and deny the entire application. This concern is particularly acute for MA organizations offering PFFS plans that are submitting applications for network-based PFFS plans. Many of these organizations currently have contracts covering a number of states. A denial of one county in one state could result in the denial of an entire application. To address this problem, AHIP recommends that CMS revise its policy to provide that an applicant for a network-based plan or service area expansion may drop a county or portion of its service area that has been identified in an intent to deny notice after receiving CMS' final decision based upon the additional information submitted by the MA organization. In addition, AHIP recommends that CMS review each proposed change to the regulation to assure that this policy result is permissible under the revised language.

+ Second, we understand that in some cases CMS has identified deficiencies in applications subsequent to the issuance of a notice of intent to deny. While we recognize CMS' interest in acting upon deficiencies identified at any point in the application process, we believe that it would be inequitable for CMS to deny an application on this basis, if the agency does not provide notice to the applicant and an opportunity to cure the deficiency, consistent with the rights accorded by the notice of intent to deny process. Accordingly, we recommend that the agency explicitly provide in the regulation for a process to permit applicants to cure deficiencies identified by CMS subsequent to issuance of the notice of intent to deny. If such an opportunity is not provided, CMS should base any Denial Notice only on issues raised in the notice of intent to deny and not on deficiencies that are identified later in the application review process.

+ Third, in past years, applicants have raised concerns about lack of clarity in some of the CMS review criteria (e.g., network access standards and other criteria not explicitly addressed in written guidance), and the flexibility provided by CMS in allowing applicants to cure deficiencies has mitigated the potential for adverse consequences. As CMS moves forward to apply strictly the 10 day time frame following the notice of intent to deny, AHIP believes it is essential that CMS ensure the clarity and transparency of its program requirements and review criteria so that the agency and applicants will have a consistent understanding of the expectations on which CMS bases its contract approvals and denials.

- CMS is proposing to revise the regulation at redesignated §422.501(c)(2) and §423.502(c)(2) to provide that applicants for contracts under Part C and Part D must meet all (not substantially all) program requirements. The agency provides the following explanation for this change in the preamble at page 54641:

> During the first four years of the Medicare Advantage and Part D programs, several unsuccessful applicants contested our denial of their applications for MA organization or Part D sponsor contracts. At hearings, some of those applicants were successful in arguing that the regulations were not clear in stating that an applicant needed to demonstrate that it met all program requirements to qualify for a contract.

AHIP's understanding is that Hearing Officers interpret this provision quite narrowly and have overturned CMS' denials in a very limited number of cases. For example, of the appeals that were filed in 2008, only three CMS contract denials were overturned for this reason. In addition, we note that CMS is proposing to revise redesignated §422.501(c)(2) to read, "The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part." (Emphasis added.)

Since the CMS application does not, in general, call for a narrative description of how requirements will be met but relies principally on completion of a series of attestations and tables, and in light of the extensive, detailed requirements included in the CMS regulations and related subregulatory guidance, we believe that the requirement for a comprehensive showing that all requirements have been met is not practical. We assume that CMS intends that applicants must affirm that they have met or are prepared to meet all of the requirements reflected in the attestations and that they be prepared to demonstrate the basis for their responses to the attestations as part of the application review process. We believe that substantial compliance is the appropriate standard for such a showing, particularly in light of CMS' expectation that in some cases, the applicant must provide assurances that requirements will be met in the future. Accordingly, we recommend that CMS modify the proposed rule by revising redesignated §422.501(c)(2) and §423.502(c)(2) to be consistent with the content of the attestation-based application.

3. Deny Contract Qualification Applications Based on Past Contract Performance (§422.750 & §423.750; Preamble, p. 54641)

CMS is proposing that the agency may deny an application for failure to comply, during the 14 month period preceding the application deadline, with program requirements under a current, as well as a previous contract, or failure to complete a corrective action plan

during that period. The preamble discusses the approach that CMS will utilize to make such a determination. AHIP understands CMS' interest in clarifying and providing greater specificity in the regulation concerning the agency's authority to deny an application based on a contractor's past performance. If CMS adopts the proposed regulatory changes, we have identified two implementation issues that we believe should be addressed.

- First, contractors invest substantial resources in completing and submitting the application and incur ongoing administrative expenses to sustain activities necessary to prepare for implementation of a new contract or service area expansion. However, by the deadline for the Notice of Intent to Apply, CMS is likely to have most of the information for the evaluation of past performance that could result in disapproval of the application. Accordingly, AHIP recommends that CMS signal in the preamble to the final rule that the agency will establish a process by which a potential applicant could receive, upon request, a preliminary finding that indicates whether past performance is likely to be a barrier to approval of a new contract, so that the contractor can determine whether to invest in pursuing an application.

- Second, AHIP recommends that the CMS criteria for determining whether an application will be denied based on past performance be issued in detailed subregulatory guidance that is subject to the agency's informal process for review and comment. We also recommend that the agency allow a four week period for this review to permit a thorough evaluation of the proposed criteria to ensure that the criteria are clear, transparent and can be consistently understood by MA and Part D contractors and CMS and consistently applied by CMS reviewers. The criteria should also be fair and reasonable.

  For example, an organization that has resolved deficiencies that resulted in a corrective action plan or sanction should not have an application denied for this reason absent unusual circumstances. An organization that holds multiple contracts might have a single deficiency that affects all contracts and therefore results in multiple corrective action plans. An organization in this situation should not be penalized unduly because of repeat findings stemming from a single deficiency. In addition, findings that CMS determines warrant a contract denial should be material.

  Further, in the past when the agency has utilized an outlier analysis, outlier status has triggered further investigation in order to determine whether circumstances are present that mitigate the finding. We believe that outlier status alone is inappropriate as a criterion for contract disapproval. For example, sponsoring organizations that face special challenges because of the populations they serve could inappropriately be identified as outliers on certain performance indicators that may not be suited to the

characteristics of the sponsoring organization and its members (e.g., SNPs that serve a high proportion of chronically ill beneficiaries). If outlier status is established as one of the criteria for contract disapproval, it will be important for the outlier threshold to be established in such a way that it does not call into question participation by an MA or Part D contractor that is serving its members and the program well.

4. **Use of Data to Evaluate Continued Ability to Act as a Qualified Sponsoring Organization Under Parts C and D (§422.504 & §423.505; Preamble, p. 54642)**

CMS is proposing to add a new paragraph (m) under §422.504 and a new paragraph (n) under §423.505 that would authorize CMS to determine that an organization/sponsor is out of compliance because it has failed to meet performance standards established by CMS or because the organization's performance represents an outlier relative to the performance of other MA organizations. AHIP's comments immediately above also apply to this proposal. Moreover, when, as in this case, CMS is proposing to take away a property right, i.e., the contract with CMS, whether through termination or nonrenewal, AHIP believes it is particularly important that the criteria that CMS follows to evaluate performance be fair, reasonable, and transparent to the organization/sponsor.

5. **Compliance Programs under Parts C and D (§422.503(b)(4)(vi) & §423.504(b)(4)(vi); Preamble, p. 54643)**

CMS is making a number of changes to the compliance program requirements in §422.503 and §423.504. In a number of instances, CMS is proposing to add language making the compliance program requirements more prescriptive. AHIP and our member companies agree that effective compliance program implementation is a high priority, and in general, we believe CMS' proposed changes are integral elements of a good compliance program. However, AHIP has identified two areas in which we have comments and concerns with regard to the proposed amendments to the regulations.

- First, §422.503(b)(4)(vi)(B)(1) and §423.504(b)(4)(vi)(B)(1) would require that a compliance officer, vested with the day to day operations of the compliance program, must be an employee of the MA organization/PDP sponsor. Many MA organizations and PDP sponsors have a number of related entities which may hold separate contracts with CMS. In these circumstances, it is common for the entities to centralize the compliance function for effectiveness and efficiency, so that the compliance officer who is employed by one entity is responsible for the compliance functions of several other affiliated entities. Moreover, these entities may be established for legal rather than operational reasons and may not necessarily be employing staff who are responsible for activities under the MA or Part D contract.

The accountability and responsibilities of the compliance officer with respect to each entity is maintained, and this structure promotes consistency of compliance program implementation across the contracting entities. Accordingly, AHIP recommends that CMS revise the language of the proposed rule to permit the compliance officer to be employed by the organization/sponsor or their affiliate.

- Second, under the Part C regulation at §422.503(b)(4)(vi)(C)(2), CMS is proposing that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program would be deemed to have met the training and educational requirements for fraud, waste, and abuse. AHIP supports this proposal, which has the effect of applying the same standard across the entire Medicare program. In addition, it is our understanding that, because many pharmacies have Part B supplier numbers, they also complete the Medicare enrollment process. For this reason, AHIP recommends that CMS revise the Part 423 compliance program requirements to include a comparable provision to §422.503(b)(4)(vi)(C)(2)in order to avoid duplicative training under Part D for pharmacies that enrolled into the Medicare program.

6. **Network Adequacy of Coordinated Care and Network-Based Private Fee-for-Service Plans Under Part C (§422.112; Preamble, p. 54644)**

In the preamble at page 54644, CMS explains that the agency is developing an automated system for reviewing the adequacy of provider networks proposed by MA applicants and, for this reason, is proposing to include in the regulation more specific criteria that CMS will apply in defining community patterns of care for the purpose of network adequacy determinations. AHIP supports CMS' effort to make the MA criteria for provider access and availability more transparent. It is our understanding that applicants have raised concerns about their ability to understand the basis for CMS determinations of network adequacy in order to ensure that their contracted networks are compliant with CMS expectations. We anticipate that CMS' initiative to permit potential applicants to utilize an automated system to assess their contracted networks prior to CMS review could help to mitigate this concern. Similarly, we agree that the concept of community patterns of care has the potential to permit CMS to take varying local conditions into consideration in evaluating network adequacy.

However, whether the automated system and the detailed criteria that CMS will apply are sufficiently responsive to unique local provider contracting conditions and MA organization assessments of the number and mix of providers necessary to meet anticipated member needs is unclear. We agree with CMS that these details are more appropriately addressed in subregulatory guidance, particularly because CMS is embarking on an effort to establish explicit criteria which may need to be adjusted over

time based upon experience with implementation, for example, to address the unique characteristics of some MA plans, such as dual eligible special needs plans (SNPs).

For this reason, to permit CMS to address unanticipated effects of the community standard of care standard, if CMS incorporates the proposed regulatory changes into the final rule, we recommend that the agency modify the proposed rule to provide for the establishment of an exceptions process that could be utilized at the discretion of CMS. We also urge that CMS establish a dialogue with affected organizations to permit the agency to consider MA organization provider contracting experience as subregulatory guidance is developed, and we would be interested in contributing to such an initiative.

8. **Modify the Corrective Action Plan (CAP) Process as it Relates to Procedures for Termination and Nonrenewal of a Part C or D Contract by CMS (§422.506(b)(3), §422.510(c)(1), §423.507(b)(3), & §423.509(c)(1); Preamble, p. 54646)**

CMS is proposing to revise its rules governing the process that will be used to permit MA organizations/Part D sponsors to pursue corrective action plans (CAPs) when the agency has identified deficiencies that could be the basis for issuing a notice of intent to non-renew or terminate a Part C or Part D contract. CMS would no longer review and approve CAPs but would make the organization or sponsor solely responsible for the development and implementation of a CAP to correct the deficiencies. The revised regulation would require that CMS provide at least 30 calendar days for this action prior to issuance of a notice of intent to nonrenew or terminate a contract.

AHIP disagrees with the statement in the preamble that conveys that a 30 day period in general provides a sufficiently reasonable opportunity for an organization/sponsor to correct deficiencies that may give rise to a decision to nonrenew or terminate a contract. The current regulation provides 45 days for an organization/sponsor to develop and submit a CAP to CMS and does not establish a time frame for completion of the CAP. Deficiencies of sufficient severity to prompt CMS to issue a deficiency notice that could lead to contract termination or nonrenewal are likely to require more than 30 days for the organization/sponsor to design and complete a CAP.

Therefore, we urge CMS to reconsider establishing a minimum time frame for the completion of corrective action and recommend that CMS require the organization/sponsor to develop a CAP and initiate implementation no later than 30 days following receipt of the deficiency notice. CMS could establish a reasonable time frame for completion of the CAP in consultation with the organization/sponsor based upon the particular deficiencies and plan of action. In addition, we recommend that CMS revise the proposed rule to eliminate the requirement that the time frame for completing the corrective action would be specified by CMS at the time of the deficiency notice. At this

stage of the process, it is unlikely that CMS will have sufficient information about the operational activities that must be accomplished by the MA organization to establish a reasonable time frame.

9. **Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§422.756 & §423.756; Preamble, p. 54647-54648)**

- **Role of an independent auditor.** CMS is proposing to add §422.756(c)(3)(i) and §423.756(c)(3)(i) to require the sponsor to hire an independent auditor when a sanction is in effect to provide CMS with additional information to determine if deficiencies have been corrected. The agency explains that it has sometimes been difficult for CMS to make the determination to lift a sanction, particularly when the solution implemented by the sponsoring organization involves technical systems changes, and the agency believes an evaluation by an independent auditor can be beneficial to both CMS and the sponsoring organization. CMS is also considering an alternative proposal to grant the sponsoring organization the discretion to hire an independent auditor. AHIP supports this alternative approach and recommends that CMS revise the proposed rule to reflect this policy rather than providing authority for CMS to require the hiring of an outside auditor. As the preamble points out, while hiring an independent auditor may be desirable in some circumstances, CMS does not expect that this step will be needed in all cases. Sponsoring organizations may be interested in providing CMS with documentation of thorough internal reviews to determine if this information would be sufficient evidence of compliance prior to incurring the cost of an independent auditor, which could be substantial. In any event, we believe that the nature and scope of the information necessary for CMS to determine whether compliance issues have been addressed will be resolved informally between CMS and the sponsoring organization during the period the sanctions are in effect.

- **Role of a "test period."** CMS is proposing to add §422.756(c)(3)(ii) and §423.756(c)(3)(ii) to provide CMS with the discretion to subject the sponsoring organization to a "test period" to determine if the bases for sanctions have been corrected when an enrollment and/or marketing suspension has been imposed. AHIP recognizes the practical value of a test period of this nature, and AHIP supports this proposal.

14. **Time and Place of Hearing Under parts C and D (§422.670 & §423.655; Preamble, p. 54652)**

CMS is proposing to allow CMS or the sponsoring organization to automatically obtain a 15 calendar day postponement if the request is made no later than 5 days prior to the

hearing. Any other extension would be at the discretion of the hearing officer. AHIP has two recommendations regarding this proposal.

+ First, we are concerned that the timing of such an automatic extension could disadvantage sponsoring organizations whose representatives would have invested in travel arrangements and other preparations to participate in the hearing by the time the request is made. We believe that CMS and the Hearing Officer would be similarly affected. Therefore, AHIP recommends that the proposed regulations be revised to provide that an automatic postponement would be granted if the request is made either by CMS or the sponsoring organization within three business days following the date the sponsor and CMS are notified of the hearing date.
+ Second, AHIP believes that there may be instances where an automatic fifteen day delay may not be workable, due to previous commitments of the Hearing Officer or the other party. To address this possibility, AHIP recommends that CMS add language to the rule to allow for an alternative, mutually agreeable hearing date if the Hearing Officer or the non-requesting party is not available on the hearing date that would otherwise result from the postponement.

15. Discovery Under Parts C and D (§422.682 & §423.661; p. 54652)

CMS is proposing to remove from the regulation the formal discovery process that is currently provided as part of the procedure for notice and the opportunity for a hearing when CMS makes adverse contract determinations (i.e., denial of an application or nonrenewal or termination of a contract). CMS is proposing to include new language that would require the parties to identify witness lists and documents and exchange them at least 5 calendar days prior to the scheduled hearing. The preamble states that CMS no longer believes a formal discovery process is necessary or appropriate for these kinds of proceedings. AHIP opposes deletion of the requirement for a formal discovery process that permits either CMS or the sponsoring organization to make a request to the other party for the production of documents for inspection and copying that are relevant and material to the issues before the Hearing Officer. We also believe that reduction of the period for review following production of requested documents from 10 days to 5 days undermines the ability of sponsoring organizations to evaluate the information in preparation for the hearing.

AHIP believes that this process is critical to providing the sponsoring organization with information material to the hearing that would not be required to be produced under the CMS proposal. For example, the discovery process permits sponsoring organizations to obtain and review previous decisions by Hearing Officers that are not otherwise readily available. We believe that sponsors should have access to relevant prior decisions to have a fair opportunity to evaluate the reasonableness of CMS' position, as well as to be informed about reasoning and decisions of Hearing Officers in the past.

The discovery process is also the appropriate forum for the sponsoring organization to learn, if CMS has not otherwise informed the sponsor, of the criteria CMS used in reaching the termination decision. This information is also critical to permitting the sponsoring organization to pursue effectively its hearing right. Moreover, AHIP believes that sponsors have a statutory right under 5 U.S.C. §552 to be informed of the policy that provided the basis for the denial.

AHIP recommends that CMS revise the proposed rule to retain the existing formal discovery process. We also recommend that CMS add a provision to §422.682 & §423.661 stating explicitly that the sponsor has a right to learn the basis for CMS' contract determination and obtain previous Hearing Officer decisions.

B. Changes to Strengthen Beneficiary Protections

1. Broker and Agent Requirements Under Parts C and D (Preamble p. 54654)

In the preamble, CMS highlights that the agency has implemented requirements of the Medicare Improvements for Patients and Providers Act (MIPPA) that are designed to create incentives for agents and brokers to assist beneficiaries in making choices among available plans based on the beneficiaries' health care needs rather than any financial benefit to the agent or broker. While CMS believes agents and brokers play an important role in assisting beneficiaries with their decision making and believes it is too soon to fully evaluate the impact of the MIPAA requirements, the agency remains concerned about inherent financial incentives for independent agents and brokers. CMS invites comments on several approaches that CMS is exploring to identify the most effective means of ensuring that beneficiaries receive assistance focused on selecting the plan that best meets their needs. These approaches include expanding the capacity of State Health Insurance Assistance Programs (SHIPs) and limiting the use of independent agents and brokers by MA organizations to certain times of the year or to a subset of beneficiaries.

AHIP and our member organizations have consistently supported initiatives to strengthen safeguards for beneficiaries to ensure that agent and broker marketing activities serve beneficiary interests. We believe that the strong focus by CMS, MA organizations, and other stakeholders, including many in the agent community, on promoting heightened oversight of marketing activities of independent agents and brokers is providing additional protections that are benefiting Medicare beneficiaries. We are committed to working with CMS and other stakeholders to identify additional opportunities to promote availability of information and assistance to beneficiaries that allows them to make choices that are best for them. Our comments on the new approaches that CMS is exploring are included below.

- **State Health Insurance Assistance Programs (SHIPs).** AHIP supports increasing beneficiary access to the assistance provided by SHIPs. We understand that to increase their capacity to serve beneficiaries SHIPs would require additional funding for staff and facilities. These organizations are a trusted source of information because their goal is to provide objective information about the full range of Medicare options available to beneficiaries, including Original Medicare, Medigap, Medicare health plans, and/or stand-alone PDPs. They are grounded in knowledge of the local environment and available choices, and this insight is critical to assisting beneficiaries in understanding their options. SHIPs provide face-to-face individual counseling that is a highly valued and effective means of providing information to beneficiaries.

  It is important to note that while additional beneficiaries are likely to seek information from SHIPs if their capacity is increased, improved access to SHIPs is unlikely to obviate the role of agents and brokers. For example, agents offer in-home visits, which can be a valuable service for beneficiaries, who may be homebound, lack transportation, or simply prefer this setting. Some beneficiaries have longstanding relationships with agents on whom they rely for advice about a variety of insurance products, as well as for assistance in obtaining service and coverage under their policies. Agents are licensed and appointed to carry out marketing and sales activities so that they can provide advice, commonly based upon needs assessments, about the suitability of available options based on beneficiary needs and preferences. While we understand that this service continues to be a source of concern to CMS, it is considered a benefit by many beneficiaries who are well-served by ethical agents whose livelihood depends upon maintaining the trust of their clients. We assume that expanded availability of SHIPs would not include an extension of their activities to encompass recommendations to beneficiaries about the coverage they should choose in light of their public funding and the oversight, licensure, and other issues this would raise.

- **Independent agents and brokers.** AHIP agrees that sufficient time has not elapsed to fully evaluate the success of the changes implemented as a result of MIPPA and we believe that findings concerning their impact should be considered by CMS before determining additional steps that should be taken to enhance existing safeguards. While no beneficiary should be disadvantaged by the misconduct of agents and brokers, most agents and brokers conduct their activities honestly and with integrity. We understand that satisfaction surveys administered by MA organizations as one element of their evaluation of the performance of independent agents consistently indicate high levels of beneficiary satisfaction. In light of these results and the range of services provided by independent agents to the beneficiaries who choose them, as

discussed above, we believe that it would not be appropriate for CMS to limit their role to certain times of the year or certain populations. Further, such limitations could result in unintended consequences such as foreclosing the option for beneficiaries to choose Medicare coverage with the assistance of a trusted independent agent upon initial Medicare eligibility. Also, agents may provide year-round assistance to their clients, often explaining claims issues or answering other plan-specific questions that arise after the point of sale. Limitations on the role of independent agents to certain times of the year or populations also have the potential to cause beneficiary confusion or frustration and could potentially disadvantage some beneficiaries (e.g., those with limited mobility who rely upon home visits).

We recommend that CMS continue to closely monitor and evaluate the role and performance of independent agents and that examination of beneficiary experience with their activities under both the MA and Part D programs, include assessment of beneficiary satisfaction with the services they provide to beneficiaries (e.g., including education and customer service), as well as the impact of MIPPA on agent and broker performance.

- **Other potential solutions.** To provide additional assurance that the conduct of independent agents and brokers is subject to effective ongoing oversight to safeguard beneficiary interests, we recommend that CMS consider additional avenues for identifying and disseminating best practices by MA organizations. We also recommend that CMS continue its efforts to provide a stable body of guidance and a systematic mechanism for making available to MA organizations and Part D sponsors responses to questions concerning interpretations of CMS policies that have general applicability. In addition, we recommend that CMS consider further the potential for making available information about agents for whom a high number of serious complaints have been identified or who have been terminated for cause, possibly in collaboration with the NAIC. Such a system would allow MA organizations to avoid unwittingly contracting with agents and brokers whose performance has been consistently problematic.

2. **Beneficiary Communications Materials Under Parts C and D (§422.2260, §422.2262, §423.2260 & §423.2262; Preamble p. 54655-54656)**

- **Claims processing, beneficiary specific, and situational materials.** The preamble explains that CMS is proposing to revise §422.2260 and §423.2260 to exclude materials about claims processing activities from the definition of "marketing materials" and to add a definition of "current enrollee communications materials" to provide that such materials would not be considered marketing materials. The definition would encompass communications targeted to situational or beneficiary-

specific circumstances. The preamble also indicates that these materials would be subject to a separate review process that would continue to permit CMS to require that they be modified or that their use be discontinued. AHIP supports this proposal. However, we believe that the regulatory language as proposed is not aligned with the description in the preamble and recommend that it be revised to accomplish CMS' objective. Specifically, we recommend that CMS:

+ Revise and renumber §422.2260(5)(vii) and §423.2260(5)(vii) to remove the paragraph from the list of types of marketing materials and clarify that current enrollee communication materials are not marketing materials.
+ Revise §422.2262(d) and §423.2262(d) to explicitly state that current enrollee communication materials are not subject to the review processes required under §422.2262(a) and (b) and §423.2262(a) and (b).

3. Required Use of Standardized Model Materials Under Parts C and D (§422.2262 & §423.2262; Preamble p. 54656)

CMS is proposing to add §422.2262(c) and §423.2262(c) to require, when specified by CMS, that organizations must use standardized formats, and language in model materials. The preamble explains that CMS intends to require the use of standardized marketing materials, without modification, in every instance in which CMS provides such standardized language and formatting. In light of the large number of model materials that CMS has issued and the breadth of the proposed new regulatory language which could encompass the full range of such materials, we have several significant concerns regarding CMS' emphasis on the use of standardized documents. These concerns are discussed in detail below.

- **Variable fields.** The standardized ANOC/EOC contains language and formatting that must be used as issued and also contains variable sections that permit MA organizations/Part D sponsors to include customized information to ensure that the information provided to beneficiaries accurately reflects plan benefits and rules. We recommend that CMS utilize this approach in other model documents that the agency may decide to standardize. In addition, to respond to special circumstances such as those of fully integrated dual eligible SNPs that must meet both state and MA requirements for key member information (e.g., the ANOC/EOC), the agency has made exceptions to the required use of standardized documents. We recommend that CMS continue to exercise its authority to provide exceptions, as warranted.

- **Timely issuance.** To permit MA organizations/Part D sponsors to disseminate information to beneficiaries on a timely basis, we recommend that CMS ensure any standardized model documents are issued in final form well in advance of the time that they must be used to disseminate information to beneficiaries. Revisions or

corrections that are issued late in MA organization/Part D sponsor production cycles, particularly when the materials at issue are lengthy and complex (e.g., ANOC/EOC) seriously disrupt production and distribution processes and create significant challenges for sponsoring organizations to ensure that complete and accurate materials can be provided on a timely basis to beneficiaries. CMS indicates in the preamble that the agency intends to issue standardized marketing materials through the annual Call Letter and HPMS notices. We are concerned that the Call Letter is not issued early enough in the year to permit orderly planning and production when materials are standardized, because it may be necessary for sponsoring organizations to implement systems modifications as well as other changes to their materials development and production processes. Accordingly, we recommend that CMS issue standardized model materials as early as possible in the year through separate guidance.

- **Addressing all plan types.** Increased reliance by CMS on standardized materials will necessitate ensuring that the materials appropriately reflect the characteristics of all plan types. This may be accomplished by providing differing versions of the language on specific topics within the documents that are relevant to particular plan types or by identifying portions of the materials that may be customized by sponsoring organizations depending upon the plan type. For example, rules for obtaining services in and out of network differ if the MA plan is an HMO, a PPO or a cost plan. Beneficiaries enrolled in dual eligible SNPs need information about Medicare as well as Medicaid benefits and cost sharing information is affected by the availability of subsidies. SNPs must also be responsive to state requirements concerning, for example, the reading level of beneficiary materials. Differences among plan types also affect a variety of beneficiary notices that are currently model documents.

- **Beneficiary notices.** Currently, MA organizations and Part D sponsors have received CMS approval for a variety of beneficiary notices that do not utilize the language included in CMS models. Enrollees in the plans offered by these sponsoring organizations are accustomed to the language and format of these materials (e.g., Part D EOBs) which in a number of cases have been consumer tested as well as refined based upon experience to provide clear and beneficiary-friendly information. In a number of instances sponsoring organizations have also received enrollee feedback expressing satisfaction with the materials. Efforts by CMS to improve such materials by standardizing them have the potential to cause beneficiary dissatisfaction with the required changes. We also note that while standardization of some types of information across sponsoring organizations can be useful for beneficiaries (e.g., the standardized Summary of Benefits), many other communications are not used to

make comparisons and the value of standardization may be lower than maintaining the stability of materials to which enrollees are accustomed.

For these reasons, AHIP recommends that CMS reconsider whether and to what extent increased standardization of MA organization and Part D sponsor materials is in the best interests of beneficiaries and in making this assessment that CMS seriously consider issues such as those identified above. We recommend that CMS defer the proposed change to the regulations pending completion of this analysis. If the agency moves forward to standardize additional materials that are disseminated by MA organizations/Part D sponsors to beneficiaries, we recommend that CMS staff, rather than contractors on the agency's behalf, do so in consultation with MA and Part D organizations to gain insight concerning their experience with the design and content of non-model materials. We also urge that CMS place a strong emphasis on ensuring that any standardized materials are issued in final form well in advance of the time when they must be provided to beneficiaries, as discussed above.

5. Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services (§422.100; Preamble, p. 54657)

CMS is proposing to add §422.100(d)(4) to require that all local MA plans establish an out-of-pocket maximum that must include all Medicare Part A and Part B covered services and that is no greater than the annual limit set by CMS. The preamble discussion explains that CMS believes a maximum cap that is both standard and mandatory for all local MA plan types is necessary to ensure that MA plans are non-discriminatory and transparent. While we believe that out-of-pocket maximums are a valuable supplemental benefit for beneficiaries, we are concerned that a requirement that all MA plans include such a limit at no more than a specified level would require increased premiums that are likely to be a barrier that hinders the opportunity for some beneficiaries to choose an MA plan and makes it difficult for others to remain in an MA plan that they have previously elected.

- The preamble notes that this new requirement "will likely result in increases to premiums and/or cost sharing." According to a recent report, almost half of all MA enrollees have annual incomes below $20,000. An increase in MA premiums and required cost-sharing would likely have a significant effect on the ability of these enrollees to remain enrolled in or choose an MA plan.

- The impact on enrollees in dual eligible SNPs is likely to be especially acute. It is our understanding that most dual eligible SNPs offer a benefit package that reflects cost sharing under FFS Medicare to coordinate with cost sharing subsidies available for enrollees. Under CMS bidding rules, SNPs that utilize this benefit structure are able

to make enrollment accessible to beneficiaries by offering zero premium plans. The effect of the CMS proposal would be to shift beneficiary costs from cost sharing to premium in order to accommodate the out-of-pocket cap. Since dually eligible beneficiaries are unlikely to be able to afford the premiums, the impact of such a change would differentially impact their ability to choose MA plans. However, other lower income beneficiaries are likely to be similarly affected and could find that MA plans are foreclosed as an option because all MA plans must include the same out of pocket cap. The impact would be particularly disruptive for current members who may be unable to keep their MA plans.

- The impact of an out-of-pocket maximum requirement could also adversely affect the availability to beneficiaries of PPOs. The preamble explicitly addresses the application of the cap to local PPOs and states that the cap would be inclusive of all in-network and out-of-network beneficiary cost sharing. To offer the flexibility for beneficiaries to receive covered services in- or out-of-network at their election while keeping these MA plans affordable for beneficiaries, PPOs establish differential cost sharing to encourage enrollees to consider choosing in-network providers with whom the MA organizations works to promote efficient delivery of quality care. A requirement for a single out-of-pocket maximum for all Medicare covered services would seriously weaken the incentives for the use of in-network services that are fundamental to this plan type. This would exacerbate the potential for increased premiums or increased cost sharing that could reduce the value of and accessibility to this plan type for beneficiaries. While still problematic, a requirement that permits establishment of separate in- and out-of-network out of pocket maximums would mitigate this problem.

- Individuals who could benefit from enrollment in a chronic care SNP could also be adversely impacted. These SNPs focus on beneficiaries with high health care needs and a requirement to offer an out-of-pocket cap would mean that premiums for these plans would be differentially higher than for other types of MA plans. As a result, these SNPs would likely be unaffordable for the beneficiaries they are designed to serve.

- AHIP questions whether a requirement for an out-of-pocket maximum is an appropriate exercise of CMS' authority to ensure that benefit designs are non-discriminatory and do not substantially discourage enrollment of subpopulations of beneficiaries. While we agree that CMS has a responsibility to implement effective safeguards for beneficiaries in this important area, we believe that the current approach, which focuses on an evaluation of specific cost sharing designs rather than establishing a standard that applies to all MA plans regardless of the structure of the proposed benefits carries out the statutory requirement. In contrast, we are concerned

that CMS' proposed approach does not appropriately reflect the intent of the statute. Further, as discussed above, we are concerned that the proposed policy may have unintended consequences that could have the effect of limiting beneficiary access to certain MA plans rather than ensuring their broad availability.

AHIP recommends that CMS retain the existing policy which applies criteria that include an out-of-pocket maximum in conjunction with cost sharing rules to serve CMS' goal of guarding against benefit designs that could discourage enrollment of certain beneficiaries. We believe that this policy strikes a balance that provides protection against potentially discriminatory benefit designs, while preserving flexibility that avoids unintended barriers to beneficiary access to the range of plan options contemplated by the MA statute. We support the high priority that CMS places on ensuring that benefit designs are both non-discriminatory and transparent to beneficiaries and would welcome the opportunity to contribute to improvements in beneficiary materials that would increase benefit transparency and the utility of information on which beneficiaries rely in evaluating the Medicare choices available to them. If CMS adopts the change to the regulation that the agency has proposed, we strongly recommend that it be modified in response to the issues raised in our comments above to avoid the potential for disadvantaging certain beneficiaries. In that event, we also recommend that the agency annually announce any mandatory cost sharing maximum well in advance of the deadline for bids submission (e.g., prior to the annual rate announcement) to allow MA organizations to take the requirement into account during the benefit design and bid development process.

6. Maximum Allowable Cost sharing Amount for Medicare Parts A and B Services and Prescription Drugs (§422.100 & §423.104, p. 54657-54658)

CMS is proposing to add §422.100(d)(5) and §423.104(d)(2)(iii) to provide authority for CMS to establish cost sharing maximums for Medicare Part A and Part B benefits under the MA program and for tiered cost sharing under the Part D program below which cost sharing would not have a discriminatory effect. The preamble states that the regulation would permit CMS to establish cost sharing thresholds for individual services to afford beneficiaries greater predictability and protection against high out-of-pocket costs in the event of high health care needs and ensure that high needs beneficiaries are not discouraged from enrolling in an MA plan. The CY 2010 Call Letter identified certain Medicare covered services that are of special concern to CMS and required that MA plan cost sharing for each of these services must not exceed the cost sharing that would apply under FFS Medicare, but it is unclear whether CMS intends to follow a similar practice under the proposed rule. We believe that the approach reflected in the CY 2010 Call Letter reflects an appropriate and effective strategy to ensure that cost sharing does not discourage enrollment of subpopulations of beneficiaries. If the proposed rule is intended

to signal CMS' interest in expanding the establishment of service-specific cost sharing requirements for many or all of Medicare Part A and Part B covered services, we question whether such a sweeping approach is consistent with the intent of the statute or necessary to safeguard beneficiary interests. We are also concerned, as with the proposed requirement for all MA plans to include out-of-pocket cost limits, that there could be unintended consequences that disadvantage rather than help beneficiaries.

We urge CMS to defer including in the regulation broad new authority that could result in establishment of benefit-specific cost sharing levels for many or all Medicare Part A and Part B benefits pending further evaluation of the potential for adverse consequences for the MA plan coverage offered to beneficiaries. We also recommend that, if CMS intends to significantly modify for CY 2011 the approach applicable to cost sharing for CY 2010 benefits, including changes to the cost sharing limits or the benefits to which they apply, the agency issue in draft detailed guidance early in 2010 to provide a sufficient opportunity for review and comment.

In the event that CMS adopts the changes included in the proposed rule, the preamble indicates that the cost sharing limits would be announced at the time of the Call Letter or "through HPMS memoranda during the annual bid and benefit package review process." Benefit and bid development typically begin months in advance of issuance of the final Call Letter and guidance on cost sharing that is issued subsequent to the submission of bids does not provide sponsoring organizations with a full and fair opportunity to take the requirements into consideration. AHIP recommends that CMS release this information in advance of the annual rate announcement to assure that MA organizations have ample time to consider established limits as they design their benefit packages.

7. Prohibition on Prior Notification by PPO, PFFS and MSA Plans Under Part C (§422.2, §422.4, & §422.105(b); Preamble, p. 54658-54659)

CMS is proposing to prohibit MA PPOs, PFFS plans, and MSA plans from encouraging enrollees to provide prior notification of services by providing lower cost sharing as an incentive for notification. AHIP opposes this proposal. AHIP believes that allowing prior notification programs serves beneficiary interests because the offer of lower cost sharing encourages the enrollee to voluntarily provide information to the MA organization that permits the organization to alert the beneficiary in advance of receiving the service that it may not be covered (e.g., because it is not medically necessary or is not a covered benefit). It is our understanding that the beneficiary confusion referenced by CMS as a key reason for proposing to prohibit voluntary prior notification arises principally in circumstances in which CMS has determined that MA organizations have mischaracterized the voluntary notification process as a requirement. AHIP recommends that CMS address this issue by identifying additional steps to enforce the existing

requirement (e.g., requiring greater clarity in enrollee materials). We recommend that the agency defer the proposed change to the regulation pending an assessment of the effectiveness of these steps. This approach would have the advantage of preserving the value of prior notification for beneficiaries and promoting consistent compliance with the requirement that such prior notification must be voluntary.

8. **Requirements for LIS Eligibility under Part D (§423.773; Preamble, p. 54659)**

   CMS is proposing to specify the period for which a full-subsidy eligible beneficiary will be deemed eligible for the Part D low-income subsidy (LIS) based upon when in the calendar year the eligibility determination is made. AHIP agrees that this approach adds clarity to the rules surrounding deemed status.

9. **Enrollment of Full Subsidy Eligible Individuals and Other subsidy Eligible Individuals Under Part D (§423.34; Preamble, p. 54659-54660)**

   CMS is inviting comment on all aspects of the agency's auto-enrollment and facilitated enrollment procedures for beneficiaries eligible for the Part D low-income subsidy, including ways to better assess the impact of these procedures on the dual eligible and LIS population and ways that the agency can better assist beneficiaries in identifying plan choices that best suit their individual drug needs, and encouraging them to make an active election. Part D sponsors make significant efforts to smooth the transition to Part D plans for full-subsidy eligible beneficiaries who are newly eligible for Part D or who switch plans as a result of reassignment due the calculation of the low-income benchmark each year and its impact on Part D plan premiums. We are aware of the ongoing interest in assisting LIS eligible beneficiaries in enrolling in Part D plans whose formularies are most compatible with the medications they take. However, for beneficiaries with multiple prescriptions such a process would be complex, and in any event formulary issues are only one dimension of coverage since aspects of plan operations such as the responsiveness of member service representatives and availability of medication therapy and disease management programs also materially affect the value of the plan to beneficiaries. Moreover, consideration should be given to assuring that any methodology for auto-assignment would not have the unintended effect of resulting in adverse selection for the recipient PDP sponsors. We would welcome the opportunity to work with CMS and other interested stakeholders on initiatives to improve the auto- and facilitated enrollment processes for LIS eligible beneficiaries.

10. **Special Enrollment Periods Under Part D (§423.380; Preamble, p. 54660)**

CMS is proposing to expand the special enrollment period for full-benefit dual eligible individuals so that it will be available to all LIS-eligible individuals. AHIP supports this proposal.

12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§423.464; Preamble, 54662-54664)

AHIP agrees with CMS that exploring alternative approaches to improving post-adjudication coordination of benefits due to retroactive Medicare enrollment and low-income subsidy changes is important. At this time, AHIP does not have any suggested recommendations for improvement. However, we would welcome the opportunity to participate in discussions with CMS regarding any proposed changes that CMS may consider in the future.

13. Time Limits for Coordination of Benefits (§423.466; Preamble, 54664-54665)

CMS is proposing to establish a three year time limit on Part D coordination of benefits. Thus, Part D sponsors would be required to coordinate benefits with other entities providing prescription drug coverage for a period not to exceed three years from the date on which the prescription for the covered Part D drug was filled.

AHIP recommends that CMS modify this period to be 18 months to coincide with the period that Part D sponsors have to submit PDEs. AHIP believes that an 18 month period is an adequate period of time to assure that all claims are filed. The shorter period allows the Part D sponsors to close their benefit years within a more reasonable period of time.

14. Use of Standardized Technology under Part D (§423.120; Preamble, p. 54665-54666)

CMS is proposing to add a new provision to require that sponsors and their intermediary processors establish and exclusively utilize unique RxBIN or RxBIN/RxPCN combinations to identify all Part D member claims, as well as to assign unique RxID identifiers to individual Part D beneficiaries. CMS notes in the preamble that most Part D sponsors assign unique identifiers. AHIP recommends that in establishing the proposed requirements CMS ensure that the agency accommodate continued use of unique identifiers that have already been established by Part D sponsors (e.g., with regard to length of identifiers and combination of characters) to avoid the necessity for resource intensive systems changes.

16. Prohibition of Mid-Year Mass Enrollment Changes by SPAPS Under Part D (§423.464(e); Preamble, p. 54667)

CMS is proposing to prohibit mid-year mass enrollment changes by SPAPs. AHIP agrees with CMS' assessment that such changes outside of the annual election period can be very disruptive, and we support this proposal.

17. Nonrenewal Beneficiary Notification Requirement Under Parts C and D (§422.506(a)(2)(ii)(A) & §423.507(a)(2)(ii)(A))

CMS proposes to modify §422.506(a)(2)(ii)(A) and §423.507(a)(2)(ii)(A) to provide beneficiaries affected by plan nonrenewals with notice 90 days, rather than the current 60 days, prior to the effective date of the nonrenewal. The provisions would require that when this notice is provided in written form, it must include a description of alternative plan options. However, in recent years, MA organizations/Part D sponsors have not received information about plan options sufficiently far in advance to enable them to print and disseminate the notice by October 1. For example, CMS did not release plan information for CY 2010 until October 1, 2009 and for CY 2009 until September 25, 2008. AHIP recommends that CMS revise the regulation, as needed, to ensure that the requirement for beneficiary notice is coordinated with the initial availability of the information sponsoring organizations are required to include in the notice.

18. Notice of Alternative Medicare Plans Available to Replace Nonrenewing Plans Under Parts C and D (§422.506(a)(2)(ii) & §423.507(a)(2)(ii); Preamble, p. 54668)

CMS is proposing to give the sponsoring organization the option of either providing enrollees of a nonrenewing plan with a written list of alternative MA plan options or placing outbound calls to ensure these enrollees know whom to contact to learn more about their enrollment options. If CMS adopts this proposal, we recommend that the agency clarify in the preamble or the regulation that the written list may be transmitted by mail or by e-mail in the case of beneficiaries who have opted to receive communications electronically.

19. Timeframes and Responsibility for Making Redeterminations Under Part D (§423.590; Preamble, p. 54668-54669)

- **Oral and written notice of redeterminations.** CMS is proposing revisions to §423.590 to allow a Part D sponsor to notify an enrollee of an adverse or favorable expedited redetermination orally, with a written confirmation mailed to the enrollee within three calendar days of the oral notification. This change aligns the Part D requirement with the MA requirement and codifies existing subregulatory guidance. AHIP believes that it is helpful for the appeals processes under the Part D and MA programs to be consistent, wherever appropriate, as in this case.

- **Explanation of conditions for approval of a wholly favorable redetermination.** CMS is also proposing to add §423.590(h), which requires that, when there is a completely favorable redetermination, the notice must explain the conditions of the approval in a readable and understandable form. Consistent with our comments concerning a similar requirement for completely favorable standard determinations and completely favorable expedited coverage determinations, while we believe that in the case of a redetermination that is wholly or partially adverse to the enrollee an explanation of a reason for the decision is an important element of the notice, the value of the explanation to the enrollee is unclear when the decision is wholly favorable, and we believe that the cost of providing this information for every wholly favorable redetermination outweighs its benefit. If CMS believes that enrollees may have an interest in this information, it would be more efficient to indicate in the notice that the Part D sponsor will provide the enrollee with an explanation of a wholly favorable redetermination upon request. We recommend that the proposed rule be revised accordingly.

23. Disclosure Requirements Under Parts C and D (§422.111(g) & §423.128(f); Preamble, p. 54669)

In §422.111(g) and §423.128(f), CMS is proposing to add a provision that gives the agency the discretion to require a sponsoring organization to disclose to its enrollees and potential enrollees information concerning the sponsoring organization's performance and contract compliance deficiencies in a manner specified by CMS. CMS states that such a disclosure "may be required when a sponsoring organization is sanctioned, or when a sponsoring organization's compliance and/or performance deficiencies rise to a certain level." CMS explains that this kind of transparency will provide additional incentives for sponsoring organizations to make improvements to their operations and also provide relevant information to beneficiaries and the public concerning plan choices. CMS is soliciting comment on whether these disclosure requirements should be imposed only in those circumstances where a beneficiary would be afforded the opportunity to act on them.

While we understand and appreciate the value of making available certain performance indicators to beneficiaries, CMS' intent regarding how beneficiaries would be notified and the purpose of the proposed self-disclosure is unclear. Notification sent to individual enrollees or provided to individual beneficiaries with marketing materials could be interpreted by beneficiaries as a signal that performance deficiencies may seriously impede the ability of the plan to continue to provide coverage and access to services. However, this interpretation would be unjustified because in such cases, CMS has the authority to take strong steps, such as contract termination or non-renewal or suspension

of enrollment. If CMS is interested in heightened transparency regarding certain deficiencies that the agency does not believe warrant such action, the relevance of the information to beneficiary decision making about Medicare options unclear. The value of the proposed disclosure is even more unclear, because in some cases, timing of the required disclosure could occur after or a short time before the deficiencies are resolved. Moreover, performance information is already provided through the Plan Finder and CMS CAP postings.

We are concerned that the proposed self-disclosure requirement would not serve beneficiary interests, because it could cause unjustified anxiety and unfairly imply that the plan deficiencies are more serious than CMS has determined. Accordingly, we recommend that CMS defer any self-disclosure requirement pending reevaluation of its value to beneficiaries and alternative means of supplementing the existing performance information available to beneficiaries through the Plan Finder and CMS CAP postings. If CMS nevertheless adopts such a requirement, we recommend that the agency issue subregulatory guidance, after informal review and comment, that identifies the criteria CMS will utilize in determining when self-disclosure will be required and that the agency take steps to ensure consistent application of the criteria.

Finally, we believe that, if CMS' goal is to provide beneficiaries with additional information to consider when they make plan choices, AHIP recommends that this information should only be disseminated during such periods when all beneficiaries have the opportunity to elect or switch plans.

C. Changes to Provide Plan Offerings with Meaningful Differences

1. Bid Submissions—Ensuring Significant Differences (§422.254 & §423.265, p. 54671-54672)

CMS explains in the preamble that the agency is proposing to include in the regulation a requirement that MA organizations and Part D sponsors may only submit multiple plan bids in the same area if the plans have meaningful differences in "key benefit or plan characteristics such as premiums, cost-sharing, formulary structure, or benefits." [Emphasis added.] We believe that this policy is workable and is consistent with CMS' existing policy as reflected in the 2010 Call Letter. However, we have noted that the proposed new regulatory provisions include language that is more limiting because it does not appear to reflect CMS' stated policy. Section 422.254(a)(4) requires that MA organization bid submissions must reflect substantial differences in "benefit packages and plan costs". [Emphasis added.] Section 423.265(b)(2) requires that Part D bids must reflect substantial differences in "beneficiary out-of-pocket costs and formulary structures." [Emphasis added.]

To clarify the regulatory language and conform it to CMS' intent as stated in the preamble, we recommend the following revisions:

- Revise §422.254(a)(4) as follows:

  (4) *Substantial differences between bids.* An MA organization's bid submissions must reflect differences in ~~benefit packages and plan costs~~ terms of key benefit or plan characteristics such as premiums, cost sharing, or benefits offered that CMS determines to represent substantial differences relative to a sponsor's other bid submissions.

- Revise §423.265(b)(2) as follows:

  (2) *Substantial differences between bids.* Potential Part D sponsors' bid submissions must reflect differences in benefit packages and plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to key benefit or plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered ~~beneficiary out-of-pocket costs and formulary structures.~~

2. Bid Review Process (§422.256 & §423.272; Preamble, p. 54672)

CMS is proposing to add §422.256(b)(4)(i) and §423.272(b)(3)(i) to make requirements for bid approval consistent with the requirements for bid submission discussed above. However the structure of these regulatory provisions is somewhat different than from the structure of §422.254(a)(4) and §423.265(b)(2). The revisions we recommended above for §422.254(a)(4) are already reflected in §422.256(b)(4)(i). However, in the Part D regulation, CMS cross-references the language in §423.265(b)(2). Assuming that CMS adopts AHIP's recommendations in the preceding comment, to avoid confusion by making these provisions parallel to one another, AHIP recommends that CMS revise §422.256(b)(4)(i) to cross-reference the language in revised §422.254(a)(4) and retain the cross-reference in §423.272(b)(3)(i) to §423.265(b)(2).

4. Non-renewing Low-Enrollment Plans (§422.506(b)(1)(iv) & §423.507(b)(1)(iii); Preamble, p. 54673)

CMS is proposing to add a regulatory requirement providing that a contract must be nonrenewed as to an individual plan if the plan does not have a sufficient number of

enrollees to establish that it is a viable independent plan option. The preamble language discusses how this requirement would be applied. For example, CMS would consider a waiver of the requirement in special circumstances, such a chronic care SNP which is tailored to a specific category of beneficiaries or employer group waiver plans. CMS solicits comment on the agency's proposed approach and whether CMS has provided sufficient clarity on how the agency will determine whether a low-enrollment plan will not be nonrenewed.

AHIP believes that, in general, the elements of CMS' proposal are reasonable, including establishment of an enrollment threshold that may be waived by CMS if the agency determines that this action is warranted by circumstances such as the type of beneficiary served or geographic location. We offer several recommendations for clarifying and refining the proposal.

- First, we recommend that CMS add to the grounds for considering a waiver the length of time that a plan has been offered. This recommendation reflects the agency's stated intent that in order to warrant nonrenewal, low-enrollment would need to persist over an extended period (e.g., several years).

- Second, consistent with the language in §422.506(b)(1) and §423.507(b)(1), which provides that CMS may nonrenew a contract for the listed reasons, we recommend that that CMS revise the proposed regulatory language in §422.506(b)(1)(iv) and §423.507(b)(1)(iii) by adding at the end of this subparagraph, "CMS may waive this requirement when special circumstances are present, including but not limited to the type of beneficiaries served, geographic location, and when absence of the plan would significantly limit beneficiary health care options in a service area."

- Third, we recommend that CMS announce the annual enrollment threshold for plans that would be subject to nonrenewal as early as possible in the calendar year to permit sponsoring organizations to take impact of this threshold into consideration during their planning and bid development for the subsequent calendar year. While we understand that the Call Letter has been the means of making this announcement, in some years it has been issued later in the spring when preparations for the coming year are well underway.

D. Changes to Improve Payment Rules and Processes

1. Risk Adjustment Data Validation (RADV) Appeals (§422.310; Preamble, p. 54673-54678)

CMS is proposing an appeals process (§422.311) for RADV audits and the addition of related definitions to §422.2. CMS' proposal would make three avenues available to MA organizations as possible remedies for findings that result in payment errors. These are: an attestation process, a documentation dispute process, and a RADV payment error calculation appeals process. The preamble includes a discussion of the history of the CMS HCC risk adjustment methodology and CMS' risk adjustment data validation initiatives, as well as CMS' rationale underlying the proposed elements of the appeals process.

AHIP has consistently supported CMS' efforts to ensure that the MA risk adjustment methodology is designed to pay MA organizations appropriately based upon the health status of their members and the resources needed to treat the conditions that they experience. We understand that CMS has a responsibility to ensure payments are calculated accurately under this methodology and that MA organizations are accountable on audit for demonstrating the integrity of the data they submit. However, we have a number of serious concerns about the initial design of the current RADV audits and about the appeals process proposed for inclusion in the regulation. These issues and our related recommendations are discussed in detail below. We are interested in working with CMS as the elements of the risk adjustment data validation audit process continue to evolve.

b. Risk Adjustment Validation Initiatives (Preamble, p. 54674)

Under this subheading in the preamble, CMS explains that risk adjustment diagnoses from FFS claims and from MA organization risk adjustment data submitted to CMS are used to assign a risk score to each MA enrollee and that these risk scores are used in the enrollee-level MA payment calculation. The agency audits the MA diagnosis data a few years after submission to ensure they are supported by medical record documentation. CMS indicates that this documentation is the key to accurate payment and successful data validation. While in some past years data discrepancies resulted in payment adjustments on an enrollee-specific basis, the current audit design calls for contract-level payment adjustments and has been initiated for the 2007 payment year because it is the first year in which 100 percent of MA payment amounts were risk adjusted.

We recognize the importance of MA organization submission of reliable diagnosis data for the purpose of risk adjustment and understand that the preamble is intended to provide only a high level description of the MA risk adjustment audit initiative. However, we believe that the emphasis on medical record documentation for MA diagnosis data as "the key to payment accuracy" fails to acknowledge that a comparable evaluation of FFS medical record documentation error rates is critical to

assessing payment accuracy, because of the role data from both sources play in the risk adjustment methodology. We urge CMS to conduct such an evaluation.

In addition, we have serious concerns that establishment of an audit methodology that involves retrospective contract-level payment adjustments creates the potential for unpredictable retroactive liability that MA organizations could not have considered in developing bids for affected prior years. We recommend that CMS take this critical issue into consideration as further decisions are made about the RADV audit methodology.

The uncertainty associated with the unknown extent of potential multi-year retroactive adjustments has been exacerbated by CMS' decision to move forward with the first group of 2007 audits prior to finalizing the audit design, including the methodology for determining any payment adjustments as well as the proposed appeals process. We recommend that CMS ensure that organizations selected for the pilots or the first group of audits are not disadvantaged in comparison to other MA organizations audited for the same payment year in the event that CMS makes improvements to the audit design in response to comments on the proposed rule or as a result of decisions reflected in subregulatory guidance.

d. Proposed Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures (§422.311; Preamble, p. 54674-54678)

As a result of CMS' experience to date in conducting MA RADV audits, which has included MA organization requests for an appeals remedy, the agency is proposing establishment of formal dispute and appeal rights for MA organizations undergoing RADV audits. We commend CMS for taking this important step, and we support establishment of a RADV audit appeals process. However, while the CMS proposal focuses on three key avenues for MA organizations to seek relief from potentially erroneous determinations, we believe that the scope of issues that may be raised in each case is too narrow, so that the proposal either fails to provide an opportunity to pursue the issues that are likely to be of greatest importance to organizations experiencing RADV audits or is otherwise unduly limited. We believe that substantial changes are essential in each area to provide meaningful appeal rights for MA organizations and that it is critical for CMS to provide an appeal right for all issues that could be subject to error or other material, unintended defects at each step of the audit process and payment error calculation. Our comments below address each of the avenues of appeal CMS has proposed and provide our recommendations.

- **Attestations.** Under CMS' proposal, MA organizations would be permitted to voluntarily submit to CMS pre-populated attestations that address signature and/or credential-related discrepancies from physician or outpatient medical records. Completed attestations must be submitted by the deadline for submission of medical records to substantiate the HCCs selected by CMS for the audit sample. We strongly support CMS' decision to permit the use of attestations, although we have identified several significant issues regarding the details of CMS' proposal that are discussed below.

  + First, CMS states that based upon its experience the agency has reached conclusions regarding the percentage of medical-record-related payment error determinations that are attributable to missing or illegible signature or credentials – a substantial percentage for physician and outpatient records and a relatively small percentage for inpatient records. We believe that these conclusions are premature, because previous CMS RADV reviews have been limited and the pilot audits for the 2007 payment year represent a relatively small sample in comparison to the first audit group that has recently received notice of the enrollee HCCs in the audit sample. Accordingly, we recommend that CMS revise proposed §422.311(c)(1)(ii) and §422.311(c)(1)(iii)(C) to permit attestations for inpatient, as well as physician and outpatient records, to avoid the potential for disadvantaging MA organizations pending additional experience for CMS and affected organizations.

  + Second, proposed timing for submission of attestations is likely to make it difficult for MA organizations to take full advantage of the opportunity for their submission. Following notification by CMS of the HCCs for which medical record documentation must be provided, it is highly labor intensive for MA organizations to identify the medical records that will be submitted for CMS review. Typically, MA organizations must conduct outreach to physicians, hospitals, and other practitioners and providers to request medical records substantially larger in number than the sample of HCCs identified by CMS in order to conduct reviews of these records to identify the best record for submission to CMS. In the event that practitioners cannot be located (e.g., practitioners who have retired, relocated, or died, or whose records have been destroyed, for example, in a fire or flood), initial efforts to obtain a record may be unsuccessful and the MA organization may need to pursue additional requests. These steps are time consuming, and we are concerned that organizations will face significant challenges reaching out to physicians to complete attestations during the same period they are completing data collection and review. Therefore, we recommend that CMS revise the proposed rule by providing that CMS will establish a period subsequent to the

submission deadline for medical records for MA organizations to obtain and submit physician/practitioner attestations. We recommend that the length of this period be established in subregulatory guidance, so that it can be adjusted based upon practical experience with the audit process.

+ Third, CMS is proposing in §422.311(1)(v)(C) that the CMS-generated attestation must be completed, signed, and dated by the physician/practitioner. While we understand that the signature/date must be supplied by the physician/practitioner, we believe that MA organizations should be able to facilitate completion of the attestation by pre-populating other information. MA organization experience has been that physician/practitioner offices may make errors in completing such an attestation or fail to include all required information before returning the attestation to the organization. Additional time and MA organization resources are required to work with physicians/practitioners to address these errors and the burden for physicians/practitioners is increased. This problem is more serious if CMS retains the requirement for submission of attestations by the deadline for medical record submission but is substantial even if a later attestation deadline is established. We urge CMS to play an active role in educating physicians about their obligation to provide medical records for RADV audits and complete attestations fully and accurately when requested to do so by MA organizations.

+ Fourth, as CMS has also observed under the Medicare fee-for-service (FFS) program, practitioner medical record documentation and coding practices vary in the extent and consistency of their compliance with the medical record documentation standards that CMS has established. The Department of Health and Human Services in a recent report required by the Improper Payments Information Act indicated that the agency plans to work with FFS practitioners to improve medical record documentation practices. We continue to recommend, as we have in the past, that CMS engage in collaborative efforts with MA organizations to improve compliance among Medicare participating practitioners. We also recommend that CMS consider broadening the permissible use of attestations under the initial RADV audits to permit the agency and the affected MA organizations to evaluate the implications of such a step. We understand that CMS has also proposed a documentation dispute resolution process but as discussed below, we do not believe it would serve a similar purpose.

- **Documentation dispute process.** CMS is proposing to permit MA organizations to appeal the operational processing of medical records that are submitted by the

CMS-established deadline. The example provided by CMS of an appealable error is the inadvertent separation of a two page medical record so that each page is reviewed as a separate medical record. Further, the proposed approach provides for CMS review that encompasses only errors that appear in the MA organization's RADV audit report. We support establishment of a means of appealing issues related to CMS review of RADV medical record documentation, but we believe that this appeal opportunity is so narrowly focused that it does not provide a meaningful avenue for MA organizations to seek resolution of issues arising from CMS review of medical record documentation.

While we understand that CMS has a number of years of experience conducting these reviews, and we appreciate CMS' efforts to structure its use of contractors with expertise in medical record coding to ensure the consistency and fairness of results, we believe it is unlikely that even the best review process can be completely free of errors on the fundamental issue of coding in the medical record that supports a specified HCC. In light of the potential for RADV audits to result in retroactive payment adjustments, we believe it is critical for CMS to provide reasonable opportunities for MA organizations to pursue appeals when they disagree with CMS' determination that a diagnosis is not supported by the submitted medical record. By foreclosing appeal on this critically important issue, we believe that this layer of the appeals process is rendered wholly inadequate to address MA organization concerns that may arise regarding one of the most important findings resulting from the RADV audit process. We recommend that CMS revise §422.311(c)(2) to extend the documentation dispute process to permit MA organizations to appeal potentially erroneous determinations regarding medical record coding or other documentation issues.

Further, under the limited appeal right CMS has proposed, the proposal restricts CMS' review to errors that are reflected in the MA organization's audit report. It appears that this review would not encompass errors arising from omissions from the report. We believe that this incomplete scope of review undermines the integrity of the appeals process and recommend that CMS revise §422.311(c)(2)(iv) to encompass all errors that may have occurred by eliminating the qualifying language that the errors be "listed in the MA organization's RADV audit report."

- **RADV payment error calculation appeal process.**
  - CMS is proposing to establish a process that provides an opportunity for appeal of the RADV payment error calculations. The agency explains that MA organizations may request reconsideration of the RADV payment error

calculation and proposes that the following three levels of appeal would be available:

-- The first level would include recalculation of the payment error by a CMS official or contractor not otherwise involved in payment error rate activity who would utilize CMS' RADV payment error rate calculation methodology. The outcome of this review reflecting agreement or disagreement with the result of the original RADV payment calculation would be provided to a CMS reconsideration official who would accept or reject the finding.
-- This first level decision is final and binding unless CMS or the MA organization is dissatisfied with the result of the review in which case, either party may request a hearing on the RADV payment error calculation determination.
-- The second level decision of the Hearing Officer is final and binding unless CMS or the MA organization is dissatisfied with the result of the hearing in which case either party may request discretionary review by the CMS Administrator.
-- If the Administrator agrees to review the case, the decision at this third level of appeal is final and binding.

We support establishment of an avenue for appealing issues that arise as a result of the RADV payment error calculation. While we appreciate that CMS has included such a process in the proposed rule, as with the documentation dispute process, we believe that the limited scope of the appeal right does not permit MA organizations to pursue critical issues that are likely to arise as the payment error calculation methodology is implemented. For example, we do not believe it is reasonable to expect that no errors or other material issues will arise with regard to such elements as the sampling methodology, the determination of the error rates flowing from identified documentation deficiencies, and application of the steps in payment error calculation to specific contracts, including but not limited to the narrow issue that is the focus of the proposed rule. This is particularly true because there is no previous experience with the new methodology that CMS will employ, and the magnitude of the retroactive payment adjustments that may result from its application is unpredictable. In light of the potentially significant implications of the RADV payment error methodology, we believe it is untenable for the appeals process to fail to provide MA organizations with the opportunity to seek resolution of issues arising from implementation of the payment error calculation methodology, including the statistical validity of both the sampling and extrapolation underlying the calculation. We recommend that CMS revise §422.311(c)(3) to provide that the scope of the appeal right would include these critically important issues.

+ In addition, with respect to the narrow appeal right related to the RADV payment error calculation that is included in the proposed rule, we have identified the issues and recommendations below.
  -- We agree that review of the calculation by a third party who is not otherwise involved in the RADV payment error calculation error reviews is the appropriate first step. However, the preamble explains that the findings of the third party reviewer may be accepted or rejected by a CMS reconsideration official. Neither the preamble nor the proposed rule specify the qualifications of this official nor do they specify the criteria that will be used to determine whether the third party's findings will or will not be accepted. If the purpose of the third party review is to provide an objective analysis of the calculation, it appears that this purpose is undermined by providing that the decision to accept the findings rests with the reconsideration official. We recommend that the proposed process be revised to require acceptance of the third party's findings or otherwise ensure that the decision on the findings is not made by an official who has a role in the RADV payment error calculation that is under review.

+ Further, the preamble indicates that CMS intends to provide an annual notice of the methodology that the agency will use to calculate Part C payment errors and that there will be an opportunity for MA organizations to comment on the methodology. We support this annual comment process, but note that the preamble does not explicitly state that CMS intends to provide an opportunity to comment prior to the initial establishment of the payment error calculation methodology. Due to the critical importance of ensuring that this methodology is fair and reasonable, we recommend that CMS provide a process that permits thorough review and comment by MA organizations prior to initial implementation of the methodology and annually thereafter, including for example, a 45 day review period and inclusion in CMS' final announcement of the methodology a discussion of the agency's response to comments. We also recommend that CMS ensure that the announcement of the payment error calculation methodology for RADV audits of data used for risk adjustment in the subsequent payment year takes place sufficiently far in advance of the bid submission deadline for that payment year that MA organizations can take it into consideration as they develop their bids for that year (e.g., well in advance of issuance of the MA payment rates for the payment year).

3. Determination of Acceptable Administrative Costs by Cost Contracts and Health Care Prepayment Plans (§417.564; Preamble, p. 54679)

- **Apportionment and allocation of administrative and general costs.**

  - **List of excluded costs.** CMS is proposing to include in the regulations a new §417.564(c), which contains a list of costs that must be excluded from administrative costs. AHIP's understanding is that these costs currently cannot be included in cost reports and that the new provision codifies existing CMS policy regarding the allowability of these costs. AHIP believes that clarification of the treatment of these costs in the regulation is constructive.

  - **Revisions to rules on documentation of administrative and general costs.** CMS is proposing to add a new §417.564(b)(iii) that would require, for the costs included under §417.564(b)(1)(i) - §417.564(b)(1)(iv), that include personnel costs, the cost plan:

    > must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

AHIP understands the importance of cost plans being able to document and make available to CMS during audit information that supports the costs claimed on their cost reports. AHIP recommends that CMS provide through guidance further clarification regarding CMS' expectations about how cost plans will document this information, including examples of how time should be tracked and how to evaluate the match between skill level and tasks performed. Such guidance will promote a common understanding of the requirements among cost plans and CMS' cost contract auditors. We recommend that CMS provide cost plans an opportunity to comment on this guidance before it is finalized to ensure that operational issues can be fully considered and urge CMS to ensure that the documentation requirements will be reasonable and structured in a manner that is not unduly burdensome to cost plans. In addition, to permit cost plans to take the steps necessary to comply with any new requirements resulting from the proposed change to the regulation, we recommend that such requirement apply to cost years following the year in which the regulation is effective.

E. Changes to Improve Data Collection for Oversight and Quality Assessment

1. Requirements for Quality Improvement Programs Under Part C (§422.152, §422.153 & §480.140; p. 54680-54681)

a. Quality Improvement Programs (§422.152(a)(1) & §422.152(a)(2); Preamble, p. 54680)

CMS is proposing to revise §422.152(a)(1) and §422.152(a)(2) to require that MA organizations conduct Chronic Care Improvement Programs (CCIPs) in patient populations and conduct quality improvement projects in areas identified by CMS based on the agency's review of data collected from MA organizations and the population served by the plan. The agency explains in the preamble that CMS intends to provide guidance on specific quality improvement projects that MA organizations must implement based upon an organization's specific quality improvement needs, or quality improvement needs for MA plans generally. CMS also intends to suggest methods and processes by which organizations should manage a quality improvement project, as appropriate.

Quality improvement programs and projects designed to promote quality care and service for health plan members are a hallmark of the MA organization health care delivery systems. The capacity to pursue quality improvement projects focused on strengthening plan and provider performance to positively impact health outcomes and quality of life for plan enrollees is fundamental to the value that they offer their members. Many MA organizations are accredited by the National Committee for Quality Assurance (NCQA) or another accrediting body and are deemed to comply with CMS quality assurance requirements by meeting the comparable standards of these bodies. The standards include reviews to ensure that the organizations pursue quality improvement projects that are meaningful to their members.

While the nature and scope of quality improvement activities is necessarily tailored to the plan type, as well as the characteristics of MA plan enrollees, all MA organizations dedicate substantial resources to quality improvement activities. The concerns that CMS expresses in the preamble about the focus and effectiveness of MA organization quality improvement projects and CCIPs indicate that the agency believes these existing activities should be enhanced and potentially modified. While AHIP member organizations are committed to working to strengthen their programs and performance on an ongoing basis, we have the serious concerns, which are discussed in detail below, that the strategy CMS has proposed to achieve this goal does not take advantage of the longstanding MA organization experience and achievements in the quality arena and may not be sufficiently responsive to the unique circumstances of MA enrollees and the plans that serve them. Further, we believe that the agency's proposed rule could have the unintended consequence of drawing resources away from MA organization priorities that are customized to focus on areas they have determined would be of particular benefit to their enrollees.

We note that while the focus of our comments is on the importance of ensuring that MA organizations can continue to pursue quality initiatives that are integral to their operations in the context of the CMS proposal, there are efforts underway in which AHIP and our member organizations are proactively engaged that are focused on improving health care quality for all Americans and across all public and private product types. By fostering collaboration across a broad array of stakeholders to focus efforts on consensus measures and projects that address critical national health care quality priorities, these efforts have the potential to raise the performance of the health care system for the benefit of all patients. AHIP member organizations participating in the MA program are committed to taking part in these nationally focused initiatives, as well as contributing to community-based efforts that may complement the national quality agenda, and we believe that the involvement of the Medicare fee-for-service program is also essential to their success. AHIP looks forward to working with CMS and the full spectrum of stakeholders in the health care sector as these important efforts continue.

Our issues and recommendations related specifically to CMS' proposed changes to the MA regulation are discussed in detail below:

- **Responsiveness to unique characteristics of MA organization enrollees and delivery systems.** In selecting their quality improvement projects MA organizations take into consideration detailed internal data as well as the HEDIS, CAHPS and HOS data that are reported to CMS. They also consider such factors as the demographic and health status mix of their enrollees; short term and longer term goals and the opportunities to pursue organization-wide initiatives that include population-specific evaluations; opportunities to leverage other ongoing and anticipated initiatives in clinical and non-clinical areas; previous project topics and their results, including the evaluation of targeted interventions; strategies most likely to be effective in light of provider relationships and related delivery system characteristics related to plan type and other factors; and a host of other operational considerations. MA organization decisions about the focus of their chronic care improvement programs similarly take into consideration quality goals and implementation strategies that are informed by a variety of organization and plan-specific operational and other factors related to the populations they serve.

  Consequently, if CMS mandates topics for quality improvement topics and specifies populations for CCIPs, these requirements may not be aligned with priorities MA organizations identify to benefit their enrollees and the organizations may face significant challenges in allocating sufficient resources to

both streams of activities. Further, in some cases, MA organizations could be required to pursue projects in areas in which they are already performing at a high level rather than focusing their resources in areas they believe should be strengthened. We believe that these circumstances argue strongly for continued flexibility for MA organizations to identify the focus of their quality initiatives and CCIPs.

If the agency's goal is to address concerns about the performance of specific organizations, we believe the existing regulation provides this authority. If CMS is interested in comparing performance across MA organizations, the HEDIS, CAHPS, and HOS measures appear to provide a broad range of well-established measures that could be utilized in a manner that would enrich currently available information for beneficiaries. While we appreciate that community-based quality improvement initiatives can make a valuable contribution to broad-based efforts to heighten health care quality and our member organizations actively participate in such initiatives, we also believe it is critically important to preserve the flexibility of MA organizations to pursue projects of special clinical and operational value to their enrollees. We are concerned that the proposed rule could hinder these efforts.

- **Deemed Status.** An additional consideration for MA organizations in selecting and designing their quality improvement projects is to ensure that their initiatives are consistent with the requirements for maintaining their accreditation by NCQA or other accrediting bodies. We are concerned that if CMS establishes required topics for quality improvement projects and designates populations for CCIPs, these requirements could impinge on the efforts of MA organizations to satisfy accreditation standards. It is our understanding that one reason for the approach currently reflected in CMS' quality improvement program requirements is to coordinate with and leverage the impact of well-respected private sector accreditation programs as well as to permit MA organizations to pursue organization-wide projects and participate in community projects that offer opportunities to benefit all of the populations served in addition to engaging in targeted initiatives they may implement for MA plan enrollees. CMS' adoption of Healthcare Effectiveness Data and Information Set (HEDIS) and Consumer Assessment of Health Providers Survey (CAHPS) reporting requirements is evidence of this focus. We urge CMS to continue to provide the flexibility necessary to facilitate MA organization contributions to broader quality improvement initiatives, particularly in light of the importance of such efforts in the context of health care reform.

- **Coordination of MA and State Requirements for Dual Eligible Special Needs Plans (SNPs).** Dual eligible SNPs that also have contracts with state Medicaid agencies must comply with state as well as MA requirements to pursue quality improvement projects. We are concerned that dual eligible SNPs will face significant challenges meeting state as well as MA requirements in the event that CMS requirements for specific quality improvement topics differ from the focus of state requirements. Dual eligible SNPs could be required to pursue an increased number of mandated projects which as discussed above could hinder their ability to allocate sufficient resources for required activities as organization-specific priorities. Because they must meet Medicaid as well as Medicare requirements, dual eligible SNPs could also face a higher burden than other MA plan types. We note that CMS has been engaged in the development of SNP-specific quality measures for all SNP types and we believe this initiative has the potential to provide a more effective means of promoting SNP accountability for quality performance based on dimensions that are tailored to their enrollees' characteristics.

AHIP shares CMS' interest in promoting strong MA organization performance in the implementation of quality improvement projects that serve enrollee interests. However, in light of the concerns described above, we believe that the approach reflected in the proposed rule is problematic and we recommend that CMS revise the proposed rule to defer establishment of any general requirement that MA organizations implement CMS-determined quality improvement projects and establish chronic care improvement programs for CMS-identified populations. We recommend that CMS initiate an ongoing dialogue with MA organization staff experts in quality improvement to assist the agency in assessing the operational implications of the proposed approach, explore alternative approaches, and explore avenues for identifying and disseminating best practices for all plan types. AHIP and its member organizations would welcome the opportunity to participate in such a process.

c. Use of Quality Improvement Organization for Review Information (§422.153 & §480.140; Preamble, p. 54681)

CMS is proposing to collect quality review study (QRS) information from Quality Improvement Organizations (QIOs). The preamble states that this information could be used to develop a standardized core set of clinical and non-clinical quality measures that could be applied to all MA plans. CMS indicates that the agency plans to use these measures to develop minimum performance levels and requirements that address clinical and non-clinical areas. The agency envisions utilizing these data to

allow beneficiaries to make better comparisons among plans, ensure compliance, and create a competitive value-based purchasing program based upon quality of care.

While AHIP supports efforts to provide beneficiaries with better information on which to base informed decisions when selecting an MA plan, the value of supplementing HEDIS, CAHPS, and HOS information with QRS information is unclear. Our concerns about the proposed uses of QRS information include:

+ **Consistency of QIO assessments/findings.** HEDIS, CAHPS, and HOS measures have been developed and tested over many years and are standardized so that they are applied in a consistent manner. It is our understanding that QIO assessments of an issue may differ from QIO to QIO, meaning that MA organizations can receive differing assessments of the same issue, depending on the reviewing QIO. Such inconsistency raises a fundamental issue about the appropriateness of using these data for the purposes CMS has identified.

+ **Timeliness of QIO assessments/findings.** We understand that MA organizations have experienced substantial delays in the receipt of QIO study findings, so that MA organizations do not have timely notice of deficiencies, if any, that are identified through these studies nor are the findings available for use in MA organization quality improvement activities. Further, substantial delay in dissemination of findings suggests that this information may not be sufficiently timely for CMS' intended purpose.

In light of these concerns, we recommend that the agency reconsider the proposed use of QRS information and that the agency defer the proposed revision of the MA and QIO regulations to provide authority for CMS to obtain QRS data and utilize it for the purposes specified in the proposed rule. We recommend that CMS include the issues of current MA experience with QIO studies and the potential future uses of QRS information in the dialogue with MA organizations that is proposed in our comment above to inform CMS' further evaluation of this issue.

2. **CAHPS Survey Administration Under Parts C and D (§417.472, §422.152, & §423.156; Preamble, p. 54681)**

- CMS is proposing to codify the requirement announced in the 2010 Call Letter for cost plans, MA organizations and PDP sponsors with 600 or more enrollees in July of the prior year to enter into contracts with CAHPS survey vendors to conduct the satisfaction survey. We have one technical comment. AHIP recommends that CMS revise the proposed regulatory language in §422.152(b)(5) to eliminate the reference to cost plans that has been included in error. Application of the requirement to these

organizations is accomplished through the cross reference proposed for inclusion in the cost plan regulations at §417.472(i).

- CMS is proposing in §417.472(i) to require cost plans to contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey for "MA plan enrollees." We recommend that CMS correct this error by deleting "MA plan enrollees" and inserting "cost plan enrollees." We also recommend that CMS remove references to plan types other than cost plans from the proposed new language in §417.472(j).

3. **Validation of Part C and Part D Reporting Requirements (§422.516 & §423.514; Preamble, p. 54682)**

CMS is proposing to add a paragraph (g) to §422.516 and §423.514 to require each Part C and Part D sponsor to subject information collected under paragraph (a) of those sections to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS. We understand CMS' interest in requiring validation of data that is submitted by sponsoring organizations to CMS and agree that submission of required information that is accurate and complete is an important priority under the MA and Part D programs. CMS is already moving forward with a new initiative to require validation and is in the process of refining detailed guidance on this topic.

We appreciate that the agency is seriously considering operational issues raised by MA organizations and Part D sponsors as the guidance is developed. AHIP believes that the extent and complexity of the validation requirements may necessitate adjustments as implementation occurs to ensure that the initiative makes efficient and effective use of the resources of sponsoring organizations and CMS, while at the same time serving CMS goals. We are concerned that the proposed regulatory language may not provide sufficient flexibility to permit changes that CMS determines are desirable. For example, we understand that CMS may identify a subset of reported information that must be validated for the initial year of the audit, and it is unclear whether the proposed regulatory language would accommodate this approach.

For this reason, we recommend that the proposed new paragraph (g) be revised by striking "Each Part C [Part D] sponsor must" and inserting instead, "CMS may require each Part C [Part D] sponsor to..." Further, to provide additional flexibility, we recommend that CMS strike "independent audit" and insert "audit". We believe these changes will provide the regulatory foundation for the validation requirement while

permitting CMS to refine the design of the initiative or consider alternative approaches in response to issues identified as implementation takes place.

4. **Collection of Additional Part D Claims' Elements for Nonpayment-Related Purposes (§423.505; Preamble, p. 54683-54684)**

CMS is proposing to amend §423.505 to expand to all data elements included in PDE data the authority for these data to be used for non-payment related purposes. CMS is also proposing to revise the regulation to permit the release of data that includes unencrypted Part D plan identifiers to HHS grantees that meet certain criteria in addition to contractors conducting studies on behalf of CMS. It is our understanding that HHS grantees are numerous and diverse, and we do not believe that the preamble provides sufficient information about the subset of grantees that CMS believes should receive these data or the number, scope, and purpose of the studies for which it would be used. We also believe that the criteria proposed for inclusion in §423.505(m)(1)(iii)(C)*(1)*, *(2)*, *(3)*, and *(4)* are not sufficiently detailed and specific. For these reasons, AHIP opposes this proposal and recommends that CMS eliminate the changes from the proposed rule because safeguards for use of the data are insufficient.

F. Changes to Implement New Policy

1. **Protected Classes of Concern Under Part D (§423.120(b)(2)(v); Preamble, p. 54685-54689)**

CMS explains in the preamble that the agency has decided, based upon the comments received, to revisit the January 2009 interim final rule implementing the MIPPA requirement that Part D plans include in their formularies all drugs in categories and classes when the two statutory requirements are met. The agency believes that the statute does not support codification of the existing six classes and believes that various analyses are needed to determine which drug classes meet the MIPPA criteria. CMS also signals that the interpretation of specific terms in the statute is critical to key decisions concerning its implementation, and the preamble provides a detailed discussion of these terms. The analysis included in the preamble also reiterates the agency's intent to balance access to drugs for vulnerable populations with allowing Part D sponsors to undertake beneficial cost containment efforts. Further, CMS indicates an intent to avoid interfering with existing protections implemented by Part D sponsors that are intended to promote safety and efficacy. AHIP commends CMS for revisiting the interim final rule and providing a thoughtful and informative analysis of the MIPPA authority.

CMS invites comment on whether new protected classes should be announced through subregulatory guidance or through a formal rulemaking process. AHIP supports use of

subregulatory guidance which gives the agency the flexibility to make refinements, as necessary, more quickly than if CMS adopts the rules through a formal rulemaking process. In making this recommendation, AHIP strongly urges CMS to adopt a process that provides a meaningful and timely opportunity to comment on the proposed classes. Designation of protected classes will have a significant effect on the operations of Part D sponsors and is of great interest to the beneficiaries they serve. AHIP believes it is of critical importance that CMS give stakeholders ample opportunity to comment and that CMS have a similar opportunity to carefully consider and evaluate the comments.

G. Changes to Clarify Various Program Participation Requirements

3. Requirement for Sponsoring Organizations Under Part C and D to Report Other Payer Information to the Coordination of Benefits Contractor (§422.108 & §423.464; Preamble, p. 54690)

CMS is proposing to amend the Part C and Part D rules to require the reporting of coordination of benefits information when there is a payor primary to Medicare. The preamble explains that reporting will be limited to information reported to the sponsor as being inconsistent with existing information in the coordination of benefits (COB) file and states that:

> ...we propose to include in regulatory text the requirement that MA organizations and Part D sponsors, upon being notified of credible new information regarding other payers or changes to existing other payer information, report this information to the CMS COB Contractor in accordance with the processes and timeframes established by CMS.

The preamble also provides the agency's definition of "credible" information. In light of the significance accorded this discussion in the preamble, we recommend that, for clarity, the proposed new regulatory language be revised to reference "credible" information and that the agency's intent to focus reporting on information inconsistent with that in the COB file either be incorporated into the regulation or reiterated in the preamble to the final rule.

4. Visitor/Traveler Benefit Under Part C for the Purpose of Extending Enrollment Up to 12 Months (§422.74; Preamble, p. 54691)

CMS is proposing to add §§422.74(d)(4)(iii)(D) and (E) to specify that if an MA organization offers a visitor/traveler option when an individual is out of the service area for consecutive days of more than 6 months but less than 12 months, the MA

organization may permit the individual to remain enrolled if the visitor/traveler option meets certain new criteria. Specifically, under such an option the MA organization must furnish "all Medicare Part A and Part B services and all mandatory and optional supplemental benefits at the same cost sharing as apply within the plan's service area" and "meets Medicare access and availability requirements at §422.112..." It is our understanding that this proposal is less flexible than the existing rules governing the offering of visitor/traveler options.

We believe that existing programs that offer less comprehensive benefits for enrollees who are absent from the service area for 6 months or less have proven valuable to enrollees. Further, it is our understanding that in the past CMS has permitted the offering of visitor/traveler benefits that include all Medicare Part A and Part B services but not supplemental benefits. Since all MA organizations cover Medicare Part A and Part B benefits, but typically differ in the supplemental benefits offered, it may be more feasible for MA organizations to enter into arrangements with MA contractors in other areas of the country to provide network access Medicare Part A/B benefits than for supplemental benefits. While we believe that additional clarity regarding CMS policy on visitor/traveler benefits could be constructive, in order to avoid hindering the offering of benefits that are less comprehensive than required under CMS' proposal but that can be valuable for beneficiaries, we urge CMS to consider a more flexible approach. We recommend that CMS defer incorporating the proposed changes into the MA regulations and instead issue draft subregulatory guidance for review and comment. Such an approach would permit CMS to adjust or refine the requirements to ensure that the agency goals and beneficiary interests are best served

5. **Medication Therapy Management Programs Under Part D (§423.153(d); Preamble, p. 54692-54693)**

CMS proposes to revise §423.153(d) to codify policy guidance issued in the 2010 Call Letter that CMS believes reflects common practices among Part D Medication Therapy Management Programs (MTMPs). While CMS has documented that several changes reflect a number of widespread practices, the benefit of codifying these practices is unclear. With respect to other proposed new regulatory provisions, we believe there is insufficient experience to include these policies in regulation, for example, the implications of the more detailed criteria for targeting beneficiaries for MTMPs are not yet clear. CMS indicates that codification will promote greater consistency and allow for better evaluation and comparison of MTMPs. However, as with other quality initiatives, over time, the design and implementation of MTMPs can be expected to continue to evolve to take advantage of ongoing experience. We believe that CMS' goals can readily be accomplished through subregulatory guidance, which has the advantage of being more easily modified in the future if it becomes desirable to reflect refinements in the design

and implementation of these important programs. AHIP, therefore, opposes codification of more detailed MTMP requirements. We recommend that CMS remove the MTMP changes from the proposed rule and continue to address MTMP requirements in subregulatory guidance.

9. Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§423.568; Preamble, p. 54695-54696)

- **Explanation of conditions for approval of a completely favorable determination.** CMS is also proposing to add §423.568(e), which requires that, when there is a completely favorable standard determination, the notice must explain the conditions of the approval in a readable and understandable form. Consistent with our comments concerning a similar requirement for wholly favorable redeterminations and completely favorable expedited coverage determinations, while we believe that in the case of a standard determination that is wholly or partially adverse to the enrollee an explanation of a reason for the decision is an important element of the notice, the value of the explanation to the enrollee is unclear when the decision is completely favorable, and we believe that the cost of providing this information for every completely favorable standard determination outweighs its benefit. If CMS believes that enrollees may have an interest in this information, it would be more efficient to indicate in the notice that the Part D sponsor will provide the enrollee with an explanation of a completely favorable standard determination upon request. We recommend that the proposed rule be revised accordingly.

- CMS is proposing to extend this period for a Part D sponsor to notify an enrollee of a determination regarding a request for payment within 14 calendar days rather than within 72 hours of receiving the request and to require that payment be made within that same 14 day period. We support extending the time period for the Part D sponsor to make the decision and notify the enrollee. We believe this change will continue to serve the interests of enrollees in receiving timely notice while making more efficient use of Part D sponsor resources. Regarding the time frame for payment, we understand that providing payment within 14 days of receipt of the request for payment could raise a practical concern, because it could necessitate manual issuance of payments by contracted PBMs off cycle from their regular check processing schedules, which may be bi-monthly. For efficiency, AHIP recommends that CMS revise the proposed rule to permit payment to be made (when applicable) within 30 days of receipt of the request for payment.

11. Timeframes and Notice Requirements for Expedited Coverage Determinations (§423.572; Preamble, p. 54696-54697)

CMS is proposing to add §423.572(c)(1), which requires that, when there is a completely favorable expedited coverage determination, the notice must explain the conditions of the approval in a readable and understandable form. Consistent with our comments concerning a similar requirement for wholly favorable redeterminations and completely favorable standard determinations, while we believe that in the case of an expedited determination that is wholly or partially adverse to the enrollee an explanation of a reason for the decision is an important element of the notice, the value of the explanation to the enrollee is unclear when the decision is completely favorable, and we believe that the cost of providing this information for every completely favorable standard determination outweighs its benefit. If CMS believes that enrollees may have an interest in this information, it would be more efficient to indicate in the notice that the Part D sponsor will provide the enrollee with an explanation of a completely favorable expedited determination upon request. We recommend that the proposed rule be revised accordingly.

12. Clarify Novation Agreements Under Part D (§423.551; Preamble, p. 54697)

CMS is proposing to revise the regulatory provision that permits the novation of a PDP sponsor contract in the event of a change of ownership of the PDP sponsor. The proposed change would provide that CMS will only recognize the sale or transfer of the PDP sponsor's entire line of business (e.g., all contracts held by a sponsor with multiple contracts). In the preamble, CMS expresses concern about PDP sponsor requests in recent years to novate a portion of a contract and reiterates the agency's existing policy of not allowing the novation or assignment of one of a PDP sponsor's plans to another sponsoring organization. CMS states that the agency's proposal is designed to address this concern and to create consistency with the MA program.

While AHIP understands the agency's objective in not allowing a single "plan" to be novated, the implications of the novation of a portion of a contract are clearly distinguishable from the novation of an entire contract. We believe that it is unreasonable to require a sponsor to exit the Part D program entirely by novating all PDP contracts in the event that the entity wishes to novate one of several Part D contracts. If the result is the termination of a contract rather than a sale or transfer, we believe this action would be more disruptive to enrollees who would be required to select a new plan rather than remaining enrolled under the previous contract under new ownership. We recommend that CMS revise the proposed rule to recognize the sale or transfer of an entire contract. Our recommendation applies equally to the MA program although we are not aware of instances in which CMS has applied this broad requirement to MA contractors.

13. Cost Contract Program Revisions: Appeals and Marketing Requirements (§417.428, §417.594, §417.500, & §417.640; Preamble, p. 54697-54698)

- **Electronic Enrollment.** While this issue was not addressed in the proposed rule, AHIP is recommending that CMS amend the cost plan enrollment regulations to allow beneficiaries the option of electronic enrollment into cost plans in the same manner as MA organizations. AHIP notes that the statute, Section 1876, does not prescribe the manner in which a beneficiary can enroll in a cost plan. CMS currently interprets its rules to require cost plans to obtain written signatures from beneficiaries although AHIP notes that the regulation does not explicitly require that the signature be "written". See §417.430. We believe it would be in the best interests of beneficiaries, CMS and cost plans for CMS to reconsider this interpretation in order to allow the enrollment mechanisms for the MA program and the cost plan program to be aligned.

14. Appeals Processes for Contract Determinations, Intermediate Sanctions, and Civil Monetary Penalties

c. Contract Determinations (§417.492 & §417.494; Preamble, p. 54698)

- **Incorporation by reference into the cost plan regulations of MA provisions on appeals of contract determinations.** CMS is proposing to provide that the rights, procedures, and requirements for contract determinations under the MA program will also be applicable to cost plans. The proposed change to the regulation would accomplish this objective by including cross-references in §417.492 and §417.494 to requirements for notice to MA contractors applicable also to cost contractors and by revising §417.640 to state that in Part 422, Subpart N, references to Part 422 should be read as references to Part 417 and references to Medicare Advantage plans should be read as references to HMOs and CMPs. In reviewing Part 422, AHIP believes that this approach does not provide sufficient clarity to cost plans regarding the requirements that apply to cost plans. For example, there are provisions of Part 422, Subpart N, that would not apply to Medicare cost plans, and there are termination/non-renewal provisions under Part 417 that are not addressed under Part 422. Accordingly, AHIP recommends that CMS revise the language in Part 417 to incorporate a structure that is similar to the Part 422 rules and is modified to appropriately apply to Medicare cost plans.

b. Civil Monetary Penalties (§417.500; Preamble, p. 54698)

- **Intermediate sanctions and civil monetary penalties.** CMS is proposing in §417.500 to replace §417.500(a) with a statement that the "rights, procedures and requirements related to intermediate sanctions and civil monetary penalties set forth in Part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs and CMPs under Section 1876 of the Act." For clarity, AHIP recommends that CMS revise the intermediate sanctions provisions in Part 417 to incorporate the structure of Part 422, as applicable, rather than utilizing a cross-reference. AHIP makes similar recommendations with regard to the civil monetary penalties provisions in Part 417.

15. **Extending MA Marketing Requirements to Cost Program Plans (§417.428; Preamble, p. 54698-54700)**

CMS is proposing to apply the marketing requirements set forth in subpart V of 42 CFR part 422 to Medicare cost plans, with the exception of section §422.2276. Section 422.2276 exempts from the prior review and approval requirements marketing materials designed for members of an employer group. AHIP recognizes that cost plans are not eligible to offer 800 series plans except for their Part D benefits; however, CMS policy since the Medicare risk program has been that section 1876 contractors have had the discretion to negotiate with employers additional benefits. CMS continues to take the position that such negotiations are not reviewable by CMS. Consistent with this position, AHIP believes that CMS has the discretion to exempt cost plan materials for employer groups from CMS' prior review and approval requirements in the same manner as MA materials for employer groups. AHIP recommends that CMS adopt this change, which would also further align the Medicare cost contract provisions with the MA program requirements.

We have appreciated the opportunity to comment. Please contact me if additional information would be helpful or if you have questions about the issues we have raised. I can be reached at (202) 778-3209 or cschaller@ahip.org.

Sincerely,

Candace Schaller
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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

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

Assigned to Hon. Michael W. Fitzgerald

[PROPOSED] ORDER GRANTING UNITED'S MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-PARTIAL-INTERVENTION

[*Notice of Motion and Motion, Memorandum of Points and Authorities, and Declaration of David J. Schindler filed concurrently herewith*]

Date: January 29, 2018
Time: 10:00 a.m.
Ctrm: 5A

On December 8, 2017, Defendants UnitedHealth Group Incorporated, United HealthCare Services, Inc., UnitedHealthcare, Inc., UnitedHealthcare Insurance Company, Ovations, Inc., Optum, Inc., OptumInsight, Inc., AmeriChoice of New Jersey, Inc., AmeriChoice of New York, Inc., Arizona Physicians IPA, Inc., Care Improvement Plus of Maryland, Inc., Care Improvement Plus of Texas Insurance Company, Care Improvement Plus South Central Insurance Company, Care Improvement Plus Wisconsin Insurance Company, Optum Insurance Co., Citrus Health Care, Inc., Health Plan of Nevada, Inc., Medica HealthCare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., PacifiCare Life and Health Insurance Company, PacifiCare of Arizona, Inc., PacifiCare of Colorado, Inc., PacifiCare of Nevada, Inc., Physicians Health Choice of Texas, LLC, Preferred Care Partners, Inc., Rocky Mountain Health Maintenance Organization, Incorporated, Sierra Health and Life Insurance Company, Inc., Symphonix Health Insurance, Inc., UHC of California (f.k.a. PacifiCare of California), United Health Care Ins. Co. and United New York, Unison Health Plan of Tennessee, Inc., UnitedHealthcare Benefits of Texas, Inc. (f.k.a. PacifiCare of Texas, Inc.), UnitedHealthcare Community Plan of Ohio, Inc. (f.k.a. Unison Health Plan of Ohio, Inc.), UnitedHealthcare Community Plan of Texas, L.L.C. (f.k.a. Evercare of Texas, L.L.C.), UnitedHealthcare Community Plan, Inc. (f.k.a. UnitedHealthcare of the Great Lakes Health Plan, Inc.), UnitedHealthcare Insurance Company of New York, UnitedHealthcare of Alabama, Inc., UnitedHealthcare of Arizona, Inc., UnitedHealthcare of Arkansas, Inc., UnitedHealthcare of Florida, Inc., UnitedHealthcare of Georgia, Inc., UnitedHealthcare of New England, Inc., UnitedHealthcare of New York, Inc., UnitedHealthcare of North Carolina, Inc., UnitedHealthcare of Ohio, Inc., UnitedHealthcare of Oklahoma, Inc. (f.k.a. PacifiCare of Oklahoma, Inc.), UnitedHealthcare of Oregon, Inc. (f.k.a. PacifiCare of Oregon, Inc.), UnitedHealthcare of Pennsylvania, Inc. (f.k.a. Unison Health Plan

of Pennsylvania, Inc.), UnitedHealthcare of Tennessee, Inc., UnitedHealthcare of the Midlands, Inc., UnitedHealthcare of the Midwest, Inc., UnitedHealthcare of Utah, Inc., UnitedHealthcare of Washington, Inc. (f.k.a. PacifiCare of Washington, Inc.), UnitedHealthcare of Wisconsin, Inc., and UnitedHealthcare Plan of the River Valley, Inc. (collectively, "United") moved this Court to dismiss the claims asserted against them in the United States of America's First Amended Complaint-In-Partial-Intervention ("FAC"), on the grounds that the FAC failed to state a claim for relief pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). This Court has considered the Motion, the submissions of the parties, and the arguments of counsel for the parties, who appeared before this Court on January 29, 2018. After due deliberation and for good cause shown,

IT IS HEREBY ORDERED that United's Motion to Dismiss is GRANTED, and the FAC is dismissed with prejudice.

Dated: _____

_____
Honorable Michael W. Fitzgerald
United States District Court Judge