IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITEDHEALTHCARE INSURANCE COMPANY, *et al.*, Plaintiffs, v. ERIC D. HARGAN, in his official capacity as Acting Secretary of the Department of Health and Human Services, *et al.*, Defendants.	No. 1:16-cv-00157 (RMC)

***AMICUS CURIAE* BRIEF OF AMERICA'S HEALTH INSURANCE PLANS IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT**

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CORPORATE DISCLOSURE STATEMENT

America's Health Insurance Plans is a national trade association that represents the health insurance provider community, including, as relevant here, member companies that provide health coverage and other financial health and wellness benefits through Medicare and Medicaid. It has no parent company, and no publicly traded company owns 10 percent or more of its stock.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

America's Health Insurance Plans ("AHIP") is the national trade association representing the health insurance provider community. AHIP's members provide health coverage and other financial health and wellness benefits through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid.

AHIP's members include private insurance companies known as Medicare Advantage organizations ("MAOs"), with which the U.S. Centers for Medicare & Medicaid Services ("CMS") contract to provide health care coverage to Medicare beneficiaries through the Medicare Advantage ("MA") program. MA plans offer an alternative to the federally administered, traditional Medicare program. Beneficiaries who choose to receive their Medicare benefits through MAOs are entitled, through their private MA plans, to coverage for at least the same set of services covered by traditional Medicare. AHIP advocates for public policies that expand affordable health coverage for all Americans, including through the MA program.

Eighty-three of AHIP's members offer MA plans. AHIP is thus well situated (1) to explain why the Court can and should resolve the key legal questions raised in this case and thereby provide a clear explanation of the applicable statutory and regulatory standards governing the MA program; and (2) to explain how the 2014 CMS rule at issue (the "Overpayment Rule") violates the requirement that CMS make payments to MA plans in a manner that ensures "actuarial equivalence," 42 U.S.C. § 1395w-23(a)(1)(C)(i).

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than the amicus, its members, its counsel, or former member of amicus, Humana Inc., made a monetary contribution intended to fund the brief's preparation or submission. Plaintiff United is not a member of AHIP. Plaintiffs and Defendants consent to the filing of this brief. *See* Fed. R. App. P. 29; D.D.C. L.R. 7(o).

INTRODUCTION

The Court should deny the government's cross-motion for summary judgment (Dkt. 57) and invalidate the Overpayment Rule, which conflicts with the statutory mandate that CMS follow core actuarial principles and—for precisely that reason—threatens to disrupt the Medicare Advantage program, to the detriment of millions of Medicare beneficiaries.

The government seeks to avoid consideration of the critical legal issues raised in this case by arguing that United should have challenged CMS's announcement of the MA risk coefficients rather than the Overpayment Rule. But United is not asking the Court to set aside CMS's risk coefficients, and AHIP is not suggesting that is necessary. United is asking that the Overpayment Rule be invalidated because CMS failed to comply with accepted actuarial principles, under which the agency was required either to apply consistent documentation standards in the Overpayment Rule or to make an adjustment in the Rule to account for the use of different standards. Resolving the fundamental legal questions raised in this case about the use of the MA risk-adjustment model and MAOs' obligations is of critical importance to the MA program and the millions of Americans who rely on it. Risk-adjustment payments are essential to compensate MAOs adequately for the coverage they provide to members presenting different levels of risk, thereby ensuring that MAOs have the resources they need and that MA plans remain broadly available to all eligible Americans.

On the merits, there is no support for the government's position in this case. As AHIP has explained, the Overpayment Rule violates the Social Security Act's "actuarial equivalence" requirement because it applies a different documentation standard for diagnosis codes submitted by MAOs than CMS applies to itself in developing its MA risk-adjustment payment model. *See* AHIP Br. 6-12 (Dkt. 53). The government does not dispute that the Act's requirement of "actuarial equivalence" obligates CMS to determine risk-adjustment payments to MAOs

"through the application of actuarial principles." Gov't Br. 28 (Dkt. 57-1). Nor does the government contest that generally accepted actuarial principles require consistency between the way a risk-adjustment model is developed and how it is applied. Those concessions are fatal to the government's defense of the Overpayment Rule because the Rule cannot be reconciled with those principles. Instead, the government seeks to immunize the Rule from review by invoking the agency's supposed discretion. But that expedient fails: The statute does not afford discretion to disregard the statutory requirement of "actuarial equivalence."

Moreover, the government's unreasoned dismissal of the significant actuarial concerns raised by the Overpayment Rule stands in contrast to CMS's past express recognition—in the 2012 FFS Adjuster Notice—that if "the documentation standard used … to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)," then CMS must make an adjustment that "accounts for" the difference. AR 5314. The government's efforts to reinterpret CMS's prior acknowledgment are belied by the agency's plain words. And the government is not helped by its further claim that it does not yet know how use of different documentation standards will skew risk-adjustment payments to MAOs. The FFS Adjuster Notice explicitly recognized that application of different standards would require an "offset" from amounts an MAO otherwise would have to repay to CMS as a result of an audit.

Contrary to the government's assertions, the Overpayment Rule's use of divergent documentation standards finds no support in the requirement that an MAO certify the accuracy of its risk-adjustment data. In light of the requirement of "actuarial equivalence," and CMS's decision to use unsubstantiated FFS diagnosis codes to develop its risk-adjustment model, "accuracy" can only mean that the data is accurate to the same degree as the data used by CMS

to create the model. Whatever standard of accuracy CMS applies to itself should also apply to MAOs.

ARGUMENT

I. THE COURT SHOULD RESOLVE THE IMPORTANT LEGAL ISSUES RAISED IN UNITED'S CHALLENGE

Before turning to the merits of the issues before the Court, AHIP emphasizes the importance of resolving the critical statutory questions United has raised in its challenge to the Overpayment Rule. Contrary to the government's assertions, United is raising its arguments in the right vehicle—a challenge to the Overpayment Rule—and the Court can and should address those arguments in this case.

A. United Properly Challenged The Overpayment Rule

Seeking to avoid review of the Overpayment Rule, the government argues that United should have raised its statutory arguments in a challenge to CMS's risk coefficients, rather than the Rule itself. *See* Gov't Br. 36, 40-41. But it is *the Rule*, not the risk coefficients, that violates the actuarial equivalence requirement and harms both United and MAOs in general.

United had no reason to assert the present challenge prior to the enactment of the Overpayment Rule because the Rule is what defines overpayments in a manner that violates actuarial equivalence. As explained below, CMS can use risk coefficients based on unaudited FFS diagnosis data without running afoul of the actuarial equivalence requirement so long as it applies those coefficients to unaudited MA diagnosis data *or* applies an appropriate adjuster to account for any differences between the two relevant documentation standards. But by defining "overpayment" to mean any payment based on a diagnosis code that is not documented in the medical record, the Overpayment Rule applies the risk coefficients generated from *unaudited* FFS diagnosis data to *audited* MA diagnosis data *without* employing any adjuster to account for

those varying documentation standards. The Overpayment Rule—not the underlying risk coefficients—is what contravenes the actuarial equivalence requirement of the Social Security Act, and it is therefore the proper subject of United's APA challenge. *See* 5 U.S.C. § 702 ("A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.").

Indeed, while CMS could have addressed the actuarial equivalence concerns raised in comments on the Overpayment Rule by auditing the FFS diagnosis data that it uses to generate the risk coefficients, it did not need to do so. CMS could have continued to use risk coefficients based on unaudited FFS data *and* required MAOs to audit their data against the underlying medical records, so long as CMS adopted an adjuster of the kind it acknowledged is needed in the RADV audit context. *See* AR 5314-5315. This option would not have required CMS to modify the risk coefficients, and it is consistent with actuarial equivalence and thus addresses the harm to United and other MAOs.

Because United's challenge is to the Overpayment Rule, not the risk coefficients, that challenge is properly before this Court.

B. Resolution Of The Legal Issues Raised In This Case Is Critical To The Future Of The MA Program

As AHIP has explained, clarifying the standards governing the risk-adjustment system is vital to the continued functioning of the MA program, which provides affordable, high-quality care to millions of Medicare beneficiaries. AHIP Br. 15-17. AHIP thus urges the Court to resolve Plaintiffs' challenge by clearly articulating MAOs' rights and responsibilities under the statutory and regulatory framework. An order merely vacating the Overpayment Rule and remanding it for further proceedings will not provide the certainty needed to allow the program to continue to flourish.

The government's approach to this case foreshadows the difficulties that would likely be posed by a remand without guidance from this Court. Rather than address the fundamental questions raised by United's challenge, the government has sought to shield the Overpayment Rule from review. It first challenged United's standing to bring this challenge, even though the Rule directly regulates the company. *See* Dkt. 12-1. It now suggests that United should have either challenged the promulgation of 42 C.F.R. § 422.504(*l*) in 2000 or brought a suit contesting CMS's adoption of its risk coefficients. *See* Gov't Br. 25 n.7, 36, 40-41. It further seeks to forestall judicial review by arguing for discretion and deference to which it is not entitled. *See infra* pp. 8-9, 15-16. The repeated failure by the government to address the critical issues raised in this case provides no basis to believe a remand is warranted.

One third of Medicare beneficiaries—almost twenty million Americans—depend on the MA program for their health care. The uncertainty created by the Overpayment Rule threatens MAOs' ability to continue to offer the high-quality, cost-effective coverage these enrollees deserve. Clear resolution of the legal questions in this case is the only way to ensure the proper functioning of the MA risk-adjustment payment system, and thus the MA program as a whole.

II. THE OVERPAYMENT RULE VIOLATES THE STATUTE'S ACTUARIAL EQUIVALENCE REQUIREMENT

On the merits, the resolution of this case is clear. The Overpayment Rule cannot be reconciled with the statutory actuarial equivalence requirement. The Medicare Advantage payment rules are complex, but the issue in this case is simple: Can CMS use two different documentation standards in developing and applying the risk-adjustment payment model, without making an adjustment to account for the problematic actuarial effects of doing so? The answer is no. Congress foreclosed that option when it directed CMS "to ensure actuarial

equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). The Overpayment Rule disregards Congress's directive and thus is contrary to law and void.

To calculate the risk coefficients that guide risk-adjustment payments—*i.e.*, the numerical multipliers that correlate certain health conditions (and demographic factors) with expected health care expenditures in traditional FFS Medicare—CMS has chosen to rely on diagnosis codes supplied by FFS providers without independently checking the codes against patients' medical charts and removing unsupported codes. *See*, *e.g.*, Gov't Br. 7 (recognizing that "quality of the Part B diagnosis data is generally understood to be inferior to the Part A diagnosis data"); *id.* at 16-17 (explaining that the MA risk-adjustment model is based on "millions of traditional, fee-for-service beneficiaries with demographic characteristics, *reported* diagnoses, and Medicare expenses" (emphasis added)); *id.* at 37 (acknowledging that "the risk adjustment model is built on unaudited [FFS] data … which must contain errors"). Yet CMS purports in the Overpayment Rule to limit payment to MAOs to only diagnoses that are validated against members' medical charts. That divergent approach violates accepted actuarial principles, in conflict with the statute's command.

In its cross-motion for summary judgment, the government concedes that the Social Security Act's "actuarial equivalence" requirement mandates the "application of actuarial principles" to ensure that MAOs are paid "a sum equal to the cost that CMS would expect to bear in providing traditional Medicare." Gov't Br. 28.[2] Critically to this APA challenge, in

[2] Although the government focuses on expected costs for "a given beneficiary," Gov't Br. 28, the actuarial principles underlying risk adjustment are designed to compare expected costs of covering a given population of plan enrollees relative to the average Medicare population. *See* American Academy of Actuaries, *Risk Assessment and Risk Adjustment* 3 (May 2010) ("[R]isk assessment does a much better job of explaining variations in costs among larger groups than among individuals.").

announcing the FFS Adjuster, CMS likewise acknowledged the precise actuarial principle at issue in this case—that CMS must either use the same standard in developing and applying its risk model or account for the effects of different standards. AR 5314-5315. But although that same actuarial principle is implicated by the Overpayment Rule, the government neither grapples with it here, nor justifies CMS's failure to do so in promulgating the Overpayment Rule. These failures are telling.

Instead, the government principally contends (1) that this Court should defer to CMS's "broad discretion" in devising the risk model, Gov't Br. 28-31, 36-37; and (2) that CMS's own prior decision in February 2012 to require the FFS Adjuster for RADV audits is of limited significance, *id*. at 41-43—among other reasons, because the ultimate effect on the risk model from CMS's reliance on unsupported FFS diagnoses is "hard" to determine, *id*. at 17; *see id.* at 17-18, 37-38. Each of those contentions is meritless.

A. The Actuarial Equivalence Requirement Limits The Secretary's Discretion

As a threshold matter, the government's claim to "broad discretion" (Gov't Br. 28) is inconsistent with the text and purpose of the risk-adjustment provision. The Social Security Act provides that the Secretary "*shall* adjust the payment amount" to MAOs "so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i) (emphasis added). This statutory command leaves no doubt that risk-adjustment payments to MAOs that ensure actuarial equivalence are mandatory, not discretionary. *See Lopez v. Davis*, 531 U.S. 230, 241 (2001) (contrasting "Congress' use of the permissive 'may'" with "mandatory 'shall,'" which "Congress used … to impose discretionless obligations"); *Kakeh v. United Planning Org., Inc.*, 655 F. Supp. 2d 107, 123 (D.D.C. 2009) ("It is well-settled that when a statute uses the term 'shall,' it creates a mandatory duty.").

The government focuses on other language in the same provision—the phrase "and such other factors as the Secretary determines to be appropriate"—to argue that CMS has "broad discretion" in "design[ing] the Part C risk adjustment model." Gov't Br. 28; *see also id.* at 36-37. But the agency's discretion is strictly limited by the requirement that the factors in the risk model adjust payments to "ensure actuarial equivalence." *Id*. at 28. That statutory imperative governs any discretion the statute affords CMS. The agency has the discretion to construct its risk-adjustment payment model in any number of ways, and it may consider any number of factors. But it cannot use that discretion to develop a model that fails to ensure actuarial equivalence. Because the Overpayment Rule violates the actuarial equivalence requirement, it was not a proper exercise of CMS's discretion. And, in any event, CMS's discretion to select additional risk factors is beside the point here. The sole risk factor at issue in this case is health status, which is set forth in the statute. 42 U.S.C. § 1395w-23(a)(1)(C)(i).

B. The Overpayment Rule Violates The Actuarial Equivalence Requirement

As AHIP previously explained, generally accepted actuarial principles require consistency between the way a risk-adjustment model is developed and how it is used. *See* AHIP Br. 7. CMS has elected to calculate the risk factors for various health conditions by using unaudited FFS data—data known to contain a baseline rate of unsubstantiated diagnosis codes. *See supra* p. 7. Consequently, CMS cannot use a different documentation standard when applying those risk factors to MA diagnosis codes, unless it accounts for the effects of that difference. The Overpayment Rule violates this principle of actuarial equivalence because it does just that. *See* AHIP Br. 7-8, 12.

The American Academy of Actuaries, among others, pointed out the same inconsistency in the context of CMS's proposed methodology for calculating contract-level payment errors in RADV audits. *See* AR 5235-5236; *see also, e.g.*, AR 5269; AR 5053-5057. But, there, CMS

responded by admitting the need for an adjustment that "accounts for" this inconsistency between the two "documentation standard[s]." AR 5314-5315. In contrast, CMS rejected commenters' arguments that a similar adjustment was required in the Overpayment Rule. *See* AHIP Br. 11-13. Rather than directly address CMS's unexplained rejection of this principle of actuarial equivalence, the government tries (at 20, 41-43) to minimize the significance of the FFS Adjuster in several respects—none of which is supported by the record.

First, the government's suggestion that CMS in February 2012 merely "agreed to study the issue further" (Gov't Br. 42) is simply wrong. The word "study" does not appear in CMS's Notice announcing the FFS Adjuster. *See* AR 5311-5315. To the contrary, that Notice clearly represents that CMS "*will* apply" the FFS Adjuster as a required "offset" in RADV audits. AR 5314 (emphasis added); *see* AR 5311 ("Notice of *Final* Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits" (emphasis added)); *see also* Dkt. 54-1, at 4 n.2 (conceding that "this publication *finaliz*[*ed*] the sampling and extrapolation methodology for [RADV] audits," and that "the Secretary [has] repeatedly acknowledged [it] as his authoritative statement on the FFS Adjuster" (emphasis added)). CMS's intent was to "calculate[]" the FFS Adjuster, AR 5315, not to conduct a future "study" of the need for it. The only thing that CMS has not finalized is "[t]he actual amount of the adjuster." AR 5315.[3]

[3] Relatedly, the government claims that the Secretary "has said nothing more about the FFS Adjuster" since February 2012. Gov't Br. 20. But, as AHIP previously noted, CMS subsequently confirmed that it intended to finalize its "calculat[ion]" of the FFS Adjuster by "solicit[ing] public comments" on it in 2016 (although it has not yet done so). GAO, *Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments* 9 n.23 (Apr. 2016); *see* AHIP Br. 16 n.5.

Second, the government implies that CMS's concession concerning the FFS Adjuster was somehow "RADV-specific" because the issue was raised in connection with "the mechanics of extrapolating a contract-level error rate" from an audited sample of beneficiaries' diagnoses and medical records. Gov't Br. 42. But CMS's reasoning was not limited to RADV audits. Rather, in its decision, CMS was responding to comments by the American Academy of Actuaries, among others, pointing out that "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." AR 5235. The FFS Adjuster was thus adopted, in CMS's words, to "account[] for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)." AR 5314-5315. CMS's reasoning for requiring the FFS Adjuster was tied to the same documentation principle at issue here, not to the mechanics of extrapolation. CMS's endorsement of that principle and its implications requires vacatur of the Overpayment Rule: It cannot be the case that an adjustment to account for CMS's use of different documentation standards is required when CMS conducts an audit, but not when CMS compels MAOs to audit themselves.

Finally, the government faults United for allegedly presenting an overly "simplistic scenario," Gov't Br. 38, but that same basic example and analysis were presented to CMS by the American Academy of Actuaries in connection with the RADV methodology, *see* AR 5236. The result was the FFS Adjuster. The government's objection—that "[i]t is very hard to say [that unsupported diagnoses from FFS providers] would in fact cause [the] coefficients to be deflated … rather than raising one coefficient while lowering another, or shifting the weight of the model from diagnoses to demographic factors, or vice versa," Gov't Br. 38—is inconsistent with

CMS's prior acknowledgment that the FFS Adjuster would be required "as an *offset*" in RADV audits. AR 5314 (emphasis added). In the FFS Adjuster Notice, CMS recognized that to ensure actuarial equivalence it needed to account for its use of different documentation standards. *See* AR 5314-5315. Its failure to take the same approach in the Overpayment Rule exceeded the "limitations" on CMS's authority imposed by the Social Security Act. 5 U.S.C. § 706(2)(C).

C. The Certification Requirement Does Not Remedy The Overpayment Rule's Violation Of Actuarial Equivalence

The government argues that the requirement that MAOs certify the "accuracy" of their risk-adjustment data under 42 C.F.R. § 422.504(*l*) supports the Overpayment Rule's imposition of a different substantiation standard for MA risk-adjustment data than CMS uses for FFS risk-adjustment data without any adjustment. *See* Gov't Br. 32-35. But the use of the word "accurate" in the certification regulation cannot undo the Social Security Act's actuarial equivalence requirement; rather, it must be interpreted *in light of* that requirement. In the context of the statute and the MA program CMS has designed, the word "accuracy" in § 422.504(*l*) can only mean that an MAO's data is accurate to the same degree as the FFS data used by CMS to create the model.

The government concedes both that CMS's "risk-adjustment model is built on unaudited data about traditional, fee-for-service Medicare beneficiaries, which must contain errors (because it is unaudited)," Gov't Br. 37; *see id.* ("This is true, as far as it goes."), and that under the Social Security Act's actuarial equivalence requirement, risk-adjustment payments to MAOs must be determined "through the application of actuarial principles," *id*. at 28, such as requiring consistency between the way a risk-adjustment model is developed and how it is used, *see* AHIP Br. 7 (citing Actuarial Standards of Practice No. 45 § 3.2). As a result, requiring MAOs to certify the accuracy of their risk-adjustment data under the government's view would violate the

actuarial equivalence requirement. Moreover, with hundreds of millions of patient diagnoses annually, it is economically and administratively impractical to engage in auditing on the scale that would be required by the government's position—a point AHIP previously raised and the government does not dispute. *See* AHIP Br. 12 n.4, 16-17.

United and AHIP have also explained that, in the context of applying the coding intensity adjustment, CMS has indicated 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." United Br. 38-39 (Dkt. 47-1) (quoting AR 4335 (emphasis altered)); *see also* AHIP Br. 15. The government does not dispute that it interpreted the word "accurately" in this way in that context. In other words, as CMS recognized, the critical factor is not *what* standard of accuracy is applied but that the *same* standard must apply to both MA and FFS data.

There is nothing irrational or improper about requiring MAOs to adhere to the same standard of accuracy as CMS. The agency can hold MAOs to whatever standard of accuracy it applies to its own use of FFS data; it just cannot purport to hold them to a higher standard without running afoul of the actuarial equivalence requirement. Applying the same standard to MAOs as CMS applies to itself, moreover, would not raise any of the concerns the government has suggested. *See* Gov't Br. 39. An MAO certifying the accuracy of its data must have a good faith basis to certify on best knowledge, information, and belief that its data is accurate to the applicable FFS standard, as calculated by CMS. And there is nothing unworkable about that approach, which CMS has announced it will apply in the agency's own RADV audits.

The government's only response is to argue that CMS "has clearly and consistently interpreted 42 C.F.R. § 422.504(*l*) to require medical documentation" and is entitled to deference

with respect to its interpretation of its own regulation. Gov't Br. 32. But that argument is wrong on both the facts and the law.

As a factual matter, CMS has not previously articulated the interpretation of "accuracy" in § 422.504(*l*) that the government asserts in this litigation. None of the CMS regulations, guidance documents, and training materials the government cites (at 25-26, 32, 35) purports to interpret the word "accuracy" in § 422.504(*l*). Indeed, the 2001 Medicare Managed Care Manual is the only one that even mentions that provision, and it expressly acknowledges that an MAO can comply with § 422.504(*l*) even if its data is not 100% error free. *See* AR 5349. Indeed, CMS had previously made the same concession.[4] Moreover, all the 2001 Manual says is that the certification requirement under § 422.504(*l*) does not displace applicable data requirements.

The other regulations cited by the government merely provide for RADV audits, *e.g.*, 42 C.F.R. § 422.310(e), and indicate that MAOs must "obtain the risk adjustment data required by CMS" from providers and "submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data," *e.g.*, *id*. § 422.310(d)(1) & (3), which CMS does not audit. In RADV audits, moreover, CMS has conceded that there is no payment error for a contract even with some unsupported codes so long as "the FFS Adjuster amount is greater." AR 5314. It is inconceivable that an MAO could be found to have made a false certification of the "accuracy" of its risk-adjustment data even though CMS concedes that the MAO was compensated

[4] Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) ("M+C organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce."); *see also* Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893, 61,900 (Nov. 15, 1999) ("The requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of data … does not constitute an absolute guarantee of accuracy.").

appropriately based on that data. Yet this is exactly what the government now contends should occur.

As a legal matter, the government's contention that its interpretation of "accuracy" in § 422.504(*l*) is entitled to *Auer/Seminole Rock* deference—because it is CMS's interpretations of its own regulation, *see* Gov't Br. 32—fails for at least four reasons:

First, an agency interpretation of a regulation that is contrary to a statute warrants no deference. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 159 (2012) ("This new interpretation is flatly inconsistent with the FLSA[.]"); *Stinson v. United States*, 508 U.S. 36, 45 (1993). Here, as explained above, the government's interpretation is contrary to the Social Security Act's "actuarial equivalence" requirement.

Second, *Auer* deference is not warranted because the government's new interpretation of "accuracy" in § 422.504(*l*) would operate retroactively to impose liability on MAOs. The Supreme Court in *SmithKline Beecham* warned against deferring to an agency's new interpretation of its regulations where doing so would "impose potentially massive liability … for conduct that occurred well before that interpretation was announced." 567 U.S. at 155-156. CMS's unexplained reliance on § 422.504(*l*) in the Overpayment Rule was insufficient to put MAOs on notice of the interpretation now set forth by the government in this litigation, and that interpretation cannot be afforded *Auer* deference in any context in which it would impose retroactive liability.

Third, "deference is likewise unwarranted when there is reason to suspect that the agency's interpretation 'does not reflect the agency's fair and considered judgment on the matter in question.'" *SmithKline Beecham Corp.*, 567 U.S. at 155. Here, CMS provided no explanation for its reliance on § 422.504(*l*) in the Overpayment Rule itself. *See* Medicare Program; Contract

Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,921 (May 23, 2014). And as explained above, CMS has never adopted the interpretation the government advances here.

Finally, *Auer* deference is not due when an agency's interpretation is "inconsistent with the regulation" itself. *SmithKline Beecham Corp.*, 567 U.S. at 155. As AHIP has explained, applying traditional tools of construction, it is clear in this case that accuracy cannot mean completely "error-free" in the context of § 422.504(*l*). *See* AHIP Br. 13-15; *supra* p. 12.

In sum, CMS's existing regulatory requirement that MAOs certify the "accuracy" of their risk-adjustment data does not support the position taken in the Overpayment Rule.

CONCLUSION

For the reasons set forth above and in AHIP's prior brief, the Court should deny Defendants' cross-motion for summary judgment (Dkt. 57), grant United's motion for summary judgment (Dkt. 47), and vacate the Overpayment Rule.

Dated: January 18, 2018

Respectfully submitted,

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