No. _____

In the Supreme Court of the United States

UNITEDHEALTHCARE INSURANCE COMPANY, ET AL.,
Petitioners,

v.

XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Medicare provides health insurance for millions of seniors and individuals with disabilities. Congress originally authorized the Centers for Medicare & Medicaid Services (CMS) to provide health insurance directly to eligible individuals in a program known as "traditional Medicare." Congress later expanded Medicare to enable eligible individuals to elect coverage through private insurance plans instead. This latter program, which has been wildly successful and popular, is known as "Medicare Advantage" (MA).

In enacting MA, Congress created a comparative payment model that requires CMS to pay MA plans an "actuarial[ly] equivalen[t]" amount to what CMS would have paid to insure the same beneficiary in traditional Medicare, after comparing the health and costliness of the traditional Medicare and MA populations. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Congress likewise required CMS to use the "same methodology" to compute the costliness of insuring a beneficiary in the MA program and in traditional Medicare. *Id.* § 1395w-23(b)(4)(D). CMS thus for years recognized that it must use the same actuarial assumptions when calculating the cost of care for both the traditional Medicare and MA populations.

But in 2014, CMS departed from that position—without acknowledging or explaining this flip flop—in adopting a new rule implementing a separate statutory requirement that MA plans return identified "overpayments" to the agency. *Id.* § 1320a-7k(d)(1); *see* 79 Fed. Reg. 29,844, 29,918-25 (May 23, 2014) ("Overpayment Rule"). This Overpayment Rule implemented a different set of assumptions for assessing the health and costliness of the traditional

Medicare and MA populations: It imposed a stringent definition of "overpayment" on private MA insurers using one set of assumptions about their beneficiaries' health data, but failed to make any corresponding adjustment to the traditional Medicare data CMS uses to calculate MA payment rates. The Rule thus creates an apples-to-oranges payment scheme, which imposes potentially billions of dollars in additional payment obligations on MA plans and threatens the scope and affordability of care MA plans are able to provide to over 26 million seniors.

Petitioners—the nation's leading providers of MA plans—challenged the Overpayment Rule as contrary to the Medicare statute's actuarial-equivalence and same-methodology mandates, and as an arbitrary and capricious departure from the agency's prior position. The district court agreed with petitioners that the rule is invalid on those independent grounds. But the D.C. Circuit reversed. Adopting a position never advocated by CMS, the D.C. Circuit held that the Medicare statute's actuarial-equivalence and same-methodology requirements do not even *implicate* the issue of what constitutes an "overpayment." The court then held that this lack of a statutory connection negated any need for CMS to justify the agency's change in position in adopting the Overpayment Rule, and that the Rule is otherwise lawful.

The questions presented are:

1. Whether the Overpayment Rule violates the statute's "actuarial equivalence" and "same methodology" mandates.

2. Whether the Overpayment Rule is otherwise arbitrary, capricious, or not in accordance with law.

PARTIES TO THE PROCEEDINGS BELOW

Petitioners UnitedHealthcare Insurance Company; Americhoice of New Jersey, Inc.; Arizona Physicians IPA, Inc.; Care Improvement Plus South Central Insurance Company; Care Improvement Plus of Texas Insurance Company; Care Improvement Plus Wisconsin Insurance Company; Health Plan of Nevada, Inc.; Medica Healthcare Plans, Inc.; Oxford Health Plans (CT), Inc.; Oxford Health Plans (NJ), Inc.; Oxford Health Plans (NY), Inc.; Pacificare Life and Health Insurance Company; Pacificare of Arizona, Inc.; Pacificare of Colorado, Inc.; Pacificare of Nevada, Inc.; Physicians Health Choice of Texas LLC; Preferred Care Partners, Inc.; Sierra Health and Life Insurance Company, Inc.; UnitedHealthcare Benefits of Texas, Inc., formerly doing business as Pacificare of Texas, Inc.; UnitedHealthcare Community Plan of Ohio, Inc., formerly doing business as Unison Health Plan Of Ohio, Inc.; UnitedHealthcare Community Plan of Texas, LLC, formerly doing business as Evercare of Texas, LLC; UnitedHealthcare Insurance Company of New York; UnitedHealthcare of Alabama, Inc.; UnitedHealthcare of Arizona, Inc.; UnitedHealthcare of Arkansas, Inc.; UHC of California, formerly doing business as Pacificare of California, Inc.; UnitedHealthcare of Florida, Inc.; UnitedHealthcare of Georgia, Inc.; UnitedHealthcare of New England, Inc.; UnitedHealthcare of New York, Inc.; UnitedHealthcare of North Carolina, Inc.; UnitedHealthcare of Ohio, Inc.; UnitedHealthcare of Oklahoma, Inc., formerly doing business as Pacificare of Oklahoma, Inc.; UnitedHealthcare of Oregon, Inc., formerly doing business as Pacificare of Oregon, Inc.; UnitedHealthcare of Pennsylvania,

Inc., formerly doing business as Unison Health Plan of Pennsylvania, Inc.; UnitedHealthcare of the Midlands, Inc.; UnitedHealthcare of the Midwest, Inc.; UnitedHealthcare of Utah, Inc.; UnitedHealthcare of Washington, Inc., formerly doing business as Pacificare of Washington, Inc.; UnitedHealthcare of Wisconsin, Inc.; UnitedHealthcare Plan of the River Valley, Inc. ("UnitedHealth"), were appellees in the court of appeals.

Respondents Xavier Becerra, in his official capacity as Secretary of Health and Human Services; the Centers for Medicare & Medicaid Services; and the United States of America were appellants in the court of appeals.

RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, petitioner UnitedHealth Group Incorporated states that it is the indirect parent of each petitioner. No other publicly traded company owns 10% or more of petitioners' stock.

RELATED PROCEEDINGS

The following proceedings are directly related to this petition:

UnitedHealthcare Insurance Co. v. Becerra, No. 18-5326, United States Court of Appeals for the District of Columbia Circuit, amended opinion and judgment entered November 1, 2021 (16 F.4th 867), rehearing denied November 1, 2021.

UnitedHealthcare Insurance Co. v. Azar, Civil Case No. 16-157 (RMC), United States District Court for the District of Columbia, judgment entered September 7, 2018 (330 F. Supp. 3d 173), reconsideration denied January 27, 2020.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners (collectively, "UnitedHealth") respectfully petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The amended opinion of the court of appeals (App. 1a-53a) is reported at 16 F.4th 867. The court's order denying rehearing and amending its opinion (App. 107a-08a) is not published, but is available at 2021 WL 5045254. The opinion of the district court granting UnitedHealth's motion for summary judgment (App. 54a-89a) is reported at 330 F. Supp. 3d 173. The opinion of the district court denying reconsideration (App. 90a-106a) is not published, but is available at 2020 WL 417867.

JURISDICTION

The court of appeals entered its amended judgment (App. 1a-53a) and denied rehearing (App. 107a-08a) on November 1, 2021. On January 18, 2022, Chief Justice Roberts extended the time to file a petition for a writ of certiorari through February 14, 2022. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Relevant statutory and regulatory provisions are set out in the petition appendix. App. 109a-34a.

INTRODUCTION

This Court recently observed that the Medicare program "touches the lives of nearly all Americans," and that "even minor changes" to how the program is

administered "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808, 1816 (2019). This case raises those same concerns. It involves the validity of a rule that CMS adopted in 2014, which strikes at the heart of the comparative payment model Congress mandated for the hugely successful Medicare Advantage (MA) program, and thereby jeopardizes the scope and quality of healthcare coverage available to millions of seniors and other eligible Americans.

The lynchpin of the MA payment model established by Congress is that CMS must pay MA plans an amount actuarially equivalent to what CMS expects it would have spent to insure an identical beneficiary population under traditional Medicare. 42 U.S.C. § 1395w-23(a)(1)(C)(i); *see also id.* § 1395w-23(b)(4)(D) (CMS must use the "same methodology" to compute the costliness—the "risk factor"—of insuring a beneficiary in MA as CMS uses under traditional Medicare). This actuarial-equivalence requirement ensures that MA plans are fully compensated for the degree of risk they assume, and are treated on a level-playing field with the government when it acts as an insurer under Medicare. The district court held that the Overpayment Rule violates this statutory mandate and is therefore invalid. But the D.C. Circuit reversed, holding that the statute's "actuarial equivalence" mandate is simply inapplicable to the statute's overpayment provision—a position that was never advocated by CMS in this litigation or the rulemaking itself.

For two overriding reasons, the D.C. Circuit's decision warrants this Court's review. First, it rests on a blatant statutory error. The court's holding that

the statute's actuarial-equivalence requirement does not apply to the overpayment provision is based on the court's belief that the latter purportedly does not "cross-reference" the former. App. 3a, 31a, 34a-36a, 39a-40a. But, in fact, the Medicare statute explicitly links these provisions: The statute defines an "overpayment" as "any funds that a person receives or retains under *subchapter XVIII* . . . to which the person . . . *is not entitled under such subchapter*," 42 U.S.C. § 1320a-7k(d)(4)(B) (emphasis added); and "subchapter XVIII" includes the actuarial-equivalence requirement. Moreover, the funds to which an MA plan is "entitled" (under subchapter XVIII) can *only* be determined by applying the statutory requirement of actuarial equivalence, cementing the link between these two provisions.

Second, that error is enormously consequential. To begin, because it concluded that the statute's actuarial-equivalence requirement was inapplicable to the overpayment provision, the D.C. Circuit excused CMS from having to comply with its basic obligation under the Administrative Procedure Act to explain its departure from the agency's prior position on this issue, even though the district court held that CMS flunked this requirement, App. 79a-84a—a critical check on arbitrary action. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016). The court's clear statutory error thus eliminated an important check on arbitrary agency action, which itself required invalidating the Rule. But more fundamentally, by holding that this basic statutory requirement (along with the statute's accompanying "same methodology" requirement) does not apply at all, the D.C. Circuit's decision will drive up premium costs for millions of Americans, decrease

coverage options, and cause billions of dollars of disruption in the popular MA program.

As this Court has concluded in similar situations, the gravity of the court's statutory error, coupled with its disruptive impact on the healthcare available to millions of Americans, warrants review.

STATEMENT OF THE CASE

A. Medicare Advantage Program

1. Parts A and B of the Medicare Act establish the traditional Medicare program. *See* 42 U.S.C. §§ 1395c-1395i-6 (Part A, covering inpatient care); *id.* §§ 1395j-1395w-6 (Part B, covering outpatient care). Traditional Medicare uses a payment model known as "fee-for-service," in which CMS directly reimburses healthcare providers (e.g., doctors) for the medical services they provide to Medicare beneficiaries.

In 1997, Congress created Medicare Part C—now called the Medicare Advantage program—as an alternative to traditional Medicare. *Id.* §§ 1395w-21-1395w-28. In essence, the MA program allows CMS to "sub-contract its duties to private insurers." *MSPA Claims 1, LLC v. Tenet Fla., Inc.*, 918 F.3d 1312, 1316-17 (11th Cir. 2019). The MA program uses an insurance payment model instead of traditional Medicare's fee-for-service model. CMS does not pay MA plans for the services performed by providers. It instead pays private insurance plans (like UnitedHealth) to take on the *risk* of insuring Medicare beneficiaries. When a beneficiary enrolls in an MA plan, CMS pays the plan a fixed monthly amount—basically, an insurance premium—and the plan then covers all of the beneficiary's qualified healthcare costs, whatever those costs end up being. 42 U.S.C. § 1395w-23. But for the private insurance

market to work, those payment must replicate accurately the risks that are being off loaded from traditional Medicare onto MA plans.

Congress designed the MA program to achieve both fiscal and public-health goals. The insurance model incentivizes MA plans to manage their beneficiaries' care in a way that promotes long-term health and offers better, more comprehensive services, while allowing CMS to offload risk. Congress thus sought "to harness the power of private sector competition to stimulate experimentation and innovation that would ultimately create a more efficient and less expensive Medicare system." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 685 F.3d 353, 363 (3d Cir. 2012) (citing H.R. Rep. No. 105-217, at 585 (1997), 1997 U.S.C.C.A.N. 176, 205-06 (Conf. Rep.)), *cert. denied*, 569 U.S. 918 (2013).

And it has worked. Individuals eligible for Medicare coverage have flocked to private MA plans because they offer more tailored options, expanded coverage, and the ability to retain the individual's existing providers. In addition to covering the same services as traditional Medicare, "[m]ost [MA] plans offer extra benefits" like "vision, hearing, dental, and more." CMS, *Understanding Medicare Advantage Plans* 4 (Nov. 2020), https://www.medicare.gov/Pubs/pdf/12026-Understanding-Medicare-Advantage-Plans.pdf. Some MA plans offer lower out-of-pocket costs than traditional Medicare, and all MA plans are subject to a yearly limit on such costs, whereas traditional Medicare has no such limit. *Id.* at 5-6, 10.

Consequently, the MA program has grown exponentially over the past two decades—from 5 million enrollees in 2004 to more than 26 million

Americans—or 42% of all Medicare beneficiaries—today. *See* Meredith Freed, et al., *Medicare Advantage in 2021: Enrollment Update and Key Trends*, KFF at Figure 1 (June 21, 2021), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends. And the number of MA enrollees is projected to surpass the number of enrollees in traditional Medicare by 2030. *Id.* at Figure 2.

2. Importantly, Congress adopted a comparative payment model for the MA program to ensure that MA plans are compensated for the risk they assume by insuring beneficiaries commensurate with the risk assumed by CMS for traditional Medicare beneficiaries. The payment model thus compares the predicted cost CMS would incur for healthcare for particular beneficiaries with the amount an MA plan predicts it would spend to cover healthcare for identical beneficiaries. But for that comparative model to work, it must use consistent assumptions to measure the health and costs of the two groups. That is a basic actuarial tenet for all risk adjustment models. *See* Actuarial Standards Board, *Actuarial Standard of Practice No. 45: The Use of Health Status Based Risk Adjustment Methodologies* § 3.2 (2012), http://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop045_164.pdf ("The type of input data . . . used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model.").

Congress enshrined this fundamental principle in the Medicare statute in two related ways. First, Congress mandated that CMS compensate MA plans in a manner that ensures "actuarial equivalence" with traditional Medicare, which requires CMS to use the

same assumptions in calculating payments under the two programs and to pay MA plans an equivalent amount to what CMS expects it would have paid for a beneficiary if she had stayed in traditional Medicare. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i); *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011) ("Two modes of payment are actuarially equivalent when their present values are equal under a given set of actuarial assumptions." (citation omitted)), *cert. denied*, 566 U.S. 921 (2012); App. 31a-32a. Second, Congress mandated that CMS compute and publish "risk factor[s]"—the numerical measure of the relative risk (i.e., costliness) of providing health insurance to a given beneficiary—for both traditional Medicare and MA beneficiaries using the "same methodology." 42 U.S.C. § 1395w-23(b)(4)(D).

Congress required CMS to calculate MA payments under the statutory risk-adjustment model in two steps. First, the statute provides a method for CMS to calculate an initial "payment amount" for MA beneficiaries—i.e., the amount an MA plan bids to insure an average traditional Medicare beneficiary in a region, capped by the costs CMS itself incurs insuring an average beneficiary in that region. *Id.* § 1395w-23(a)(1)(C)(i), (b)(1)(B)(i). Second, the statute requires CMS to adjust that initial "payment amount" to account for beneficiaries' "risk factors," including demographic characteristics (e.g., age) and certain health conditions. Specifically, the statute states that the Secretary of HHS "*shall* adjust" the "payment amount" for "such risk factors . . . so as to *ensure actuarial equivalence*." *Id.* § 1395w-23(a)(1)(C)(i) (emphasis added). It further states that CMS may modify "such [risk] factors *if such changes will improve the determination of actuarial*

equivalence." *Id.* (emphasis added). The demographic and health risk factors are added together to arrive at the risk score for a beneficiary.

Risk adjustment—at the second step—is critical for MA insurance plans. The adjustment accounts for the fact that MA plans assume different degrees of risk when insuring beneficiaries who are healthier or sicker than those in the average Medicare pool. For example, a 65-year-old beneficiary with no chronic conditions would not be expected to incur significant health costs in a year, so an MA plan would receive lower-than-average monthly payments from CMS for insuring that individual. By contrast, a 93-year-old beneficiary with diabetes and multiple sclerosis is likely to require more care, so an MA plan would be entitled to higher monthly payments from CMS for insuring such an individual. The risk adjustment step also ensures that MA plans are incentivized to market their products to all seniors, even those with costly chronic conditions.

To determine the amount an MA plan is entitled to be paid for insuring a particular beneficiary, CMS uses a risk-adjustment model relying on data from traditional Medicare. C.A. App. 115-16.[1] In particular, CMS relies on diagnosis codes submitted by providers in traditional Medicare to retroactively calculate how much CMS spent to cover particular kinds of health conditions in a given year. App. 60a-61a. Diagnosis codes are used on claims forms to designate a patient's medical conditions. *Id.* To calculate the respective "value" of a diagnosis code—i.e., the marginal cost of providing care to a person

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1 "C.A. App." refers to the appendix in the court of appeals.

with that diagnosis—CMS starts with the actual costs it incurred to cover its beneficiary population and then uses a regression method to distribute those costs across the diagnosis codes and demographic indicators in its claims data.

After calculating the relative cost of different diagnosis codes based on claims data generated from the pool of traditional Medicare enrollees, CMS uses that valuation to set the payment rates for MA plans. *Id.* MA plans annually submit to CMS all diagnosis codes applicable to their beneficiaries. CMS then pays the MA plans a fixed monthly amount for each beneficiary, with the amount adjusted upward or downward depending on each beneficiaries' diagnosis codes and their associated risk. *Id.* at 61a-62a.

The diagnosis codes submitted by providers and hospitals to CMS in claims forms do not always correspond with beneficiaries' underlying medical charts. The rate of such unsupported codes is relatively low in Medicare Part A, because hospital payment for inpatient care is tied to diagnosis coding. *Id.* at 57a; C.A. App. 450. But there is a concededly high rate of unsupported codes in Medicare Part B (covering outpatient care), which accounts for most of CMS's claims data. App. 57a; C.A. App. 497. That high error rate exists because—although doctors submit diagnosis codes under Medicare Part B—their payment from CMS does not generally depend on those codes but rather on the type of *services* the doctors provide during office visits, e.g., a physical examination, X-ray, or blood test. App. 57a.

Yet, despite this high error rate in diagnosis coding in Part B, CMS does not take any steps to validate the diagnosis codes in the dataset it uses to calculate the MA payment rates. *Id.* at 61a, 65a.

B. CMS's Prior Position On The Need To Account For Data Mismatch

For years, CMS recognized that the Medicare statute and basic actuarial principles required the agency to assess the accuracy of diagnosis codes in claims data in a consistent manner across both traditional Medicare and MA.

1. CMS regularly audits a subset of MA plans through a Risk Adjustment Data Validation (RADV). C.A. App. 99. During such RADV audits, CMS reviews a sample of the MA plan's beneficiary data to determine whether the beneficiary's diagnosis codes are supported by his or her medical charts. C.A. App. 395-96; 42 C.F.R. § 422.310(e). In 2010, CMS proposed to extrapolate the rate of unsupported codes it found in that subset of claims data to the entire MA plan to determine the amount by which that plan had been overpaid, if at all. C.A. App. 292-94.

Numerous commenters pointed out, however, that CMS's proposal failed to account for the rate of diagnosis code errors in the traditional Medicare data that is used to set MA payment rates—a data mismatch that would violate the statutory actuarial-equivalence requirement. App. 55a; C.A. App. 312-16; 334-37; 373-75. Indeed, the American Academy of Actuaries—an independent authority that CMS relies on extensively in its administration of federal healthcare programs—submitted a comment raising this very concern. C.A. App. 392-93.

In 2012, CMS announced that it agreed with the commenters and the American Academy of Actuaries. *Id.* at 397. Accordingly, to account for coding errors in traditional Medicare, CMS decided its RADV audits would apply what it called a "fee-for-service

adjuster."[2] Under this adjuster, an MA plan would be found to have an overpayment *only* to the extent the plan's rate of unsupported codes exceeded the rate of unsupported codes in traditional Medicare. *Id.* at 397-98. As a CMS director explained in an internal agency presentation, this adjustment was required because MA plans would necessarily be *underpaid* if CMS calculated their payment rates by distributing CMS's costs over one set of data (including both supported and unsupported diagnosis codes), but only allowed MA plans to retain payment for a subset of that data (supported codes). *Id.* at 595-605.

2. CMS also effectuated the statute's actuarial-equivalence mandate by implementing a "coding intensity adjuster" that deducts money from MA plans for *supported* diagnosis codes. Because MA payment rates for beneficiaries are largely based on diagnosis codes (*see supra* at 8-9), MA plans have an incentive to review beneficiaries' underlying medical charts to ensure the provider listed all of the codes supported by the beneficiary's medical record. CMS does not conduct such reviews of its provider data to catch diagnoses that were not coded. Because of those different coding patterns, an MA beneficiary could appear to have more diagnosis codes, and thus a higher cumulative risk score, than a similar beneficiary in traditional Medicare.

Congress accordingly directed CMS to analyze any "differences in coding patterns" between traditional Medicare and MA plans and to adjust MA risk scores in light of those differences "*to ensure payment accuracy*." Pub. L. No. 109-171, § 5301(b)(2), 120

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[2] Fee-for-service, or FFS, is shorthand for the traditional Medicare payment model.

Stat. 4, 51 (2006) (emphasis added). As each of the relevant congressional committee chairs emphasized in connection with this provision, payment accuracy required "establishing risk scores that are consistent across both fee-for-service [i.e., traditional Medicare] and Medicare Advantage settings," a view CMS endorsed. C.A. App. 178 (quoting 152 Cong. Rec. 511 (2006) (statement of Sen. Grassley); *see* 152 Cong. Rec. at 558 (statement of Rep. Barton); *id.* at 567 (statement of Rep. Thomas).

Since 2010, CMS has imposed downward adjustments to the risk scores it uses to pay MA plans to offset these different coding patterns. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(ii); C.A. App. 176. In doing so, CMS has rejected the argument from MA plans that a downward adjustment would be appropriate only if plans were submitting *unsupported* codes. CMS recognized that MA plans may simply "be coding more completely" than traditional Medicare, but it explained that because the "MA payment methodology . . . is designed to compare the risk scores of MA plan enrollees to . . . 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." C.A. App. 152, 177.

In short, CMS's coding intensity adjuster recognizes that, under the comparative payment model established by Congress for the MA program, the agency must account for "differential coding patterns in MA and [traditional Medicare]" to "ensure payment accuracy"—and cannot determine if plans are paid accurately merely by determining whether or not a particular code is supported. *Id.* at 266.

C. CMS's About-Face In Promulgating The Overpayment Rule

In 2014, however, CMS abandoned its prior position on the MA payment model and promulgated the Overpayment Rule.

In 2010, as part of the Affordable Care Act (ACA), Congress amended the Medicare statute by imposing an obligation on MA plans to report and return "overpayments." 42 U.S.C. § 1320a-7k(d)(1). Congress defined "overpayment" as "any funds that a person receives or retains under subchapter XVIII [the Medicare program] or XIX [of chapter 7 of title 42] to which the person, after applicable reconciliation, is not entitled under such subchapter." *Id.* § 1320a-7k(d)(4)(B). Part C of subchapter XVIII—the MA program—addresses "Payments" to MA plans and includes the actuarial-equivalence requirement discussed above. *See id.* § 1395w-23(a)(1)(C).

In the Overpayment Rule, CMS sought to "clarify" the meaning of "overpayment." *See* 79 Fed. Reg. 29,844, 29,918-25 (May 23, 2014) (promulgating 42 C.F.R. § 422.326). During notice-and-comment, UnitedHealth and other commenters explained that determining whether an MA plan has received an "overpayment" requires accounting for the error rate in CMS's data from traditional Medicare in order to achieve equivalence, just as CMS had agreed since 2012. C.A. App. 64. But this time, CMS changed assumptions. Instead, under the Overpayment Rule, *any and every* unsupported diagnosis code identified by an MA plan is deemed an overpayment: "[A] risk adjustment diagnosis that . . . does not have supporting medical record documentation would result in an overpayment." *Id.*

The result is that the Overpayment Rule uses a different set of assumptions in comparing the health status and costliness of the traditional Medicare and MA populations—treating *all* beneficiaries in traditional Medicare who have a diagnosis code as actually having the condition (whether or not the code is actually supported in the medical record), while disregarding the equivalent codes of similar MA beneficiaries whenever a code is unsupported.

D. Proceedings Below

1. Petitioners challenged the Overpayment Rule under the APA on the grounds that the Rule (1) contravenes the Medicare statute's actuarial-equivalence and same-methodology mandates, and (2) represents an unexplained departure from CMS's prior position. *See* App. 55a. The district court (Collyer, D.J.) agreed on both grounds, and held that the Rule must be vacated. *Id.* at 54a-55a.

First, the court held that the Rule violates the statute's actuarial-equivalence requirement by adopting different assumptions for the accuracy of diagnosis codes in measuring the risks and costliness of the traditional Medicare and MA populations. The court explained that "without some kind of adjustment" to account for the error rate in CMS's own data—like the one CMS adopted before the Overpayment Rule—"[MA] insurers will be paid less to provide the same healthcare coverage to their beneficiaries than CMS itself pays for comparable patients." *Id.* at 73a; *see id.* at 78a (explaining that, because CMS distributes its costs across "all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for [MA] coverage because essentially no errors would be

reimbursed"); *see also id.* at 92a-93a & n.3. The court further held that the Rule violates the statute's same-methodology requirement for similar reasons. *Id.* at 78a-79a.

Second, the court held that the Rule is arbitrary and capricious because CMS departed from its prior position—that the statute's actuarial-equivalence mandate required an adjustor to account for the coding discrepancies across both programs—"without a reasoned explanation." *Id.* at 83a-84a. Reviewing CMS's earlier statements, the court held that CMS had failed to explain its refusal to account for the coding errors in traditional Medicare, despite having committed to account for such errors when identifying overpayments in RADV audits. *Id.* at 79a-84a.[3]

2. The D.C. Circuit, in an opinion by Judge Pillard, reversed. Adopting a position never advanced by the agency in this case or in the rulemaking itself, the court held that the statute's actuarial-equivalence requirement does not "implicate" the Overpayment Rule *at all*. *Id.* at 3a, 52a. The court based this conclusion on its belief that "[r]eference to actuarial equivalence appears in a different statutory subchapter from the requirement to refund overpayments, and neither provision cross-references the other." *Id.* at 3a; *see also id.* at 31a, 34a-36a, 39a. And, absent such a link, the court reasoned that the provisions "serve different ends": As the court saw it, the actuarial-equivalence mandate provides "a directive to CMS" on how to develop its risk-adjustment model, but does not speak to or implicate

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[3] The district court also invalidated the Overpayment Rule's definition of "identified," App. 85a-89a, which the government did not appeal.

the kinds of overpayments CMS may collect from MA plans. *Id.* at 3a-4a, 36a-38a.

That central statutory ruling drove each step of the rest of the D.C. Circuit's decision. First, for "much the same reasons," the court concluded that the Medicare statute's "same methodology" requirement also was not relevant to the Overpayment Rule. *Id.* at 6a-7a. Second, the court held that this lack of a statutory connection eliminated any need for CMS "to provide further explanation of its decision" to adopt the Rule. *Id.* at 52a. And, third, in concluding that UnitedHealth had not shown that the mismatch in data validation brought about by the Rule would inevitably underpay MA plans, *id.* at 48a, the court relied on the premise that "[a]n unsupported code submitted by" an MA plan "triggers overpayment in every case"—a premise itself predicated on the court's threshold ruling that the actuarial-equivalence requirement does not require the same treatment of diagnosis codes across both programs. *Id.* at 46a.

UnitedHealth sought panel rehearing to correct a clear mistake in the court's remand instructions. The panel issued an amended opinion correcting that mistake, but at the same time purported to deny rehearing and took the extraordinary step of immediately issuing its mandate—thus precluding UnitedHealth from seeking rehearing en banc on any other issues. *See id.* at 107a-08a.

REASONS FOR GRANTING THE WRIT

The D.C. Circuit's decision in this case destabilizes a hugely popular Medicare program relied upon by more than 26 million Americans for their healthcare, based on a blatant misreading of the Medicare statute never advanced by the agency itself. Based on that

clear statutory error, the D.C. Circuit then excused CMS from having to satisfy a basic check on arbitrary agency action—the requirement that an agency must acknowledge and explain a change in position. If allowed to stand, the D.C. Circuit's error will significantly impact the range and quality of healthcare coverage available under MA plans, the premiums paid by millions of Americans, and the overall success of the popular MA program. This Court's intervention is warranted.

I. The Decision Below Is Egregiously Wrong

The D.C. Circuit's decision is grounded on its ruling that the Medicare Act's actuarial-equivalence requirement does not apply to—or even implicate—the statute's overpayment provision. This clear statutory error concerning an important federal program warrants this Court's review.

A. The D.C. Circuit Clearly Misread The Medicare Statute

At its heart, the dispute in this case concerns whether the Medicare Act's actuarial-equivalence requirement applies to the statute's overpayment provision, thereby requiring CMS to use the same assumptions in determining whether MA plans have been overpaid as it does in calculating the costliness of its traditional Medicare population. The district court answered that question in the affirmative. App. 71a-78a. The D.C. Circuit disagreed, adopting a reading of the statute that has never been advanced by the agency or anyone else, contradicts the statute's plain text, and defies common sense.

1. The D.C. Circuit's Holding That The Actuarial-Equivalence Requirement Does Not Apply To The Overpayment Provision Is Plainly Wrong

a. The key question in this case is whether the Medicare Act's actuarial-equivalence requirement applies to the "overpayment" provision Congress added to the Medicare program in 2010, the latter of which obligates MA insurers to report and return overpayments they identify. 42 U.S.C. § 1320a-7k(d)(1); *see generally id.* § 1320a-7k(d). If it does, as the district court correctly held, then the Overpayment Rule is clearly invalid. App. 71a-78a.

As explained, the Medicare statute establishes a comparative payment model requiring CMS to compensate MA plans in a manner that ensures "actuarial equivalence" with traditional Medicare. *See* 42 U.S.C. § 1395w-23(a)(1)(C); *supra* at 6-12. "Actuarial equivalence" has an "established meaning" of which Congress presumably was aware when it enacted this baseline requirement: "Two modes of payment are actuarially equivalent *when their present values are equal under a given set of actuarial assumptions*." *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011) (emphasis added); App. 31a-32a, 74a-76a, 93a.

Here, the actuarial-equivalence requirement entitles MA plans to receive payments based on the same "actuarial assumptions" CMS uses in measuring the health status and costliness of the traditional Medicare population—meaning that CMS must use the same assumptions to measure risk in both programs and pay MA plans the amount it would expect to spend covering an identical beneficiary

population in traditional Medicare. App. 31a-32a. The Overpayment Rule, however, results in the use of fundamentally different criteria for assessing the costs of insuring identical beneficiary populations in the two programs. Because CMS—in calculating the costliness of insuring the traditional Medicare population—calculates the value of diagnosis codes by distributing its actual costs across *both* supported and unsupported codes, it attributes some of the *actual costs* of insuring *actual conditions* to unsupported codes. But by requiring MA plans to return the payment for *every* unsupported code they identify, the Overpayment Rule subjects MA plans to a fundamentally different set of assumptions concerning the actual costs of the same population.

Yet, instead of enforcing the actuarial-equivalence mandates, the D.C. Circuit held that it does not apply to the overpayment provision *at all*. *Id.* at 3a. In other words, the court concluded that, even if requiring MA plans to delete every unsupported code they discover causes them to be paid significantly less than the costs CMS would incur for the same population, that poses no statutory problem. The court based this conclusion on an interpretation of the Medicare statute that has never been advanced by CMS, either in this litigation or anywhere else: that the "[r]eference to actuarial equivalence appears in a different statutory subchapter from the requirement to refund overpayments, and neither provision cross-references the other." *Id.* This ruling was the key to the court's decision, as underscored by the fact that the court repeatedly returned to it. *See id.* at 31a, 34a-36a, 39a. But it is obviously wrong.

A plain reading of the text of the Medicare statute shows that Congress explicitly linked the "actuarial-equivalence" and "overpayment" provisions:

- Congress defined "overpayment" as "any funds that a person receives or retains *under subchapter XVIII* . . . to which the person, after applicable reconciliation, is not entitled *under such subchapter*." 42 U.S.C. § 1320a-7k(d)(4)(B) (emphases added).
- Subchapter XVIII covers the Medicare program. The section of Subchapter XVIII addressing the MA program—Part C—addresses "Payments to Medicare [Advantage] Organizations." *Id.* § 1395w-23.
- That subsection not only is *the* basis for determining MA payment accuracy—*i.e.*, the "funds" to which an MA plan is "entitled under such subchapter," *id.* § 1320a-7k(d)(4)(B)—but also includes the actuarial-equivalence requirement, *id.* § 1395w-23(a)(1)(C)(i).
- Thus, the overpayment provision *does* cross-reference the actuarial-equivalence provision. There is no other defensible reading.[4]

The D.C. Circuit either ignored or glossed over these provisions. In its quotations of the overpayment provision, the D.C. Circuit paraphrased or used ellipses to erase the explicit statutory cross-reference to "subchapter XVIII" and the language "under such subchapter." App. 23a-24a, 33a, 39a. Then, the D.C. Circuit simply declared that "[t]here is no cross-

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[4] The actuarial-equivalence provision does not "cite" the overpayment provision because the former was enacted years earlier.

reference or other language suggestive of overlap, nor does UnitedHealth so contend." *Id.* at 34a. But the omitted language plainly connects the two provisions, and *the government* never contended otherwise. This blatant textual error, and the destabilizing impact it will have on the MA program, warrants certiorari.

The court also overlooked the plain language of Congress's definition of "overpayment" in another important respect. An "overpayment" consists of funds "under subchapter XVIII" to which a person is "not *entitled under [subchapter XVIII]*." 42 U.S.C. § 1320a-7k(d)(4)(B) (emphasis added). Thus, not surprisingly, to determine whether there is an *over*payment, one must first determine the payment to which an insurer was "entitled." But the payment to which MA plans are entitled under subchapter XVIII is governed by the actuarial-equivalence and other provisions of subchapter XVIII—which the D.C. Circuit disregarded. *Id.* § 1395w-23(a)(1)(C)(i). The court's holding thus severs the overpayment inquiry—determining the payments to which MA plans are "not entitled"—from the only statutory source that can possibly answer the question.

The D.C. Circuit's holding was also premised on a basic misunderstanding of the actuarial-equivalence requirement. The court stated that this requirement pertains only to the initial "design" of the payment model but does not prevent CMS from lowering those payment amounts later through its definition of "overpayments." App. 37a (citation omitted). But nothing in the statute supports that reading. Instead, the D.C. Circuit cited CMS's reply brief to support this theory, but even there CMS expressly acknowledged that the actuarial-equivalence requirement *does* apply to the Overpayment Rule. *See* Gov't C.A. Reply

Br. 5-6 ("[T]o establish that the [Overpayment] Rule causes a statutory violation, UnitedHealth must demonstrate that application of the Rule will . . . produce 'payment amount[s]' that violate 'actuarial equivalence.'" (alteration in original)).

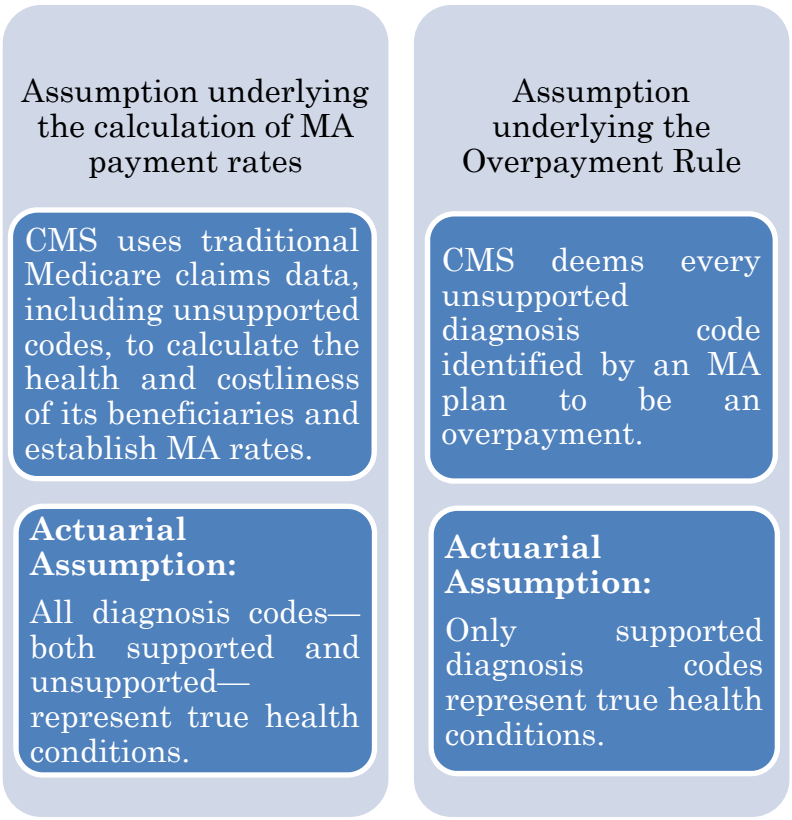
The D.C. Circuit's belief that the actuarial-equivalence requirement applies only to one end of the payment inquiry also defies common sense. Under that view, as long as CMS set an equivalent payment rate up front, it could then require repayment of any portion of that rate as an alleged "overpayment," even if that left MA plans with a fraction of the actuarially equivalent payment amount that Congress mandated the Secretary "ensure." Congress could not have intended such an end-run around the statute's actuarial-equivalence mandate for the calculation of MA payments.

b. The D.C. Circuit similarly erred in dismissing the statute's "same methodology" requirement. That requirement further underscores that Congress adopted a comparative payment model for the MA program, requiring MA payments to be calculated in comparison to traditional Medicare. Determining the "sameness" of a methodology requires a comparison. Yet, the D.C. Circuit held that the same-methodology requirement was not "implicate[d]" by the Overpayment Rule based on "the same reasons that support [its] holding regarding UnitedHealth's actuarial-equivalence claim." App. 50a. In other words, the court's statutory error in rejecting the actuarial-equivalence requirement led it to reject the same-methodology requirement as well.

2. The Overpayment Rule Plainly Violates The Statute's "Actuarial Equivalence" And "Same Methodology" Requirements

As the district court held, the Overpayment Rule plainly flunks the actuarial-equivalence and same-methodology requirements. App. 71a-79a.

a. As discussed, to achieve actuarial equivalence in this context, CMS must pay MA plans based on an apples-to-apples comparison of (1) the risk assumed by an MA plan in insuring its beneficiaries and (2) the risk that CMS would incur for identical beneficiaries. App. 32a; C.A. App. 178, 573, 688; Gov't C.A. Br. 1. But as the following diagram illustrates, the Overpayment Rule creates an apples-to-*oranges* comparison in which CMS uses different assumptions about diagnosis codes to measure healthcare costs and health status in the two programs.



In terms of costs, the Rule uses unverified diagnosis codes to measure costs in the traditional Medicare dataset (even though it is indisputable that a substantial number of those codes are unsupported), but assumes that *every* time an MA plan receives payment for an unsupported code the plan has received an "overpayment." C.A. App. 64. In terms of health status, the Rule results in CMS measuring health in the traditional Medicare population based on the prevalence of diagnosis codes in CMS's claims data (which includes many codes unsupported by medical charts), but requiring MA plans to measure the health of their populations based only on

supported diagnosis codes. Those different ways of measuring risk, for purposes of calculating payments, do not reflect "the same set of actuarial assumptions," thereby violating the statute. *Id.* at 713-14.

As the district court put it:

> The record is clear that payments for care under traditional Medicare and Medicare Advantage are both set annually on costs from *unaudited* traditional Medicare records [including diagnosis codes], but the 2014 Overpayment Rule systematically devalues payments to Medicare Advantage insurers by measuring "overpayments" based on *audited* patient records [and diagnosis codes]. This distinction makes an actuarial difference.

App. 72a (emphases added).

Further—as the district court explained—including unsupported codes when allocating costs on the traditional Medicare side, then excluding those same codes when determining payment amounts on the MA side, will underpay MA plans for the same risks. *Id.* at 72a-74a. That is because "diagnosis codes are presumed to have been accurate when CMS inputs all the data concerning beneficiaries of traditional Medicare into its regression model, which ultimately computes a value for each diagnoses," yet "[t]he same unverified diagnosis is, under the 2014 Overpayment Rule, treated as an overpayment that must be repaid, thus reducing the reimbursement to a [MA] insurer while requiring no such reduction in payment under traditional Medicare." *Id.* at 73a-74a.

In reaching that conclusion, the district court relied on the American Academy of Actuaries—the gold standard in actuarial science—which "strongly

advised CMS" in the RADV audit context "that it was not actuarially sound to compare unaudited figures to calculate per-capita payments and then audited figures to calculate overpayments." *Id.* at 65a; *see* C.A. App. 392-93. "This type of data inconsistency," the Academy warned, "not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities." C.A. App. 393.

Moreover, the D.C. Circuit's failure to appreciate the comparative nature of MA payment explains why the court thought it would be "absurd" to allow MA plans to retain any unsupported diagnosis codes, along with its suggestion that UnitedHealth's challenge would enable MA plans to "*knowingly* submit unsupported diagnosis codes" to increase payment. App. 38a-39a (emphasis added). But nothing of the sort is necessary for CMS to comply with its actuarial equivalence obligations—and, for similar reasons, the D.C. Circuit was wrong to believe that the agency's Overpayment Rule was required to prevent "known overpayments." *Id.*

There are multiple ways to achieve actuarial equivalence—while nonetheless accounting for the possibility of erroneous diagnosis codes. For instance, CMS could audit a sample of its traditional Medicare data at the front end, factor the error rate into the initial calculation of MA payment rates, and then deem every unsupported diagnosis code from an MA plan an "overpayment" (since the error rate would have been built into the initial payment calculation). Or else the agency could account for its error rate after-the-fact with an adjuster—similar to its adjuster for RADV audits—in which case it may deem

every erroneous diagnosis code from an MA plan beyond the adjuster an "overpayment."

But what CMS *cannot* do is subject diagnosis codes to one set of criteria when using traditional Medicare data to calculate MA payment rates, and then use fundamentally different criteria to determine when an MA plan has been overpaid. That directly contravenes the Medicare statute's requirement to calculate MA payment rates based on the same actuarial assumptions as traditional Medicare.

b. The D.C. Circuit alternatively held that UnitedHealth had failed to show that the Overpayment Rule *violates* the actuarial-equivalence requirement. App. 40a-48a. That holding also cannot stand. Most fundamentally, the court's threshold misreading of the statute infected this alternative holding as well. In explaining its alternative holding, the court relied on the mistaken premise that an "unsupported code submitted by" an MA plan "triggers overpayment in every case." *Id.* at 46a. In other words, the court continued to assume that CMS can define an unsupported diagnosis code as an "overpayment" without regard for the apples-to-apples comparison required by the statute's actuarial-equivalence mandate. That underlying error alone requires rejection of this alternative holding.

In any event, the Overpayment Rule is fundamentally antithetical to the actuarial-equivalence requirement, as the district court held. At its core, actuarial *equivalence* is an exercise in *comparing* the two populations. The Overpayment Rule, however, allows for no comparison whatsoever by deeming every unsupported code an MA plan identifies as an "overpayment," regardless of the comparative error rate in CMS's data. If the D.C.

Circuit had truly applied the actuarial-equivalence requirement, it would have invalidated the Rule (as the district court did) for failing to engage in the basic comparative process. Instead, the D.C. Circuit flipped the burden onto *UnitedHealth* to show that the Overpayment Rule "in fact has led or will lead to systemic underpayment" of MA plans that is "inevitable." *Id.* at 31a, 45a-47a. But that misstates UnitedHealth's legal burden and fails to apply faithfully the actuarial-equivalence requirement.

The court's alternative holding was plainly wrong in other respects as well. For example, even though CMS itself had conceded that "the risk adjustment model is built on *unaudited* data" and "*must contain errors*," C.A. App. 689 (emphases added); *see also id.* at 600 (agency internal payment expert acknowledging that "some portion of diagnoses" in traditional Medicare "are not documented in medical records"), the D.C. Circuit insisted that UnitedHealth had "failed to provide any logical or empirical basis to question the accuracy of traditional Medicare data." App. 41a. In addition, the D.C. Circuit incorrectly assumed that the "underlying premise of UnitedHealth's overall position" requires proving that "traditional Medicare data includes a significant rate of unsupported diagnosis codes." *Id.* at 42a. Again, that misunderstands the basic statutory argument. *Whatever* the rate of unsupported codes in traditional Medicare, the Overpayment Rule violates the actuarial-equivalence requirement by calculating MA payment based on *both* supported and

unsupported codes, but deeming *every* unsupported code MA plans identify an "overpayment."[5]

The court's alternative holding fails for an even more basic reason: it violates the "fundamental principle[]" that judicial review of agency action is limited to the "administrative record already in existence, not some new record made initially in the reviewing court." *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). The only evidence in the administrative record addressing actuarial equivalence were analyses from CMS's internal payment expert and from the American Academy of Actuaries. Both of those analyses concluded that the presence of unsupported codes in CMS's data, while requiring MA plans to delete unsupported codes, will tend to *underpay* MA plans. C.A. App. 392-93, 595-605. Despite UnitedHealth's arguments, the D.C. Circuit ignored this record evidence and, instead, relied on extra-record evidence that CMS produced years *after* the Overpayment Rule (in attempting to salvage the Rule in this litigation). *See* App. 47a-48a.

In short, the court's alternative holding provides no cover for the threshold and far-reaching statutory error at the heart of this case.

c. The Overpayment Rule also violates the statute's requirement that CMS calculate the risk scores—the numerical measure of costliness—of the two populations using the "same methodology." *Id.* at 79a. CMS calculates the risk scores of the beneficiaries in traditional Medicare by assigning the

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[5] The rate of unsupported codes in traditional Medicare goes only to the *degree* to which MA plans are underpaid under the Overpayment Rule, not the fact of underpayment.

values it calculated for each condition to each diagnosis code in its beneficiaries' profiles, including unsupported codes. But when calculating the risk scores of MA plan beneficiaries, CMS subtracts the value of any codes that plans identify as unsupported. These are obviously two different methodologies. And the methodologies necessarily result in artificially reducing the risk scores of MA beneficiaries compared to *identical* CMS beneficiaries.

B. Based On This Statutory Error, The D.C. Circuit Also Disregarded A Critical Check On Arbitrary Agency Action

The D.C. Circuit's misreading of the Medicare statute also led it to excuse CMS from complying with a basic tenet of administrative rulemaking: that an agency must provide a reasoned explanation for departing from a prior position, showing both an "awareness" that it was changing positions and "good reasons" for doing so. *Federal Commc'ns Comm'n v. Fox*, 556 U.S. 502, 515 (2009). CMS did neither when adopting the Overpayment Rule. Thus, as the district court held, the agency was "arbitrary and capricious in adopting the 2014 Overpayment Rule without explaining its departure from prior policy." App. 84a. Yet the D.C. Circuit summarily dismissed this argument on the basis of its erroneous statutory ruling that "the Overpayment Rule does not violate, or even implicate, actuarial equivalence." *Id.* at 52a.

In adopting a fee-for-service adjuster in its RADV audits, CMS addressed the same question of what constitutes an "overpayment." C.A. App. 99. But in that earlier instance, the agency answered the question completely differently: CMS agreed that before it could determine the existence or amount of

an MA overpayment, it needed to apply an "adjuster" to offset the impact of errors in its own data and ensure actuarial equivalence. *See supra* at 10-11.

Instead of acknowledging and explaining this switch in positions during the rulemaking for the Overpayment Rule (as the APA requires), CMS's only reference to the fee-for-service adjustment was the nonsensical statement that the "RADV methodology does not change [the] existing contractual requirement" that MA plans certify "the accuracy . . . of the risk adjustment data they submit to CMS." C.A. App. 64. But MA plans that undergo a RADV audit submit the exact same certifications as all other MA plans. So this statement explained nothing.

The Overpayment Rule also inexplicably departed from CMS's past statements about the coding intensity adjuster. *See supra* at 11-12. In that context, CMS recognized that "MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid," and that "'to pay plans accurately'" requires "'establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings.'" C.A. App. 177-78 (citation omitted); *see also id.* at 259. Here again, the Overpayment Rule was an abrupt about-face. Yet CMS never acknowledged, much less tried to explain, this departure from its prior understanding.

As this Court's decisions illustrate, the basic requirement that an agency recognize and explain its departure from prior policy is a critical check on arbitrary and capricious agency action. *See, e.g.*, *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224, (2016). Here, the district court concluded that CMS had violated that principle in adopting the Overpayment Rule. App. 79a-84a. Yet the D.C.

Circuit simply dismissed this independent basis for invalidating the Rule based on its threshold misreading of the statute—giving the agency a "free pass" on its unexplained flip in positions. *Id.* at 52a.

This basic check on arbitrary agency action is especially important here because CMS was not acting simply as a neutral regulator in adopting the Overpayment Rule. Rather, it has a significant financial stake in this issue. CMS implements the MA program by entering into contracts with private insurers to provide health benefits in CMS's stead, and the impact of the Rule is to reduce the payments CMS is obligated to make under those contracts. That makes it all the more important to ensure that the agency acted lawfully—and not arbitrarily and capriciously—in adopting the Rule.

The D.C. Circuit's error in excusing CMS from having to meet this basic APA check on agency decisionmaking also warrants this Court's review.

II. The Questions Presented Are Exceptionally Important And Review Is Warranted Here

The exceptional importance of this case warrants this Court's immediate intervention.

A. The Decision Below Will Destabilize The MA Program And Reduce The Scope And Quality Of Healthcare Coverage

The questions presented implicate the continued ability of MA plans to provide their rich array of healthcare benefits to more than 26 million Americans. *See* Freed, *Medicare Advantage in 2021*. The MA program is extremely popular because of its enhanced benefits and the ability for beneficiaries to keep their own providers, as underscored by the fact that enrollment in MA has steadily climbed over the

past decade. *See* Gretchen Jacobson et al., *A Dozen Facts About Medicare Advantage in 2019*, at 1 (June 6, 2019), https://files.kff.org/attachment/Data-Note-A-Dozen-Facts-About-Medicare-Advantage-in-2019. In addition to its popularity with millions of everyday Americans, the MA program enjoys widespread bipartisan support in Congress.[6]

None of this is surprising. MA plans promote the provision of better healthcare while decreasing costs and using those savings to provide additional benefits to members. For example, MA plans coordinate physician services, hospital care, and prescription drug benefits through an integrated approach that ensures members receive streamlined treatment in a timely and efficient manner. *See Medicare Advantage Hearing on Promoting Integrated and Coordinated Care for Medicare Beneficiaries: Hearing Before the H. Subcomm. on Health of the Comm. on Ways and Means*, 115 Cong. 96 (2017) (statement of AHIP), https://www.congress.gov/115/chrg/CHRG-115hhrg33429/CHRG-115hhrg33429.pdf.

Studies have shown that MA plans outperform traditional Medicare "on nearly all clinical quality and most patient experience measures."[7] The MA

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[6] More than 400 members of Congress recently signed letters expressing strong support for the MA program. *See* AHIP, *AHIP Thanks Congress for the Record-Setting Bipartisan Support for Medicare Advantage* (Feb. 5, 2020).

[7] Justin W. Timbie et al., *Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures: Comparisons from Three Large States*, 52 Health Servs. Res. 2038, 2058 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5682140/pdf/HESR-52-2038.pdf.

program also helps control Medicare spending generally: High baseline MA penetration rates in counties is associated with a decrease in per-patient annual spending in traditional Medicare.[8] In short, given the significant contributions made by the MA program, its continued success is vital to the U.S. healthcare system as a whole.

The decision below jeopardizes that success by foisting on MA plans a radical and unjustified change to the payment model Congress established. The payment model's central purpose is to "take into account the health status of the plan's enrollees" so "that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees)." Medicare Program; Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005); C.A. App. 92. Actuarially equivalent risk adjustment thus ensures that MA plans have the resources they need to provide coverage to their enrollees. It also furthers Congress's goal of making MA plans broadly available to all eligible Americans by eliminating structural incentives that would otherwise favor enrollment of only lost-cost (i.e., healthier) individuals. *See* American Academy of Actuaries, Issue Brief, *Risk Assessment and Risk Adjustment* 1 (May 2010), https://www.actuary.org/sites/default/files/files/publications/IssueBrief_Risk_Assesment_and_Adjustment_May2

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[8] *See* Garrett Johnson et al., *Recent Growth In Medicare Advantage Enrollment Associated With Decreased Fee-For-Service Spending In Certain US Counties*, 35 Health Affs. 1707, 1711 (Sept. 2016) https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2015.1468.

010.pdf ("A well-designed risk-adjustment system is one that properly aligns incentives, limits gaming, and protects risk-bearing entities (e.g., insurers, health plans).").

The D.C. Circuit's decision threatens the long-term stability of MA plans. For the MA program to be viable, the monthly payments from CMS must accurately reflect the risk MA plans assume by insuring their beneficiaries. Indeed, before the MA program entered its current stage of steady growth in 2004, the program had been in serious disarray. After a change in the MA reimbursement formula in 1997, MA plans withdrew from the program in droves, leaving many regional areas without coverage. *See* C.A. App. 495; Lori Achman & Marsha Gold, The Commonwealth Fund, *Medicare+Choice 1999-2001: An Analysis Of Managed Care Plan Withdrawals And Trends In Benefits And Premiums* 3-6 (2002), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2002_feb_medicare_choice_1999_2001__an_analysis_of_managed_care_plan_withdrawals_and_trends_in_benefits_and_p_achman_m_cwithdrawals_497_pdf.pdf. The remaining MA plans then increased their premiums and decreased benefits. *Id.* It was not until Congress intervened years later and fixed this problem that the MA program began to recover.

If allowed to stand, the D.C. Circuit's ruling will leave MA plans with no choice but to reduce coverage, cut benefits, or raise premiums for potentially millions of beneficiaries—and in some cases even consider exiting the market. *See* C.A. App. 361-63, 366-68 (detailing these implications in the RADV audit context before CMS adopted an adjuster). What is more, these effects are likely to be felt most acutely

by the most vulnerable members of society. MA plans that offer special-needs insurance plans to low-income beneficiaries eligible for both Medicare and Medicaid effectively have less flexibility with respect to reductions in benefits or increases in premiums. *See id.* at 368. MA plans that serve these dual-eligible populations may be forced to stop offering such services because the plans would be unable to formulate a bid that was actuarially sound and meets CMS's bid instructions. On top of that, the D.C. Circuit's decision could significantly reduce competition among MA plans, as plans scale back offerings or even withdraw from the MA program.

The Medicare system provides important coverage and benefits to a population that often presents the most challenging and complex health conditions. The MA program was enacted to allow for comprehensive, coordinated care for these beneficiaries in a manner that focuses holistically on the individual rather than on a specific treatment or procedure. A payment system designed for that form of care was needed, it was developed, and it was thriving. The decision below seriously compromises that model.

B. The Court's Review Is Warranted Here

This Court regularly grants certiorari to resolve exceptionally important questions concerning the implementation of major government programs like Medicare, with multi-billion dollar and transformational impacts at stake, even in the absence of a circuit conflict. *See, e.g.*, *American Hospital Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted*, 141 S. Ct. 2883 (2021) (No. 20-1114); *American Lung Ass'n v. EPA*, 985 F.3d 914 (D.C. Cir. 2021), *cert. granted*, 142 S. Ct. 420 (2021) (No. 20-

1530); *FERC v. Electric Power Supply Ass'n*, 136 S. Ct. 760 (2016); *Michigan v. EPA*, 576 U.S. 743 (2015); *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302 (2014); *Whitman v. American Trucking Ass'ns*, 531 U.S. 457 (2001); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000); *MCI Telecomms. Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218 (1994). Certiorari is likewise warranted here.

Indeed, this petition likely will be the Court's *only* opportunity to address the questions presented. First, the six-year statute of limitations under the APA (28 U.S.C. § 2401(a)) for challenging the Overpayment Rule has run, and there are no other pending challenges to the Rule. *See National Ass'n of Mfrs. v. Department of Def.*, 138 S. Ct. 617, 626-27 (2018). Second, the sheer breadth of the D.C. Circuit's holding—completely decoupling the actuarial-equivalence provision from the overpayment provision—precludes MA plans from even *attempting* to show they are being underpaid in comparison to traditional Medicare. As a result, the questions presented are unlikely to arise on an as-applied basis. And, third, this issue is unlikely to come before this Court through an alternative vehicle.

In any event, the D.C. Circuit's decision in this case will have a direct and immediate impact on the healthcare available to millions of American seniors and others. Even if a conflict could somehow arise, the decision below will impose multi-billion dollar obligations on MA plans that, as discussed, will diminish the scope and quality of healthcare coverage available under MA plans, increase the premiums due under such plans, and threaten the success of the MA program. Especially given that the decisions below

fully ventilate both sides of the dispute in this case, this Court's intervention is warranted here and now.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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February 14, 2022

APPENDIX

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UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

UNITEDHEALTHCARE INSURANCE COMPANY, et al., Appellees,

v.

Xavier BECERRA, in His Official Capacity as Secretary of Health and Human Services, et al., Appellants.

No. 18-5326

Argued November 3, 2020
Decided August 13, 2021
Reissued November 1, 2021

16 F.4th 867

Before: ROGERS, PILLARD and WALKER, Circuit Judges.

OPINION

PILLARD, Circuit Judge:

UnitedHealthcare Insurance Company and other Medicare Advantage insurers under the umbrella of UnitedHealth Group Incorporated (collectively, UnitedHealth) challenge a rule the Centers for Medicare and Medicaid Services (CMS) promulgated under the Medicare statute, 42 U.S.C. §§ 1301-1320d-8, 1395-1395hhh. The Overpayment Rule is part of the government's ongoing effort to trim unnecessary costs from the Medicare Advantage program. Neither Congress nor CMS has ever treated an unsupported

diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer. Consistent with that approach, the Overpayment Rule requires that, if an insurer learns a diagnosis it submitted to CMS for payment lacks support in the beneficiary's medical record, the insurer must refund that payment within sixty days. The Rule couldn't be simpler. But understanding UnitedHealth's challenge requires a bit of context.

As explained in more detail below, people who are eligible for Medicare may elect to receive their health insurance through a private insurer under Medicare Advantage rather than directly through the government under traditional Medicare, and approximately forty percent of beneficiaries have chosen Medicare Advantage. CMS pays private Medicare Advantage insurers, in a prospective lump sum each month, the amount it expects a month's care would otherwise cost CMS in direct payments to healthcare providers treating the same beneficiaries under traditional Medicare. For each Medicare Advantage beneficiary, CMS pays the insurer a per-capita amount that varies according to demographic characteristics and diagnoses that CMS has determined, based on its past experience in traditional Medicare, to be predictive of healthcare costs.

Payments to the Medicare Advantage program depend on participating insurers accurately reporting to CMS their beneficiaries' salient demographic information and medically documented diagnosis codes. To better control erroneous payments, including those garnered from reported—but unsupported—diagnoses, Congress in 2010 amended the Medicare program's data-integrity provisions.

The amendment specified a sixty-day deadline for reporting and returning identified overpayments and confirmed that such payments not promptly returned may trigger liability under the False Claims Act. *See id.* § 1320a-7k(d). CMS promulgated the Overpayment Rule to implement those controls on Medicare Advantage. *See* 42 C.F.R. § 422.326. As relevant here, the Overpayment Rule establishes that, if a Medicare Advantage insurer has received a payment increment for a beneficiary's diagnosis and discovers that there is no basis for that payment in the underlying medical records, that is an overpayment that the insurer must correct by reporting it to CMS within sixty days for refund. *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) (hereinafter Overpayment Rule), J.A. 64.

UnitedHealth claims that it is unambiguous in the text of the Medicare statute that the Overpayment Rule is subject to a principle of "actuarial equivalence," and that the Rule fails to comply. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). But actuarial equivalence does not apply to the Overpayment Rule or the statutory overpayment-refund obligation under which it was promulgated. Reference to actuarial equivalence appears in a different statutory subchapter from the requirement to refund overpayments, and neither provision cross-references the other. Further, the actuarial-equivalence requirement and the overpayment-refund obligation serve different ends. The role of the actuarial-equivalence provision is to require CMS to model a demographically and medically analogous beneficiary

population in traditional Medicare to determine the prospective lump-sum payments to Medicare Advantage insurers. The Overpayment Rule, in contrast, applies after the fact to require Medicare Advantage insurers to refund any payment increment they obtained based on a diagnosis they know lacks support in their beneficiaries' medical records.

UnitedHealth contends that the actuarial-equivalence principle reaches beyond its statutory home to impose an implied—and functionally prohibitive—legal precondition on the requirement to return known overpayments. As UnitedHealth would have it, Congress clearly intended enforcement of the statutory overpayment-refund obligation, which the Overpayment Rule essentially parrots, to depend on a prior determination of actuarial equivalence. That principle, UnitedHealth says, prevents CMS from recovering overpayments under the Rule unless CMS first shows that the rate of payment errors to healthcare providers in traditional, fee-for-service Medicare is lower than the rate of payment errors to the Medicare Advantage insurer, or that CMS comprehensively audited the data from traditional Medicare before using it in the complex regression model—the CMS Hierarchical Condition Category (CMS-HCC) risk-adjustment model—that predicts the cost to insure Medicare Advantage beneficiaries.

There is no legal or factual basis for UnitedHealth's claim. Actuarial equivalence is a directive to CMS. It describes the goal of the risk-adjustment model Congress directed CMS to develop. It does not separately apply to the requirement that Medicare Advantage insurers avoid known error in their payment requests. It assuredly does not unambiguously demand that, before CMS can collect

known overpayments from Medicare Advantage insurers, it must engage in unprecedented self-auditing to eliminate an imagined bias in the body of traditional Medicare data CMS used in its regressions. The implausibility that Congress would have so intended is underscored by the lack of parallelism between the context and effects of, on one hand, unsupported diagnoses in the traditional Medicare data CMS uses to model generally applicable risk factors and, on the other, the specific errors the Overpayment Rule targets.

Even if actuarial equivalence applied as UnitedHealth suggests, it would be UnitedHealth's burden to show the systematically skewed inaccuracies on which its theory depends, which it has not done. Also fatal to UnitedHealth's claim is that it never challenged the values CMS assigned to the risk factors it identified or the level of the capitation payments resulting from CMS's risk-adjustment model. It cannot belatedly do so in the guise of a challenge to the Overpayment Rule.

UnitedHealth's next claim relies on the Medicare statute's requirement that CMS annually compute and publish certain traditional Medicare data "using the same methodology as is expected to be applied in making payments" to Medicare Advantage insurers. *Id.* § 1395w-23(b)(4)(D). That "same methodology" requirement does not bear on the overpayment-refund obligation. Meant to facilitate Medicare Advantage insurers' bidding for contracts with CMS, that requirement merely clarifies that, in computing the data it publishes, CMS must use the same risk-adjustment model that it already uses to set monthly payments to Medicare Advantage insurers; like the

actuarial-equivalence requirement, it says nothing about what constitutes an "overpayment."

UnitedHealth's final claim is that the Overpayment Rule is arbitrary and capricious in violation of the Administrative Procedure Act (APA). That claim hinges on what UnitedHealth sees as an unexplained inconsistency between the Overpayment Rule and another error-correction mechanism to which Medicare Advantage insurers are subject: Risk Adjustment Data Validation (RADV) audits. With those audits, CMS proposed a systemic adjustment involving the traditional Medicare data used to model risk factors to account for any errors in that data set before requiring any contract-level repayments from insurers. UnitedHealth sees inconsistency in obligating repayments under the Overpayment Rule without any such adjustment. But the system-level adjustment that CMS said it would apply in the context of contract-level RADV audits came in direct response to concerns about actuarial equivalence. Because we hold that the actuarial-equivalence requirement does not pertain to the statutory overpayment-refund obligation or the Overpayment Rule challenged here, and the two error-correction mechanisms are plainly distinguishable in other ways, CMS's one-time intention to apply the adjustment in one context but not the other was reasonable.

In sum, nothing in the Medicare statute's text, structure, or logic applies actuarial equivalence to its separate overpayment-refund obligation, and thus the Overpayment Rule does not violate actuarial equivalence. For much the same reasons, we reject UnitedHealth's claim that the Rule violates the statute's "same methodology" requirement, and we

also deny its claim that the Rule is arbitrary and capricious as an unexplained departure from prior policy. We therefore reverse the judgment of the district court vacating the Overpayment Rule and remand this case with orders to enter judgment in favor of Appellants, except with respect to the Overpayment Rule's definition of "identified."

BACKGROUND

Overpayment to Medicare Advantage insurers is a serious drain on the Medicare program's finances. In 2016 alone, audits of the data submitted by Medicare Advantage insurers to CMS showed that CMS paid out an estimated $16.2 billion for unsupported diagnoses, equal to "nearly ten cents of every dollar paid to Medicare Advantage organizations." *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 673 (9th Cir. 2018) (citing James Cosgrove, U.S. Gov't Accountability Off., GAO-17-761T, *Medicare Advantage Program Integrity: CMS's Efforts to Ensure Proper Payments* 1 (2017), https://www.gao.gov/assets/690/685934.pdf). UnitedHealth is the Nation's largest provider of Medicare Advantage plans. Meredith Freed et al., *A Dozen Facts About Medicare Advantage in 2020*, Kaiser Family Found. (Jan. 13, 2021), https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/.

A. Statutory and regulatory background

1.

Since 1965, most older adults and many people with disabilities in the United States have received their health insurance through Medicare, administered by CMS. In Medicare Parts A and B, or "traditional" Medicare, CMS itself acts as the insurer,

paying healthcare providers directly for beneficiaries' medical services. Medicare Part A covers inpatient hospital treatment and other institutional care and is generally provided without charge to Medicare-eligible individuals. But for outpatient services, like visits to doctors' offices, the Medicare statute provides Medicare-eligible individuals a choice of whether and how to receive such coverage: They can receive that, too, by having the government pay providers for services, under Medicare Part B; or they can opt for private insurance paid for at least in part by the government, under Medicare Part C, also known as Medicare Advantage (and formerly known as Medicare+Choice).

Unlike Medicare Part A, coverage under Medicare Part B and Medicare Advantage generally requires payments from beneficiaries to the government or, if applicable, private insurance companies. Medicare Advantage insurers must provide coverage of at least the same services as Medicare-eligible individuals would receive through traditional Medicare, 42 U.S.C. § 1395w-22(a), and those private insurers often attract subscribers by offering additional benefits, such as dental and vision coverage, that they are able to include due to efficiencies and other cost-saving measures. More than twenty-four million Americans, or nearly forty percent of all Medicare beneficiaries, choose to receive their health insurance through Medicare Advantage. *See generally* Freed et al., *supra*.

Medicare Parts A and B and Medicare Advantage pay healthcare providers in different ways. Under Medicare Part A, CMS pays a hospital or institutional care provider based on a beneficiary's diagnoses at the time of discharge, which translate to a "Diagnosis-

Related Group." Under Medicare Part B, CMS pays outpatient providers on a fee-for-service basis under fee schedules that set the payment for each service provided, such as an office visit, examination, or immunization. A beneficiary's diagnoses do not directly affect the level of payment made to a healthcare provider under Part B, but because a service is reimbursable only if it is "reasonable and necessary for the diagnosis or treatment of illness or injury," 42 U.S.C. § 1395y(a)(1)(A), providers still must generally submit diagnosis codes to CMS showing why a beneficiary received the services that she did.

Private Medicare Advantage insurers likewise pay healthcare providers based on the services provided to beneficiaries but, as noted above, under Part C those insurers themselves receive in advance a monthly lump sum from CMS for every beneficiary that they enroll, without regard to the services that the beneficiaries will actually receive. The prospective, lump-sum payment approach has the potential to curb costly and unnecessary overtreatment that the fee-for-service approach tends to encourage, and it favors preventative care and other health-protective measures, enabling cost efficiencies that can elude a fee-for-service system. *See* Advance Notice of Methodological Changes for CY 2004 Medicare+Choice Payment Rates, at 5 (Mar. 28, 2003), J.A. 115. The core idea is that a Medicare Advantage insurer that covers all of a beneficiary's health care at least as well as traditional Medicare but does so at lower cost may pocket the difference as earned revenue, or pass along that revenue to beneficiaries in the form of extra benefits meant to entice and retain subscribers.

2.

It is the Medicare statute that requires CMS to pay Medicare Advantage insurers in advance, on a monthly basis, for each of the Medicare-eligible beneficiaries that they insure. 42 U.S.C. § 1395w-23(a)(1)(A). The statute also requires CMS to adjust those monthly, per-capita payments to reflect what traditional, fee-for-service Medicare paid in a base year for a beneficiary population modeled—by reference to demographics, diagnoses, and other factors CMS selects—to be actuarially equivalent to the Medicare Advantage insurer's beneficiary population. *Id.* § 1395w-23(a)(1)(C)(i). Specifically, Congress instructed that the Secretary of Health and Human Services (HHS)

> shall adjust the payment amount . . . for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . , so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

Id. The point of the Secretary's discretion to select, and obligation to apply, risk factors is "to ensure that [Medicare Advantage insurers] are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees)." Medicare Program; Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005), J.A. 92. Indeed, "the goal of risk adjustment" is "to pay [Medicare Advantage] plans

accurately." 152 Cong. Rec. S438-02 (daily ed. Feb. 1, 2006) (statement of Sen. Grassley).

Specifically, identifying salient risk factors enables CMS to determine prospectively, based on Medicare Advantage beneficiaries' actuarially relevant, known demographic and health characteristics, the per-capita payment rate that will fairly compensate that Medicare Advantage insurer. More broadly, the demographic- and health-adjusted, capitated payment scheme is designed to blunt the incentives to enroll only the healthiest, and thus least expensive, beneficiaries while steering clear of the sickest and costliest—thereby rewarding Medicare Advantage insurers to the extent that they achieve genuine efficiencies over traditional Medicare in addressing the same health conditions. *See* Gregory C. Pope et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, Health Care Fin. Rev., Summer 2004, at 119, 119-20, J.A. 487-88; *see also* H.R. Rep. No. 105-217, at 585 (1997) (Conf. Rep.); H.R. Rep. No. 108-391, at 524-25 (2003) (Conf. Rep.).

To adjust the monthly payments, CMS uses a model—called the CMS Hierarchical Condition Category, or CMS-HCC, risk-adjustment model—that it periodically studies and improves based on clinical information and cost data. The model isolates demographic characteristics CMS has determined to be predictive of differing costs of care, including the risk factors expressly mentioned in the statute: age, sex, disability status, and whether the beneficiary lives in a long-term institutional setting. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). It adjusts for health status by isolating cost-predictive diagnoses. CMS uses expert judgment to determine, for example,

"which diagnosis codes should be included, how they should be grouped, and how the diagnostic groupings should interact for risk adjustment purposes." Gregory C. Pope et al., *Evaluation of the CMS-HCC Risk Adjustment Model: Final Report* 8 (Mar. 2011), J.A. 525. Diagnostic categories must be reasonably specific and clinically meaningful. And, to fine-tune its predictive utility, CMS's model accounts for interactions between multiple diagnoses where total joint costs are more than additive. CMS also establishes a hierarchy of diagnoses to avoid double counting, zeroing out the cost effects of less severe disease manifestations when a patient also has a more severe diagnosis that fully accounts for treatment costs for both. *Id.*

CMS's risk-adjustment model applies a regression analysis to the mass of data from traditional Medicare for a previous year to convert each demographic and health characteristic into an expected cost of coverage. *See id.* at 2, J.A. 519. CMS inputs traditional Medicare beneficiaries' data, including the diagnosis codes that healthcare providers are required to report (even though, as noted above, CMS itself bases Medicare Part B payments on services, not diagnoses), along with the total cost for covering those beneficiaries. The model isolates the anticipated cost of care associated with each demographic and health characteristic by first determining the average marginal cost of that characteristic in dollars and then dividing that dollar amount by traditional Medicare's average cost per beneficiary. That process produces a "relative factor" for each demographic and health characteristic. The model "use[s] data from a large pool of beneficiaries (full sample sizes over 1 million for the CMS-HCC

models) to estimate predicted costs on average for each of the component factors (e.g., age-sex, low income status, individual disease groups)." *Id.* at 5, J.A. 522. Using regression analysis on such a vast data sample mutes the effect of individual errors in traditional Medicare data, so long as errors are not so widespread or systemically skewed as to raise or lower the values of particular relative factors. *See id.*; *see also* Amy Gallo, *A Refresher on Regression Analysis*, Harv. Bus. Rev. (Nov. 4, 2015), https://hbr.org/2015/11/a-refresher-on-regression-analysis.

To enable CMS to apply those relative factors to pay Medicare Advantage insurers at the correct risk-adjusted rate, the insurers must report to CMS the salient demographic and health characteristics of each of their Medicare-eligible beneficiaries. 42 C.F.R. § 422.310(b), (d). CMS then combines the relative factors for a particular beneficiary to arrive at her individualized overall "risk score." *See* Pope et al., *Evaluation of the CMS-HCC Risk Adjustment Model: Final Report* 15, J.A. 532. CMS posits that an "average beneficiary" in traditional Medicare has a risk score of 1.0. If a Medicare Advantage beneficiary has a risk score of exactly 1.0, CMS pays the insurer the base payment rate for that beneficiary's location. For Medicare Advantage beneficiaries with risk scores above 1.0, meaning they are of higher-than-average risk, CMS pays insurers more than the base payment rate; for beneficiaries with risk scores below 1.0, the payments are correspondingly lower than the base rate. But Medicare Advantage beneficiaries are not presumptively scored as 1.0; the per-capita payments that CMS makes to insurers instead

depend on an aggregation of the beneficiaries' cost-predictive demographic and diagnostic factors.

CMS illustrates the operation of relative factors with an example:

> [U]nder the 2014 model, a 72-year-old woman living independently (relative factor 0.348), with diabetes without complications (relative factor 0.118), and multiple sclerosis (relative factor 0.556) would have a total risk score of 1.022, which means that she is expected to cost Medicare slightly more than the average traditional Medicare beneficiary (who would by definition have a risk score of 1.0).

Gov't Br. 7 (citing Announcement of CY 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, at 67-68 (Apr. 1, 2013), J.A. 276-77). In other words, as a woman near the younger end of the Medicare-eligible population and living outside any long-term institutional setting, this sample beneficiary starts with a risk score well below the overall Medicare average. The fact that she suffers from diabetes raises her risk score, but not by much, presumably because she has not experienced complications and ordinary diabetes care is not as costly as many other conditions common among older Americans. The larger bump, putting her over the average predicted cost of care even for the cost-intensive Medicare population, is that she suffers from multiple sclerosis. A Medicare Advantage insurer providing coverage to this woman therefore "would be paid 102.2 percent of the relevant base rate." *Id.* at 8.

This example illustrates the importance of risk-adjusted payment. Assume a similar woman, but without her diagnoses. With a risk score of just 0.348, her care would then be predicted to be far less expensive than that of the average Medicare beneficiary, whose risk score is, by definition, 1.0. If Medicare Advantage insurers were paid an unadjusted base rate for every beneficiary, they could receive an enormous, and unjustified, net surplus insofar as they enrolled beneficiaries with such low anticipated costs. Conversely, an unadjusted, per-capita base payment would likely fall far short of fairly compensating a Medicare Advantage insurer for the costs of care for the woman in the example with both of the posited diagnoses, and the shortfall would only grow with any added complications or diagnoses she developed.

There is some evidence that Medicare Advantage insurers in fact have tended to attract healthier-than-average beneficiaries—perhaps because of the additional premiums they may charge, and the well-established correlation between wealth and health. *See Is Medicare Advantage More Efficient than Traditional Medicare?*, Nat'l Bureau of Econ. Rsch. (Mar. 2016), https://www.nber.org/bah/2016no1/medicare-advantage-more-efficient-traditional-medicare; *see also* Pope et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, at 119-20, J.A. 487-88; Pope et al., *Evaluation of the CMS-HCC Risk Adjustment Model: Final Report* 7, J.A. 524. Without the corrective provided by risk-adjusting the capitated payment amounts, payment levels would not be fair, and incentives to attract the healthy and deflect the sick would be overwhelming.

CMS determines the base payment rate—which, again, is the amount a Medicare Advantage insurer would receive for any beneficiary with a risk score of exactly 1.0, and which is the denominator for calculation of every capitated payment to Medicare Advantage—by reference to traditional Medicare's per-capita expenditures in a particular place and bids submitted by Medicare Advantage insurers. Each county in the United States has its own base rate, and every year Medicare Advantage insurers bid for contracts after CMS announces each county's benchmark for the coming year. *See* 42 U.S.C. § 1395w-23(b)(1)(B). To inform Medicare Advantage insurers' bids to participate in the program, the Medicare statute requires CMS to compute and publish, on an annual basis, the "average risk factor" for traditional Medicare beneficiaries in each county. *Id.* § 1395w-23(b)(4)(D). The statute specifies that the published average risk factor must be "based on diagnoses for inpatient and other sites of service, using the same methodology as is expected to be applied in making payments under subsection (a)," *i.e.*, the subsection that includes the actuarial-equivalence requirement. *Id.* UnitedHealth separately claims the "same methodology" criterion supports its challenge to the Overpayment Rule.

3.

CMS's regulations have long obligated Medicare Advantage insurers to certify the accuracy of the data that they report to CMS. Since 2000, those regulations have made it "a condition for receiving a monthly payment" that a Medicare Advantage insurer

> agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract [with CMS] on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests.

42 C.F.R. § 422.504(*l*); *see also United States ex rel. Swoben v. UnitedHealthcare Ins. Co.*, 848 F.3d 1161, 1168 & n.2 (9th Cir. 2016) (citing 42 C.F.R. § 422.502(*l*) (2000)). CMS's regulations specifically apply that obligation to the data Medicare Advantage insurers report to CMS to identify their beneficiaries' actuarially salient attributes—*i.e.*, demographic and health characteristics, including diagnosis codes. *See* 42 C.F.R. § 422.504(*l*)(2) (referencing data reported under 42 C.F.R. § 422.310).

But, as Congress has recognized, even accurate diagnosis codes that Medicare Advantage insurers report can lead to disproportionately high payments to insurers. That is because Medicare Advantage insurers have a financial incentive to code intensely—*i.e.*, to make sure that they report to CMS their beneficiaries' every diagnosis—given that their monthly, per-capita payments are higher to the extent that their beneficiaries have more or graver diagnoses. Meanwhile, healthcare providers to traditional Medicare beneficiaries lack that same incentive because their payments from CMS depend on services rendered, not diagnoses. *See* U.S. Gov't Accountability Off., GAO-12-51, *Medicare Advantage:*

CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices 2 (Jan. 2012), J.A. 546. Thus, if one were to imagine that traditional Medicare and Medicare Advantage had identical populations of beneficiaries, the latter would generally end up reporting more diagnoses (and therefore appear sicker and receive additional payments) even though their true health conditions were the same. To account for that difference in incentives and coding practices, Congress enacted a Coding Intensity Adjuster that reduces the risk scores of all Medicare Advantage beneficiaries by a specified percentage. *See* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1102(e)(3)(D), 124 Stat. 1029, 1046. For 2019, Congress set that reduction at a minimum of 5.9 percent. 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III). The Coding Intensity Adjuster does not, however, address unsupported or inaccurate codes reported by Medicare Advantage insurers, but only the practice, relative to traditional Medicare, of overreporting codes that are nonetheless accurate.

UnitedHealth's challenge to the Overpayment Rule adverts to yet another data-integrity measure providing for Risk Adjustment Data Validation, or RADV, audits. To supplement the regulatory obligations on Medicare Advantage insurers to certify the accuracy of the diagnosis codes and other data they report to CMS, and because CMS cannot confirm in real time the data insurers submit for their millions of beneficiaries, CMS seeks to confirm that its payments to insurers are correct by retrospectively spot-checking the data submissions going back several years. *See* 42 C.F.R. § 422.310(e); *see also* Medicare Program; Policy and Technical Changes to

the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009), J.A. 96. For these RADV audits, CMS selects a subset of Medicare Advantage insurers and compares a sample of their reported diagnosis codes to the underlying medical charts and records for the relevant beneficiaries. *See* Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 74 Fed. Reg. at 54,674, J.A. 96. The Medicare Advantage insurers must return to CMS any payments that an audit reveals were based on unsupported diagnoses—that is, diagnoses reported to CMS but that the audit found lack support in the relevant beneficiaries' medical record documentation. *See id.*

CMS has conducted such audits for well over a decade, and their results show that a significant number of reported diagnoses are in fact unsupported. *See, e.g.*, U.S. Dep't of Health & Human Servs., Off. of Inspector Gen., *Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007*, A-06-09-00012, at 4 (May 2012), J.A. 471 (stating that the risk scores for forty-three out of 100 sampled beneficiaries of the audited insurer "were invalid because the diagnoses were not supported"); U.S. Dep't of Health & Human Servs., Off. of Inspector Gen., *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007*, A-09-09-00045, at i (Nov. 2012), J.A. 476 (stating that the risk scores for forty-five out of 100 sampled beneficiaries "were invalid because the diagnoses were not supported by the documentation that [the Medicare Advantage] insurer provided").

Medicare Advantage insurers' obligation to return mistaken payments pursuant to RADV audits differs from their obligation under the Overpayment Rule: With the former, insurers are required to refund payments based on unsupported diagnoses that CMS discovers through its audit, whereas with the latter, insurers are required to refund payments based on unsupported diagnoses that they themselves discover through the course of their business. CMS also audits traditional Medicare data, although it does so through different mechanisms that may result in a lower percentage of traditional Medicare payment claims being audited than Medicare Advantage ones. *See* Gov't Br. 35-38; Appellees Br. 42-43.

In 2008, CMS announced an expansion of its RADV audit program for Medicare Advantage: Rather than requiring repayments only for the unsupported diagnosis codes identified in the limited sample itself, CMS would take the payment error in an audited sample, extrapolate that error rate across CMS's entire contract with that Medicare Advantage insurer, and require the insurer to make a repayment based on the extrapolated, or contract-level, degree of error. *See* Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 74 Fed. Reg. at 54,674, J.A. 96; *see also* Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, at 22 (Apr. 7, 2008). (Because not all errors are created equal—that is, some are more costly than others—the extrapolated error rate would account for the magnitude of the errors by factoring in the difference between original and corrected payment amounts in an audited sample.) In late

2010, CMS sought comments on its proposal for contract-level RADV audits, and in early 2011 various commenters, including UnitedHealth and the American Academy of Actuaries, objected.

One criticism the commenters leveled at expanded RADV audits was that, "[u]nder sound actuarial principles, it is impossible to know whether [Medicare Advantage insurers] have been paid accurately by conducting a review of the medical records supporting [Medicare Advantage] coding, without also considering the medical records supporting [traditional Medicare] coding." Aetna Inc.'s Comments on Proposed Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits, at 4 (Jan. 21, 2011), J.A. 298. In other words, "CMS must audit and validate *both* [a Medicare Advantage insurer's data and the traditional Medicare data that goes into the risk-adjustment model] before extrapolating any potential RADV audit results" and requiring the insurer to return amounts thereby identified as excessive. Humana Inc., Comment on RADV Sampling and Error Calculation Methodology, at 3 (Jan. 21, 2011), J.A. 334. "If it does not, CMS will dramatically underpay [Medicare Advantage insurers] for the benefits they provided to Medicare beneficiaries," in violation of the Medicare statute's actuarial-equivalence requirement. *Id.*; *see also id.* at 5, J.A. 336.

In a move that UnitedHealth describes as important context for this case, CMS responded to the comments by announcing in 2012 that it would apply a Fee-for-Service, or FFS, Adjuster before requiring repayments based on contract-level RADV audits. With the FFS Adjuster, Medicare Advantage insurers

would be liable for repayments only to the extent that their extrapolated, contract-level payment errors, *i.e.*, the dollar amounts that they received in error, exceed any offsetting payment error in traditional Medicare. CMS said that it would determine the actual amount of the FFS Adjuster "based on a RADV-like review of records submitted to support [traditional Medicare] claims data." Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage RADV Contract-Level Audits, at 5 (Feb. 24, 2012), J.A. 398.

But CMS then conducted an empirical study from which it discovered that "errors in [traditional Medicare] claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systemic effect on the payments made to [Medicare Advantage insurers]." CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* 5 (Oct. 26, 2018) (hereinafter CMS Study), J.A. 731. That result is unsurprising. Providers paid on a fee-for-service basis, as is the case in Medicare Part B, would appear to lack incentives that bear on Medicare Advantage insurers to overreport costly diagnoses or other factors predictive of worse-than-average health, and any underreporting of diagnoses is likely the result of not catching the least costly beneficiaries with a given diagnosis (perhaps because they require little or no treatment), which would tend to reduce the average cost of a particular condition. *See* Gov't Br. 45-46. And individual errors within the mass of data used to model a relative factor would tend to have little to no effect on the factor's value, given the large sample sizes—on the order of one million beneficiaries, *see*

Pope et al., *Evaluation of the CMS-HCC Risk Adjustment Model: Final Report* 5, J.A. 522—together with "the fact that the relative factors are summed across each enrollee's [hierarchical condition categories] and then across a plan's enrollment, lead[ing] the inaccuracies to mitigate each other due to offsetting effects," CMS Study at 5, J.A. 731. Based on the study results, CMS announced in October 2018 that it would not, after all, use an FFS Adjuster for contract-level RADV audits. *See* CMS Study at 5-6, J.A. 731-32. That conclusion is preliminary, and the review and rulemaking are ongoing. *See* Oral Arg. Tr. 14:4-22. In the meantime, CMS does not use any FFS Adjuster in that context.

4.

Against the backdrop of concern about costly errors in the data reported by Medicare Advantage insurers, but before CMS even solicited comments on the proposed FFS Adjuster to contract-level RADV audits it ultimately deemed unnecessary, Congress enacted the provision that undergirds the Overpayment Rule. The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), obligates Medicare Advantage insurers to report and return any overpayment that they receive from CMS within sixty days of identifying it, 42 U.S.C. § 1320a-7k(d)(1), (2). The Act defines "overpayment" as "any funds that a person receives or retains under [the Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled." *Id.* § 1320a-7k(d)(4)(B). In section 1320a-7k(d)(3), it establishes that failure to report and return a known overpayment within sixty days of discovering it violates the False Claims Act, 31 U.S.C.

§ 3729 *et seq.*, which carries the potential for treble damages and other serious penalties, *see id.* § 3729(a)(1).

In 2014, CMS promulgated the Overpayment Rule to implement the statutory requirement to report and return overpayments. The Rule similarly defines "overpayment" as "any funds that [a Medicare Advantage insurer] has received or retained under [the Medicare Advantage program] to which the [Medicare Advantage insurer], after applicable reconciliation, is not entitled." Overpayment Rule, 79 Fed. Reg. at 29,958 (codified at 42 C.F.R. § 422.326(a)), J.A. 85. In the Rule's preamble, CMS explained that, among other things, any "diagnosis that has been submitted [by a Medicare Advantage insurer] for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment." *Id.* at 29,921, J.A. 64.

One commenter on the proposed Overpayment Rule, a Medicare Advantage insurer not a party to this case, had objected that it ran afoul of the Medicare statute's actuarial-equivalence requirement because it did not also require an adjuster akin to the FFS Adjuster that CMS had proposed two years earlier in the context of contract-level RADV audits. *See id.*; *see also* J.A. 50-51 (comment from Humana on proposed rule). In the final Rule, which does not provide for such an adjuster, CMS stated that it "disagree[d] with the commenter" because the "RADV methodology does not change [CMS's] existing contractual requirement that [Medicare Advantage insurers] must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they

submit to CMS." Overpayment Rule, 79 Fed. Reg. at 29,921, J.A. 64. Nor, said CMS, did the statutory overpayment-refund obligation, as implemented by the Rule, "change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by [a Medicare Advantage insurer] for payment purposes must be supported by medical record documentation." *Id.* at 29,921-22, J.A. 64-65.

B. Factual and procedural history

UnitedHealth filed this challenge to the Overpayment Rule in January 2016. Following the district court's denial of CMS's motion to dismiss in March 2017, the parties cross-moved for summary judgment. On September 7, 2018, the court granted UnitedHealth's motion in full and vacated the Overpayment Rule. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 192 (D.D.C. 2018).

The district court held that the Overpayment Rule violated the Medicare statute's requirement of "actuarial equivalence." *Id.* at 187. It concluded that the Rule would "inevitabl[y]" lead to the loss of actuarial equivalence, *id.* at 185, because "payments for care under traditional Medicare and Medicare Advantage are both set annually based on costs from unaudited traditional Medicare records, but the 2014 Overpayment Rule systematically devalues payments to Medicare Advantage insurers by measuring 'overpayments' based on audited patient records," *id.* at 184. The court emphasized that CMS had actually "recognized and mitigated" "the same actuarial problem" when, in 2012, it provisionally committed to using an FFS Adjuster for contract-level RADV audits to account for the fact that extrapolating an error rate across a Medicare Advantage insurer's entire contract

effectively corrected for any unsupported codes in the insurer's data. *Id.* Relying on much the same reasoning, the court held that the Rule also violated the Medicare statute's "same methodology" requirement. *Id.* at 187. The court then deemed the Rule arbitrary and capricious in violation of the APA as an unexplained departure from CMS's prior policy, namely, its stated intent to use an FFS Adjuster in the context of contract-level RADV audits. *Id.* at 187-90. The court noted only in passing that CMS had not yet determined an appropriate amount of any FFS Adjuster for contract-level RADV audits. *See id.* at 188.

The district court also rejected the Overpayment Rule's imposition of a negligence standard of liability for failure to identify and report an overpayment. The Rule as promulgated provided that a Medicare Advantage insurer "has identified an overpayment when the [insurer] has determined, *or should have determined through the exercise of reasonable diligence*, that the [insurer] has received an overpayment." 42 C.F.R. § 422.326(c) (emphasis added). But section 1320a-7k(d)(3) of the Medicare statute provides that an overpayment that is not timely reported and returned "is an obligation (as defined in section 3729(b)(3) of title 31)," *i.e.*, the False Claims Act, under which liability requires proof of "knowingly" submitting false claims for payment to the government, 31 U.S.C. § 3729(a). The False Claims Act defines "knowingly" as having "actual knowledge" or acting "in deliberate ignorance" or "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). The district court thus held the Rule's negligence-based liability inconsistent with the False Claims Act's "knowingly"

standard. *UnitedHealthcare*, 330 F. Supp. 3d at 190-91. The court held that the final Rule's negligence-based definition of "identified"—which the proposed rule had defined to track the False Claims Act's fault standard before CMS adopted the negligence standard in the final version—also violated the APA because it was not a logical outgrowth of the proposed rule. *Id.* at 191-92. CMS's appeal does not challenge either of those two holdings regarding the Rule's negligence standard; it contests only the district court's rulings on actuarial equivalence, same methodology, and the question whether the Rule was arbitrary and capricious as an unexplained departure from the FFS Adjuster CMS had proposed to adopt in the context of RADV audits. *See* Gov't Br. 20-22.

In November 2018, CMS moved for partial reconsideration, which the court denied in January 2020. CMS based that motion on the results of the October 2018 study of the error rate in traditional Medicare, conducted as groundwork for the anticipated FFS Adjuster for contract-level RADV audits. As noted above, the results of that study were made public several weeks after the district court's summary judgment ruling in this case. The study revealed that "errors in [traditional Medicare] claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model," undermining the case for an adjuster. CMS Study at 5, J.A. 731; *see also UnitedHealthcare Ins. Co. v. Azar*, No. 16-cv-157, 2020 WL 417867, at *1, *3 (D.D.C. Jan. 27, 2020), J.A. 801, 805. In denying the motion, the district court stated that it "need not linger on the details of the[ ] arguments" regarding the validity of the study and CMS's preliminary conclusion not to apply any FFS Adjuster to contract-

level RADV audits. *UnitedHealthcare*, 2020 WL 417867, at *5, J.A. 811. The court deemed it "sufficient to say that [UnitedHealth's] arguments [opposing the study] are fully explained and the government does not adequately respond." *Id.*

CMS timely appealed on November 6, 2018, and we removed the case from abeyance in February 2020 following the district court's denial of reconsideration.

Finally, it bears noting that the issue of actuarial equivalence has come up in other litigation between the parties. The federal government and *qui tam* plaintiffs have pursued several False Claims Act cases against Medicare Advantage insurers in the last several years, charging failures to report and return overpayments that the insurers knew were based on unsupported diagnoses. At least some such cases are still pending. *See, e.g.*, *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, No. 16-cv-8697 (C.D. Cal.); *United States ex rel. Osinek v. Kaiser Permanente*, No. 13-cv-3891 (N.D. Cal.). Medicare Advantage insurers, including UnitedHealth, have raised actuarial equivalence as a defense to False Claims Act liability. *See* Appellees Br. 55. At least one court has rejected that defense, *see United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1067-71 (N.D. Cal. 2020), while another denied the government's request for an early partial summary judgment on that basis, *see United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, No. 16-cv-8697, 2019 WL 2353125, at *1, *5-8 (C.D. Cal. Mar. 28, 2019), but has not finally resolved the issue.

DISCUSSION

We review a district court's grant of summary judgment de novo. *See, e.g.*, *Clarian Health W., LLC*

v. Hargan, 878 F.3d 346, 352 (D.C. Cir. 2017). Under the APA, we must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2). The party challenging agency action bears the burden of proof. *See, e.g.*, *Abington Crest Nursing & Rehab. Ctr. v. Sebelius*, 575 F.3d 717, 722 (D.C. Cir. 2009) (citing *City of Olmsted Falls v. FAA*, 292 F.3d 261, 271 (D.C. Cir. 2002)).

A. The Overpayment Rule does not violate the Medicare statute's requirement of "actuarial equivalence"

UnitedHealth's central challenge to the Overpayment Rule is that it violates the Medicare statute's command to CMS to adjust payment amounts to a Medicare Advantage insurer based on risk factors "so as to ensure actuarial equivalence" between that insurer's beneficiary population and the traditional Medicare beneficiaries whose healthcare cost data CMS uses to calculate capitated, monthly payments to the insurer. 42 U.S.C. § 1395w-23(a)(1)(C)(i). UnitedHealth argues that the Rule "results in different payments for identical beneficiaries because it relies on both supported and unsupported codes to calculate risk in [traditional Medicare], but only supported codes in the [Medicare Advantage] program," which "necessarily means that [Medicare Advantage] plans are *not* paid the same as CMS for identical beneficiaries"—and in fact are "inevitably underpa[id]." Appellees Br. 22-23; *see also id.* at 26-27. In other words, UnitedHealth objects to CMS's reliance on minimally audited traditional

Medicare data in the risk-adjustment model that CMS uses to calibrate the monthly payment rates for Medicare Advantage insurers, while CMS at the same time obligates insurers to refund each individual payment that they know is not supported by a beneficiary's medical records. *Id.* at 26. The Overpayment Rule, UnitedHealth seems to say, disrupts actuarial equivalence between Medicare Advantage and traditional Medicare insofar as data from traditional Medicare that is used to model the expected cost of a given diagnosis is subject to laxer documentation standards than is a diagnosis a Medicare Advantage insurer reports in support of payment.

UnitedHealth claims, and the district court agreed, that before CMS may lawfully apply the Overpayment Rule, it must implement one of two measures to remedy the claimed imbalance. First, CMS could devise and apply an adjuster akin to the FFS Adjuster it had intended to use (but since has preliminarily decided is unwarranted) in the context of contract-level RADV audits of Medicare Advantage insurers' risk-adjustment data. In that scenario, Medicare Advantage insurers would be liable for overpayments only to the extent that their payment error rate exceeded that of traditional Medicare. Alternatively, CMS could comprehensively audit traditional Medicare data before using it in the risk-adjustment model that sets Medicare Advantage insurers' monthly payments. Only then would UnitedHealth be prepared to accept that the traditional Medicare data used to arrive at relative factors did not contain the unsupported codes that, it asserts, should bar CMS from recouping overpayments pursuant to the Rule for codes that a

Medicare Advantage insurer reported to CMS but later discovered were unsupported by beneficiaries' medical records.

There are two main problems with UnitedHealth's argument. First, nothing in the Medicare statute's text, structure, or logic makes the actuarial-equivalence requirement in section 1395w-23(a)(1)(C)(i) applicable to the overpayment-refund obligation in section 1320a-7k(d) or to the Overpayment Rule promulgated under that section. Second, even if the actuarial-equivalence requirement did indirectly relate to Medicare Advantage insurers' overpayment-refund obligation, we could not here invalidate the Overpayment Rule as violating actuarial equivalence. UnitedHealth notably does not challenge the risk-adjustment model itself or the resultant values CMS assigned to any relative factor. Nor did it provide evidence that the obligation to refund overpayments, as defined by the Medicare statute and the Rule, in fact has led or will lead to systematic underpayment of Medicare Advantage insurers relative to traditional Medicare.

1.

We have not previously decided any case involving "actuarial equivalence" as referenced in section 1395w-23(a)(1)(C)(i) for the Medicare Advantage program. In the context of the Employee Retirement Income Security Act (ERISA), we have said that "[t]wo modes of payment are actuarially equivalent when their present values are equal under a given set of actuarial assumptions." *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011). UnitedHealth and CMS agree that "actuarial equivalence" in this provision of the Medicare statute

means that CMS aims to pay the same amount to Medicare Advantage insurers for their beneficiaries' care as CMS would spend on those same beneficiaries if they were instead enrolled in traditional Medicare. *See* Gov't Br. 1; Appellees Br. 26; *see also* Defendants' Memorandum in Support of Their Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment at 28, *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. 2018) (No. 16-cv-157), J.A. 688.

The parties disagree about whether the Overpayment Rule even implicates the actuarial-equivalence requirement. UnitedHealth assumes the Overpayment Rule creates a sweeping obligation that effectively requires Medicare Advantage insurers to self-audit all their data. It thus asserts that, because of actuarial equivalence, before CMS may police overpayments in the manner of the Overpayment Rule, CMS must either audit traditional Medicare data before it goes into the risk-adjustment model or, alternatively, adopt a systemic corrective similar to the FFS Adjuster CMS contemplated in the context of proposed contract-level RADV audits. In the context of the RADV audit expansion, the insurers' objection was that applying a sampled payment error rate across an entire contract would effectively audit all of an insurer's data while leaving unaudited the traditional Medicare data used to set monthly payments in the first place, thus requiring the application of an adjuster that would also effectively audit all of the data on the traditional Medicare side. Here, UnitedHealth asserts much the same: that the Overpayment Rule essentially requires insurers to audit all of the data they submit to CMS (especially given the prospect of liability under the False Claims

Act), leaving that data set with no unsupported codes, while traditional Medicare data remains unaudited, leaving that data set with a significant number of unsupported codes. And, UnitedHealth says, the presence of unsupported codes in traditional Medicare data depresses the value of relative factors, so removing unsupported codes from a Medicare Advantage insurer's data but not traditional Medicare's will cause CMS to underpay insurers.

UnitedHealth's premise is unsupported. Nothing in the Overpayment Rule obligates insurers to audit their reported data. As the district court held, *see UnitedHealthcare*, 330 F. Supp. 3d at 190-91, and CMS does not here dispute, *see* Gov't Br. 22, 30, the Rule only requires insurers to refund amounts they *know* were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary's medical records. That limited scope does not impose a self-auditing mandate.

No part of the Medicare statute or the Overpayment Rule supports UnitedHealth's challenge. The statute's actuarial-equivalence requirement does not apply to the separate statutory obligation on insurers to refund overpayments they erroneously elicit from CMS; nor, by the same token, does actuarial equivalence apply to the Overpayment Rule that implements that statutory obligation and, in relevant part, essentially parrots it. *Compare* 42 U.S.C. § 1320a-7k(d)(4)(B) (defining "overpayment" as "any funds that a person receives or retains under [the Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled"), *with* 42 C.F.R. § 422.326(a) (defining "overpayment" as "any funds that [a Medicare Advantage insurer] has received or retained under

[the Medicare Advantage program] to which the [Medicare Advantage insurer], after applicable reconciliation, is not entitled"). Nothing in the text of either the actuarial-equivalence requirement in section 1395w-23(a)(1)(C)(i) or the overpayment-refund obligation in section 1320a-7k(d) applies the former to the latter. There is no cross-reference or other language suggestive of overlap, nor does UnitedHealth so contend. Indeed, even the district court acknowledged that the overpayment-refund obligation does not "state how 'overpayments' and 'actuarial equivalence' in payments are related." *UnitedHealthcare*, 330 F. Supp. 3d at 181.

More specifically, nothing in either provision renders actuarial equivalence a defense against the obligation to refund any individual, known overpayment. Notably, Congress through the Affordable Care Act strengthened Medicare Advantage insurers' data-reporting obligations by requiring insurers to report and return overpayments within sixty days of their discovery, and it made specific provision for False Claims Act liability for those that do not. In so doing, Congress made no reference to the Medicare statute's longstanding actuarial-equivalence requirement, let alone any suggestion that it could be interposed as a defense. *See* 42 U.S.C. § 1320a-7k(d).

If anything, the text of section 1395w-23(a)(1)(C)(i) limits the scope of the actuarial-equivalence requirement. It states that CMS "shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii)" for demographic and health characteristics "to ensure actuarial equivalence." Those cross-referenced subparagraphs identify the

manner in which CMS "shall make monthly payments under this section in advance to each [Medicare Advantage] organization." *Id.* § 1395w-23(a)(1)(A). Section 1395w-23(a)(1)(C)(i)'s reference to risk-adjusting the amount paid to Medicare Advantage insurers "under" certain cross-referenced subparagraphs, and those subparagraphs' focus on the predetermined monthly payments made to insurers "under this section," indicate that the actuarial-equivalence requirement is not broadly applicable, but instead limited to the specified context of CMS's calculation and disbursement of monthly payments in the first instance. *Cf. Davis v. Pension Benefit Guar. Corp.*, 734 F.3d 1161, 1170 (D.C. Cir. 2013) (interpreting ERISA's actuarial-equivalence requirement as limited by statutory text and structure).

Stephens v. U.S. Airways Group, Inc., cited by the district court in support of its holding, *see UnitedHealthcare*, 330 F. Supp. 3d at 185-86, actually cuts the other way. There, we held that an ERISA actuarial-equivalence requirement did not obligate the airline to pay pensioners interest on requested lump-sum payments made well after annuity payments would have begun had the same benefit been disbursed periodically. *Stephens*, 644 F.3d at 440. When we held that interest was required under IRS regulations regarding unreasonable delay of such payments, *id.*; *see also id.* at 442, we were also clear that the lump-sum payments did not violate actuarial equivalence where the airline "accurately calculated [the] lump sums to be the 'actuarial equivalent' of the annuity option as of the annuity start date," *id.* at 440. Because the actuarial equivalence of the annuity and lump-sum payments had been calculated based

on a common initial payment date, and the statute was silent on whether interest was owed when an otherwise actuarially equivalent pension was paid later, we declined to grant the interest claim on that basis. *Id.*

Here, the Medicare statute is similarly silent, as it speaks not at all to whether the actuarial-equivalence requirement in section 1395w-23(a)(1)(C)(i) bears on section 1320a-7k(d)'s requirement to refund overpayments. That is, the statute never says that the later refund of individual, known overpayments implicates the earlier-in-time requirement that the lump-sum monthly payments to Medicare Advantage insurers be set as if an insurer's beneficiary pool were actuarially equivalent to traditional Medicare's population. In the face of such silence, actuarial equivalence is satisfied consistently with *Stephens* so long as CMS reasonably concluded when it set its monthly payments to UnitedHealth that the traditional Medicare data it used was sufficiently accurate and free of systemic biases that modeling based on that data would generate relative-factor values enabling CMS to "adjust the payment amount" to UnitedHealth "so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). As discussed in the next section, there is no evidence of any such systemic skew in traditional Medicare data, and, indeed, UnitedHealth never challenged the values CMS assigned to the relative factors. CMS permissibly reads the Medicare statute to authorize it to recover overpayments for diagnosis codes UnitedHealth submitted but knew or learned were unsupported—and to do so without first either remaking its underlying actuarial-equivalence calculation to prove that traditional Medicare data is

completely free of unsupported diagnoses, or re-defending its calculation as already accounting for unsupported diagnoses.

As CMS points out, the actuarial-equivalence requirement is not an "entitle[ment] . . . to a precise payment amount" for a Medicare Advantage insurer, but only "an instruction to the Secretary regarding the design of the risk adjustment model as a whole . . . describ[ing] the type of 'payment amount[s]' that the risk adjustment model should produce"; "[i]t does not directly govern how CMS evaluates the validity of diagnoses or defines 'overpayment.' " Reply Br. 5-6 (third alteration in original); *see* Gov't Br. 42-43. To that end, the Medicare statute grants the agency considerable discretion in determining how to structure the risk-adjustment model to achieve actuarial equivalence. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

The actuarial-equivalence requirement and the overpayment-refund obligation apply to different actors, target distinct issues arising at different times, and work at different levels of generality. The actuarial-equivalence provision directs CMS to develop a system of relative factors to use in adjusting the amount of the monthly payments to each Medicare Advantage insurer. *See id.* It calls on CMS to use its expert judgment to identify cost-predictive risk factors in the Medicare population and to analyze the data accumulated in traditional Medicare to determine average costs associated with those factors.

The point of that exercise is to enable CMS to pay only as much for coverage of Medicare Advantage beneficiaries as it would if they were instead enrolled in traditional Medicare, notwithstanding differences between the actual populations—for example, that

Medicare Advantage populations have tended to be healthier than traditional Medicare's population. *See* Reply Br. 20-21 (citing Pope et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, at 119, J.A. 487). Thus, the actuarial-equivalence requirement is focused on accounting for the distinct profiles of each insurer's beneficiary population, listing "age, disability status, gender, institutional status, and . . . health status" as potentially relevant considerations in the risk-adjustment model. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Significantly, section 1395w-23(a)(1)(C)(i)'s use of the qualifier "actuarial" necessarily implies an assessment made at the group or population level, not the individual level, so as to support credible statistical inferences. *Cf.* Pope et al., *Evaluation of the CMS-HCC Risk Adjustment Model: Final Report* 5, J.A. 522 (explaining that "risk assessment is designed to accurately explain the variation at the group level, not at the individual level, because risk adjustment is applied to large groups," and that "the Actuarial Standard Board's Actuarial Standard of Practice for risk classification" requires that "risk classes are large enough to allow credible statistical inferences"). By contrast, the overpayment-refund obligation in both the Medicare statute and the Overpayment Rule corrects particular mistaken payments to Medicare Advantage insurers that exceed what the relevant medical records support.

Finally, applying actuarial equivalence to the Medicare statute's separate obligation to refund particular, known overpayments would seriously undermine that obligation, with the potential for absurd consequences. As UnitedHealth acknowledged at oral argument, under its view of

actuarial equivalence as a defense against its obligation to reimburse CMS for known overpayments, a Medicare Advantage insurer could be entitled to retain payments that it knew were unsupported by medical records so long as CMS had not established that the insurer's overall payment error rate was higher than traditional Medicare's payment error rate. *See* Oral Arg. Tr. 50:12-18. Indeed, under that line of thinking, a Medicare Advantage insurer could knowingly submit unsupported diagnosis codes and retain payment for them unless and until CMS established—based on fully audited data of both traditional Medicare and the Medicare Advantage insurer at issue—that the particular overpayment resulted in a net gain to the insurer relative to traditional Medicare. There is no basis on which we can conclude that Congress intended the distinct actuarial-equivalence requirement to so thwart the overpayment-refund obligation—an obligation that, again, Congress strengthened through the Affordable Care Act without any reference to the accuracy or actuarial equivalence of the prospective monthly payments that CMS calculates and disburses to Medicare Advantage insurers. Congress gave no sign that it was limiting the obligation in the way UnitedHealth now suggests.

UnitedHealth asks us to rewrite the statutory overpayment-refund obligation, which was the basis for the Overpayment Rule, by narrowing the capacious "any funds" to which a Medicare Advantage insurer "is not entitled," 42 U.S.C. § 1320a-7k(d)(4)(B), with an actuarial-equivalence exception. But in the absence of any textual or structural connection between the two provisions, we decline to hold that the actuarial-equivalence requirement

in section 1395w-23(a)(1)(C)(i) applies to the overpayment-refund obligation in section 1320a-7k(d) or the Overpayment Rule CMS promulgated to comply with that provision.

2.

Even if the Medicare statute could theoretically support UnitedHealth's reading, we lack the necessary grounds here to invalidate the Overpayment Rule as a violation of actuarial equivalence. Recall that UnitedHealth's claim is that CMS cannot demand that UnitedHealth refund overpayments unless CMS shows it meets what UnitedHealth posits as a symmetrical auditing or error-correction obligation regarding traditional Medicare. But Congress has spelled out distinct obligations for traditional Medicare and Medicare Advantage, such as the Coding Intensity Adjuster that applies to the latter program but not the former, *see id.* § 1395w-23(a)(1)(C)(ii)(III); and CMS has long employed different audit mechanisms for the claims submitted by healthcare providers for traditional Medicare beneficiaries as compared to the data submitted by Medicare Advantage insurers to enable CMS to calculate accurate risk scores for Medicare Advantage beneficiaries, *see* Gov't Br. 16-19, 35-38.

Congress's and CMS's use of measures tailored to the differing structures of and incentives in the two programs makes sense; indeed, it could be irrational not to use distinct tools as needed to respond to different problems. UnitedHealth does not challenge the Coding Intensity Adjuster imposed by Congress. And UnitedHealth has never taken the opportunity that arises annually to challenge the accuracy of the risk-adjustment model or pricing when CMS

announces the relative factors and base payment rates that it will use for the upcoming year. *See* Oral Arg. Tr. 12:12-13:16; *see also Ormsby*, 444 F. Supp. 3d at 1068 n.442. We accordingly accept the unchallenged validity of the overall design of the model, the risk factors considered by CMS pursuant to its discretion under section 1395w-23(a)(1)(C)(i), and the accuracy of the resultant values of relative factors. UnitedHealth cannot now use actuarial equivalence to litigate belated objections to the risk-adjustment model or the level of its monthly payments through the back door of the Overpayment Rule.

UnitedHealth has failed to provide any logical or empirical basis to question the accuracy of traditional Medicare data. UnitedHealth asserts that the obligation to refund overpayments, at least as defined by the Overpayment Rule, leads to systematic underpayment of Medicare Advantage insurers relative to traditional Medicare. But it is by no means "inevitable" that Medicare Advantage insurers will be underpaid without the correctives that UnitedHealth would require. *UnitedHealthcare*, 330 F. Supp. 3d at 185, 187. Congress and CMS have long recognized that the uses of and incentives bearing on data in traditional Medicare and Medicare Advantage are very different, and accordingly have designed a range of distinct obligations and error-correction mechanisms for the two programs. As is by now familiar, CMS pays healthcare providers for Medicare Part B beneficiaries on a fee-for-service basis; thus, whereas providers may have incentives to overtreat those beneficiaries, they lack incentives to overreport diagnosis codes. By contrast, Medicare Advantage insurers, which CMS pays based

on their beneficiaries' demographic and health characteristics, including diagnoses, have financial incentives to code intensely and overreport diagnoses but not necessarily to overtreat beneficiaries. *See* Advance Notice of Methodological Changes for CY 2004 Medicare+Choice Payment Rates, at 5, J.A. 115; U.S. Gov't Accountability Off., *Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices* 2, J.A. 546.

UnitedHealth complains of "a substantial number" of unsupported diagnosis codes in the minimally audited traditional Medicare data set. Appellees Br. 26. But UnitedHealth identifies no reason why the traditional Medicare data that goes into the risk-adjustment model would suffer systematically from unsupported codes like those the Overpayment Rule targets, *i.e.*, codes lacking substantiation in medical records. If anything, the fact that providers for traditional Medicare beneficiaries are generally paid based on services, not diagnoses, would seem to tend toward underreporting, not overreporting, of diagnoses within traditional Medicare. The underlying premise of UnitedHealth's overall position is that traditional Medicare data includes a significant rate of unsupported diagnosis codes that ultimately depresses the payments to Medicare Advantage insurers. But the different ways the programs' reimbursement schemes work in practice make that premise implausible.

Nor has UnitedHealth established another premise of its position—that the unsupported codes it posits in traditional Medicare would both be materially analogous to those the Overpayment Rule

targets, and would cause UnitedHealth to be underpaid. To start, it is not even clear which kind of payment error in traditional Medicare, relative to Medicare Advantage, UnitedHealth believes is overlooked to its detriment. UnitedHealth identifies the problem in traditional Medicare as "a substantial number" of unsupported codes, *id.*, though, as discussed more below, it does not specify what, if any, payment implications it sees as necessarily attending them. To the extent that unsupported codes in traditional Medicare would be associated with erroneous payments that CMS need not have made to healthcare providers—*i.e.*, overpayments analogous to any CMS makes to Medicare Advantage insurers and targets with the Overpayment Rule—that kind of error would, if anything, tend to raise, not lower, overall payments to Medicare Advantage insurers. That is, because CMS's expenditures on traditional Medicare contribute to setting the base rate later used to make payments to Medicare Advantage insurers, the more money CMS spends on traditional Medicare, the higher the baseline for its expenditures on Medicare Advantage.

UnitedHealth nonetheless defends its position and the district court's ruling as founded "on straightforward math: Including unsupported codes when allocating costs on the traditional Medicare side, then excluding those same codes when determining payment amounts on the [Medicare Advantage] side, will underpay plans." *Id.* at 27. UnitedHealth's math does not add up. To illustrate its assertion of inevitable underpayment, UnitedHealth riffs on CMS's example involving a 72-year-old woman living independently (relative factor 0.348), with diabetes without complications (relative

factor 0.118), and multiple sclerosis (relative factor 0.556), who would have a total risk score of 1.022. *See* Gov't Br. 7. But for UnitedHealth that woman is a twin: Her sister (Twin A) is a traditional Medicare beneficiary, and she (Twin B) is "identical in all respects" but is a Medicare Advantage beneficiary. Appellees Br. 32. UnitedHealth asks us to imagine that the diabetes code for both twins (who, again, are identical) is "unsupported." *Id.* It says that, under the Overpayment Rule, the woman's Medicare Advantage insurer "would need to delete her unsupported diabetes code after identifying it, and the resulting risk score for Twin B would be 0.904." *Id.* So, if her sister, Twin A, "cost CMS $10,000 to insure . . . the [Medicare Advantage] plan would receive only $8,845 to insure its identical beneficiary (0.904/1.022 x $10,000)." *Id.* at 32-33.

UnitedHealth's twin example ignores that unsupported codes are likely to occur for different reasons and with differing effects in the two programs: Unlike an unsupported diabetes code associated with Twin B in Medicare Advantage, which leads to an unwarranted increase in payment to the insurer, the mere existence of an unsupported diabetes code for Twin A in traditional Medicare does not mean CMS spent more money on that beneficiary. That is, CMS's expenditure for Twin A (at least in fee-for-service Part B) is not likely to have been higher if she were miscoded as diabetic than it would be without that error. CMS's expenditure on the twin in traditional Medicare would increase only if CMS paid for treatment corresponding to that unsupported code. But if Twin A's unsupported diabetes code is only an administrative error that does not correspond to treatment actually provided and paid for,

UnitedHealth's hypothetical uses the wrong starting point, and so the wrong figures, for Twin A's side of the comparison. Her costs in traditional Medicare from the outset (and even if her unsupported diabetes code is never caught) would be at the same, lowered level as Twin B's in Medicare Advantage once that diabetes code was removed—in both cases, the payment level appropriate for a non-diabetic.

Even assuming Twin A's unsupported diabetes code were associated with erroneous payment by CMS, one would need to know more about the nature and scale of such errors to determine whether they could have affected the results of the regression analysis used to calculate relative factors, and in what direction. For example, if UnitedHealth is assuming that Twin A's unsupported diabetes code triggered payment for treatment that had no medical purpose, UnitedHealth still has not made its case of inevitable underpayment. Specifically, if an unsupported code in traditional Medicare pairs with diabetes treatment for which CMS paid, UnitedHealth has not explained how, in coding it as just that—a cost of diabetes treatment, however unnecessary—CMS would inevitably depress the value of the relative factor for diabetes. As UnitedHealth sees it, every unsupported diabetes code in traditional Medicare lowers the value of the relative factor for diabetes, as CMS's expenditure on diabetes is divided among more and more beneficiaries. But UnitedHealth does not account for the possibility of an unsupported code associated with *payment* by CMS, which would enlarge both the total costs and the beneficiary pool in traditional Medicare and thus, if anything, tend to keep constant the value of the relative factor at issue.

Alternatively, if UnitedHealth's concern is with a diabetes code that is unsupported because treatment was delivered, medically necessary, and paid for, but just administratively associated with the wrong code—diabetes rather than celiac disease, for example—it also has not shown inevitable underpayment. In such a case, a data point that should have gone into the regression analysis supporting the relative factor for celiac disease would have instead been part of the data crunched to arrive at the diabetes relative factor. But, without any basis to conclude that any such errors occur at scale or in any particular pattern, the misattribution of some costs in the data cannot be assumed to distort CMS's analysis.

The implications of any unsupported diabetes code in traditional Medicare are quite different from those of the same unsupported code in Medicare Advantage. The former will not lead to Medicare Advantage insurers' inevitable underpayment because, as already noted, any erroneous code in traditional Medicare is aggregated with millions of others in the regressions called for under the risk-adjustment model. Errors that are isolated and random, not systemic, cannot alone be assumed to affect the value of a relative factor that bears on how much CMS will pay Medicare Advantage insurers for beneficiaries with any particular condition. An unsupported code submitted by a Medicare Advantage insurer, in contrast, triggers overpayment in every case. That is because individual codes in that program are used to determine payments, not as data points in a complex and rigorous statistical model.

In sum, UnitedHealth has given no reason to think that miscoding in traditional Medicare necessarily

leads to any inflated or deflated relative factors and, if it did, which ones are affected in which direction. We cannot assume based on UnitedHealth's reasoning alone that Medicare Advantage insurers are inevitably underpaid under any of the circumstances possible in its example.

What's more, the empirical evidence that we do have—CMS's October 2018 study concerning an FFS Adjuster in the context of contract-level RADV audits—suggests that Medicare Advantage insurers are not underpaid relative to traditional Medicare, contrary to UnitedHealth's and the district court's belief that underpayment is inevitable. Through that study, CMS "found that errors in [traditional Medicare] claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to [Medicare Advantage] organizations." CMS Study at 5, J.A. 731. In fact, CMS determined that the impact of errors in traditional Medicare data "is less than one percent on average and in favor of the [Medicare Advantage] plans." *Id.*

Together with its opposition to CMS's motion for partial reconsideration before the district court, UnitedHealth submitted a declaration from an actuarial expert "reflect[ing] [the expert's] professional interpretation" of CMS's study. Declaration of Julia Lambert at 2, *UnitedHealthcare Ins. Co. v. Azar*, 2020 WL 417867 (D.D.C. Jan. 27 2020)), J.A. 771. UnitedHealth's expert criticized the study by asserting that the underlying data in fact showed that, "if you take [a Medicare Advantage insurer] with risk profiles identical to those in the [traditional Medicare] data, the [insurer] would be

underpaid if the relative factors generated using both supported and unsupported data [from traditional Medicare] were applied only to supported codes in the [insurer's] data." *Id.* at 19, J.A. 788. But neither CMS's study nor UnitedHealth's expert's declaration tells us what happens when a Medicare Advantage insurer removes some, but not all, unsupported codes from its data, as is the reality here with the overpayment-refund obligation for only known overpayments. Indeed, UnitedHealth's expert's declaration unquestioningly presumes that, as a result of the Overpayment Rule, a Medicare Advantage insurer's data will consist of only supported codes. *See id.* UnitedHealth has not shown, though, that the overpayment-refund obligation, as defined by the Overpayment Rule and limited to codes known to lack support, in fact will result in Medicare Advantage insurers receiving payment for only supported codes, or that there is a point at which the removal of some, even if not all, unsupported codes from an insurer's data would violate actuarial equivalence.

The burden of proof is UnitedHealth's to show that the Overpayment Rule is unlawful. *See, e.g.*, *Abington Crest*, 575 F.3d at 722 (citing *City of Olmsted Falls*, 292 F.3d at 271). In the absence of such proof—or even persuasive logic in UnitedHealth's favor—we could not here invalidate the Overpayment Rule as violating actuarial equivalence even if we held that such requirement bore on the overpayment-refund obligation.

B. The Overpayment Rule does not violate the Medicare statute's requirement of "same methodology"

UnitedHealth's second claim—that the Overpayment Rule violates the Medicare statute's "same methodology" requirement in section 1395w-23(b)(4)(D)—is likewise without merit. As explained above, each county in the United States has its own base payment rate, which provides the starting point for the monthly, per-capita payment to a Medicare Advantage insurer covering a beneficiary in that area. Every year, Medicare Advantage insurers bid for contracts after CMS announces the county-specific benchmarks for the coming year. *See* 42 U.S.C. § 1395w-23(b)(1)(B). The base rate for a given county is then determined by the benchmark derived from traditional Medicare's per-capita expenditures in the county and the winning bid submitted by a Medicare Advantage insurer. An insurer covering a beneficiary with a risk score of 1.0 can expect to receive the base rate for the beneficiary's home county, whereas beneficiaries with risk scores higher or lower than 1.0 will draw prorated payments above or below the base rate, respectively.

As UnitedHealth acknowledges, the annual computation and publication requirement in section 1395w-23(b)(4) is meant to facilitate Medicare Advantage insurers' yearly submission of viable, competitive bids for contracts with CMS. *See* Appellees Br. 33-34. In a section titled "Annual announcement of payment rates," the Medicare statute requires CMS to compute and publish annually the "average risk factor" for traditional Medicare beneficiaries on a county-by-county basis, "using the same methodology as is expected to be

applied in making payments under subsection (a)." 42 U.S.C. § 1395w-23(b)(4)(D). Subsection (a) is, at this point, familiar: It contains the actuarial-equivalence requirement and governs the design of the risk-adjustment model. *See id.* § 1395w-23(a)(1)(C)(i).

The "same methodology" requirement plays a specific role in the computation and publication of data to aid the bidding process. It does not impose a substantive limit on the operation of the risk-adjustment model, which is governed by a separate provision. Nor does it have any bearing on whether a particular payment to a Medicare Advantage insurer constitutes an "overpayment." Rather, the requirement to "us[e] the same methodology" clarifies that CMS, in computing the traditional Medicare data it publishes, must use the same risk-adjustment model that it already uses to set monthly payments to Medicare Advantage insurers, not devise a new model or method for that purpose. Thus, for the same reasons that support our holding regarding UnitedHealth's actuarial-equivalence claim, we conclude that the Overpayment Rule simply does not implicate the Medicare statute's separate "same methodology" requirement.

C. The Overpayment Rule is not an unexplained departure from prior policy

UnitedHealth's third and final claim on appeal is that CMS's response to a comment calling for the use of an adjuster under the Overpayment Rule was arbitrary and capricious in violation of the APA. That comment advocated "appl[ication of] the principles adopted by CMS in the RADV audit context" to argue that "the sole instance in which an 'overpayment' can

be determined" is when CMS first has shown that the overall payment error for a given Medicare Advantage insurer is higher than that in traditional Medicare. Overpayment Rule, 79 Fed. Reg. at 29,921, J.A. 64.

In 2012, CMS proposed to use an FFS Adjuster in the context of contract-level RADV audits used to review Medicare Advantage insurers' risk-adjustment data. It did so in response to objections by Medicare Advantage insurers and the American Academy of Actuaries that failure to use an adjuster would violate the Medicare statute's requirement of "actuarial equivalence." Specifically, those commenters had argued that the actuarial-equivalence requirement prohibited CMS from using traditional Medicare data—which is subject to minimal auditing—to make monthly payments to Medicare Advantage insurers in the first instance, but then requiring an insurer to return some portion of those payments once CMS had effectively audited all the insurer's data by applying an extrapolated payment error rate to its entire contract with CMS. *See, e.g.*, Aetna Inc.'s Comments on Proposed Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits, at 4 & 18-22, J.A. 298 & 312-16; Humana Inc., Comment on RADV Sampling and Error Calculation Methodology, at 2-5 & 12, J.A. 333-36 & 343. Notably, the Academy did not object to the proposed Overpayment Rule based on actuarial equivalence, and CMS has preliminarily decided not to use an FFS Adjuster for contract-level RADV audits after all because "errors in [traditional Medicare] claims data do not have any systematic effect on the risk scores

calculated by the CMS-HCC risk adjustment model." CMS Study at 5, J.A. 731.

Because, as discussed above, the Overpayment Rule does not violate, or even implicate, actuarial equivalence, CMS had no obligation to consider an FFS Adjuster or similar correction in the overpayment-refund context. Contract-level RADV audits, which would effectively eliminate—and require repayment for—all unsupported codes in a Medicare Advantage insurer's data, are an error-correction mechanism that is materially distinct from the Overpayment Rule challenged here, which requires only that an insurer report and return to CMS known errors in its beneficiaries' diagnoses that it submitted as grounds for upward adjustment of its monthly capitation payments. Thus, CMS was not required to provide further explanation of its decision. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). CMS's response to the comment reiterated Medicare Advantage insurers' longstanding obligations, under other of CMS's regulations not challenged here, *see, e.g.*, 42 C.F.R. § 422.504(*l*), to certify the accuracy of the data that they report to CMS, *see* Overpayment Rule, 79 Fed. Reg. at 29,921-22, J.A. 64-65. Its response was therefore reasonable. *See id.*[1]

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[1] As mentioned above, CMS has since proposed not to use an FFS Adjuster in the context of contract-level RADV audits. *See* CMS Study at 5, J.A. 731. We express no opinion on whether the actuarial-equivalence requirement in section 1395w-23(a)(1)(C)(i) of the Medicare statute requires such an adjuster in that context. For current purposes, it suffices that the contexts of contract-level RADV audits and overpayment refunds are plainly distinguishable, such that CMS did not need

* * *

For the foregoing reasons, we hold that the Overpayment Rule does not violate the Medicare statute's "actuarial equivalence" and "same methodology" requirements and is not arbitrary and capricious as an unexplained departure from prior policy. We accordingly reverse the judgment of the district court vacating the Overpayment Rule and remand this case with orders to enter judgment in favor of Appellants, except with respect to the Overpayment Rule's definition of "identified."

So ordered.

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to further explain, when it issued the Overpayment Rule in 2014, why it then intended to use an adjuster in the former context but not the latter.

**UNITED STATES DISTRICT COURT,
DISTRICT OF COLUMBIA**

UNITEDHEALTHCARE INSURANCE COMPANY, et al, Plaintiffs,

v.

Alex M. AZAR II, Secretary of the Department of Health and Human Services, et al., Defendants.

Civil Case No. 16-157 (RMC)

Signed 09/07/2018

330 F. Supp. 3d 173

OPINION

ROSEMARY M. COLLYER, United States District Court

Health insurance is provided to most seniors and many disabled Americans through Medicare, paid for by taxes and administered by the Centers for Medicare and Medicaid Services (CMS). As amended, the Medicare statute (formally part of the Social Security Act), includes a "Medicare Advantage" program whereby Medicare-eligible individuals can elect to receive their health insurance coverage through a private insurance company. The insurance company must provide at least the same coverage as traditional Medicare, although it often expands coverage, and is to make its profit from Medicare through efficiencies and other cost-saving methods. The statute requires "actuarial equivalence" between CMS payments for healthcare coverage under

Medicare Advantage plans and CMS payments under traditional Medicare. In this case, a large group of insurance companies that provide Medicare Advantage coverage challenged a Final Rule, adopted in 2014, by which the documentation used to set the rates to pay the insurance companies is inconsistent with the documentation used to determine if the insurers have been overpaid. The insurers allege that the Final Rule will inevitably fail to satisfy the statutory mandate of actuarial equivalence.

There is a history to this dispute over actuarial equivalence. The government previously had proposed an audit program for Medicare Advantage insurers and some insurers challenged its methodology for determining overpayments. Since government records for traditional Medicare payments are used to set rates but are not audited, the insurers contended that imposing a 100% accuracy requirement on their records, on pain of being required to return any "overpayment," would violate the statutory requirement for actuarially equivalent payments between traditional Medicare and Medicare Advantage. Heeding the advice of actuaries, the government ultimately adjusted its audit plan to recognize the different data sets. For the 2014 Final Rule at issue here, however, CMS has refused to make such an adjustment although the different data sets are again in use.

After full briefing and oral argument, this Court concludes that the 2014 Final Rule violates the statutory mandate of "actuarial equivalence" and constitutes a departure from prior policy that the government fails adequately to explain. The Court will grant summary judgment to the Medicare Advantage insurers and vacate the Rule.

I. BACKGROUND

This lawsuit is brought by Medicare Advantage (MA) organizations in the UnitedHealth Group family of companies, the nation's leading provider of Medicare Advantage health benefits plans (collectively, UnitedHealth).[1] Known as Medicare Part C, the Medicare Advantage program allows Medicare-eligible individuals to receive healthcare benefits through private insurance companies that have contracted with CMS, a constituent agency of

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[1] Plaintiffs are UnitedHealthcare Insurance Company, AmeriChoice of New Jersey, Inc., Arizona Physicians IPA, Inc., Care Improvement Plus South Central Insurance Company, Care Improvement Plus of Texas Insurance Company, Care Improvement Plus Wisconsin Insurance Company, Health Plan of Nevada, Inc., Medica Healthcare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., Pacificare Life and Health Insurance Company, Pacificare of Arizona, Inc., Pacificare of Colorado, Inc., Pacificare of Nevada, Inc., Physicians Health Choice of Texas, LLC, Preferred Care Partners, Inc., Sierra Health and Life Insurance Company, Inc., UnitedHealthCare Benefits of Texas, Inc., UnitedHealthCare Community Plan of Ohio, Inc., UnitedHealthCare Community Plan of Texas, LLC, UnitedHealthCare Insurance Company of New York, UnitedHealthCare of Alabama, Inc., UnitedHealthCare of Arizona, Inc., UnitedHealthCare of Arkansas, Inc., UHC of California, 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., UnitedHealthCare of Oregon, Inc., UnitedHealthCare of Pennsylvania, Inc., UnitedHealthCare of the Midlands, Inc., UnitedHealthCare of the Midwest, Inc., UnitedHealthCare of Utah, Inc., UnitedHealthCare of Washington, Inc., UnitedHealthCare of Wisconsin, Inc., and UnitedHealthCare Plan of the River Valley, Inc.

the Department of Health and Human Services (HHS). Alex M. Azar II, HHS Secretary, is sued in his official capacity. CMS administers traditional Medicare and pays its benefits. However, some 20 million Americans, approximately one-third of Medicare-eligible individuals, have opted for Medicare Advantage coverage.

Medicare Parts A, B and C are relevant here. Medicare Part A is mandatory for senior Americans who take Social Security benefits; Part A provides coverage for hospital expenses. Medicare Part B is voluntary and provides partial coverage for doctor expenses. Medicare Part C offers the Medicare Advantage program through which private insurance companies replace CMS and provide full Medicare coverage to beneficiaries.

Initially, Medicare paid all "reasonable costs" ("fee for service") to a hospital caring for a Medicare beneficiary. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994). Over time, that standard has changed and Medicare now pays a hospital based on the "Diagnosis-Related Group" (DRG) shown by the patient's diagnoses at the time of discharge. Medicare Part B also started by paying doctors a reasonable "fee for service," but now pays them according to fee schedules that limit the amount they may charge and be paid for each defined service. *See United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 968 (D.C. Cir. 1999). Under Part B, doctors must submit diagnosis codes to identify the reason a patient received treatment, but "payments depend only on the services (or durable goods) provided [office visit, examination, shot, etc.] and not in any way on the diagnoses submitted." Defs.' Mem. in Support of Their Cross-Mot. for Summ. J. and Opp'n to Pls.' Mot.

for Summ. J. (CMS Mot.) [Dkt. 57-1] at 7.[2] In contrast, Medicare Advantage insurers are not paid based on medical services but "are paid a pre-determined monthly sum for each person they cover, based in part upon the characteristics of the particular beneficiary being covered." *Id.* (internal citation omitted).

A Medicare Advantage insurer must provide, at a minimum, the same level of benefits provided by traditional Medicare itself, except for hospice care. *See* 42 U.S.C. § 1395w-22(a). Under a Medicare Advantage policy, the insurance companies pay doctors, other healthcare providers, and hospitals for their services and are reimbursed by CMS on a per-member-per-month rate that is determined beforehand. *See id.* § 1395w-23(a).

By law, CMS must pay Medicare Advantage insurers in a manner that ensures "actuarial equivalence" between payments for healthcare under Medicare and Medicare Advantage plans:

> [T]he Secretary shall adjust the payment amount [of fixed monthly payments to Medicare Advantage insurers] for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate,

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[2] Although all parties used the initials "FFS" (fee-for-service) to reference traditional Medicare (and compare it to Medicare Advantage), this term is "now, something of a misnomer" because CMS has changed its fee structures for hospitals and doctors. *See* CMS Mot. at 4. The Court eschews the use of the acronyms for clarity, except when quoting. *See D.C. Circuit Handbook of Practice and Internal Procedures* 41 (2016).

> including adjustment for health status . . . , so as to ensure actuarial equivalence.

Id. § 1395w-23(a)(1)(C)(i). Risk factors represent the risk that a given beneficiary, or beneficiary population, will need healthcare from doctors or hospitals in the next year as it may be diagnosed. "A risk adjustment model is required to translate the diagnosis data into expected costs of coverage." CMS Mot. at 14. For this purpose, CMS relies on its model, the CMS Hierarchical Condition Category (CMS-HHC) risk-adjustment model, to "perform that conversion":

> CMS-HCC is a complex regression model built to estimate the costs associated with certain characteristics of Medicare beneficiaries. The inputs to the model are data from individuals who receive their benefits through the traditional, fee-for-service Medicare system. Its outputs are a set of multipliers—that is, "coefficients"—that "represent the marginal (additional) cost" of each medical "condition or demographic factor (e.g., age/sex group, Medicaid status, disability status)." The coefficients are added together to form a "risk score," and then computed against a base payment rate (which varies depending on geography and the bid submitted by the insurer, among other things).

Id. (internal citations omitted).

By this process, CMS calculates the average monthly expenditure for an average beneficiary under traditional Medicare in the past year. The "base rate establishes . . . what it would cost to treat a beneficiary of average risk in a given area." *See*

Transcript of Aug. 8, 2018 Motions Hearing (Hearing Tr.) [Dkt. 73] at 5. CMS adds a geographical differential, based on data from the past year, to calculate an average per-capita monthly payment for each county in the nation.

This is no straightforward task. Each traditional Medicare beneficiary has a "demographic risk coefficient" which reflects that person's age, gender, institutional status, and disability status, among others. *See id.* at 4. Additional coefficients represent the health status of the beneficiaries in traditional Medicare, taken from their diagnosis codes as reported to CMS by their doctors. Using such CMS data, "the model estimates the marginal cost of each disease and cluster of demographic characteristics. . . . By mapping known expenditures . . . , the model calculates the expected cost of each medical condition and demographic factor." CMS Mot. at 17. Using the data from the demographic characteristics, reported diagnoses, and Medicare expenses of the beneficiaries in traditional Medicare, the model can estimate the marginal cost of each condition, disease and cluster of demographic characteristics.

The "average beneficiary" is given a risk score of 1.0, which is then adjusted upwards or downwards according to the risk score determined by an individual's demographic and health status information. For example, if a beneficiary has a condition that CMS has determined based on its Medicare data increases average costs by 20%, that person will have an adjusted risk score of 1.2 and the Medicare Advantage payment rate applicable to that person will be set at 120% of the average benchmark rate. *See, e.g.*, Advance Notice of Methodological

Changes for CY 2004 Part C Rates (Mar. 28, 2003) (2004 Advance Notice) at AR3895-97 (describing how CMS uses the model to "associate diseases categories with incremental costs").[3] Thus, the costs in a prior year of the "risk coefficients" in the traditional Medicare system are used to determine the costs of similar risk coefficients for Medicare Advantage beneficiaries. The underlying logic is that developing risk coefficients with data from traditional Medicare, and then adjusting a Medicare Advantage beneficiary's risk score (and the payment to the Medicare Advantage insurer accordingly), will render the cost to CMS under traditional Medicare and the cost to the insurer under Medicare Advantage actuarially equivalent.

In conducting these analyses, CMS relies entirely on the diagnosis codes submitted by healthcare providers under traditional Medicare. "[T]he risk adjustment model is built on unaudited [traditional Medicare] data . . . which must contain errors." CMS Mot. at 37. Indeed, doctors treating traditional Medicare patients are paid based on their services and not the diagnosis codes they might submit to report why the patient saw the doctor. As UnitedHealth's counsel explained at argument, physicians bill traditional Medicare by procedure, not diagnosis codes, so that "physicians are essentially indifferent to the diagnosis . . . . There's no financial incentive to be particularly careful." Hearing Tr. at 13. "[W]hat matters is the procedure they did." *Id.* at 14; *see also* CMS Mot. at 7 (agreeing that traditional

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[3] CMS publishes annual Advance Notices of changes to its risk-adjustment methodology for the coming year. *See* 42 U.S.C. § 1395w-23(b).

Medicare payments to doctors "depend only on the services . . . and not in any way on the diagnoses submitted"). Given this incentive scheme, it can be no surprise that diagnosis reports for Medicare Part B are considered much less reliable than hospital diagnosis reports for Part A. *See* CMS Mot. at 7 (noting "the quality of the Part B diagnosis data is generally understood to be inferior to the Part A diagnosis data").

Medicare Advantage insurance companies bid annually after CMS issues notice of each county's benchmark rate for the forthcoming year. *See* 42 U.S.C. § 1395w-23(b)(1)(B). The insurers are paid on a per-capita basis for each covered individual, including applicable risk scores. As a result, a Medicare Advantage insurer undertakes to provide insurance coverage at least identical to Medicare at annual fixed rates even though the health care needs of the covered populations, mostly the elderly, vary greatly.

Humans being human, diagnoses in healthcare records may be miscoded, inappropriately added, or otherwise faulty by accident or mal intent. UnitedHealth suggests that the error rate can be as high as 20%. *See* Compl. [Dkt. 1] ¶ 38; *see also* Hearing Tr. at 28. In the past, neither CMS nor the insurers made efforts to review proactively the diagnosis codes assigned by healthcare providers. Indeed, as stated above, CMS treats diagnosis codes as categorically valid for its own purposes under traditional Medicare, including for setting rates for Medicare Advantage. Nonetheless, CMS has long required Medicare Advantage insurers to certify "based on best knowledge, information and belief" that the information they provide to CMS, including

all diagnosis codes, is "accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*)(2). CMS contends that this pre-existing regulation, and other existing agency practices, have long required that diagnosis codes submitted by Medical Advantage insurers be supported by underlying medical records (*i.e.*, patient medical charts). UnitedHealth responds that neither this pre-existing regulation, nor any other law or regulation, has previously obligated the insurance companies who provide Medicare Advantage insurance to validate independently the underlying medical records that support diagnosis codes submitted by health care providers.

For more than a decade, CMS has conducted audits of a subsection of insurers in the Medicare Advantage program, through which it has compared the diagnosis codes in bills paid by the insurance companies to the underlying patient medical charts and records, which it requires the insurers to obtain for this purpose. It has then required repayment to CMS of any costs that were based on unsupported diagnosis codes. In 2008, CMS announced that it would begin applying these "Risk Adjustment Data Validation (RADV)" audits to extrapolate the error rate in the audited sample across an entire insurance contract.[4] The insurer would be responsible for

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[4] *See* Policy and Technical Changes to Parts C and D, 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009) (2009 Proposed RADV Rule) at AR2409 (summarizing the history of the RADV audit program); Policy and Technical Changes to Parts C and D, 75 Fed. Reg. 19,678, 19,742-53 (Apr. 15, 2010) (2010 RADV Rule) at AR2819; Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits:

returning any overpayment to CMS, based on the extrapolated error rate.

When CMS sought comments on its new methodology for conducting RADV audits, Medicare Advantage insurers immediately protested that the rates paid for each diagnosis code are based on traditional Medicare records that are not audited or verified in any way; requiring repayment of all amounts seemingly "overpaid" to a Medicare Advantage insurer based on audited records would ignore errors in CMS records and violate the statutory requirement of actuarial equivalence.[5]

This argument ventures deep into the weeds of actuarial science but is not actually disputed by the parties. Nor could CMS really debate it: as a result of the comments it received, CMS adopted a "Fee-for-Service Adjuster" or "FFS Adjuster" to the results of RADV audits of Medicare Advantage insurance contracts. The FFS Adjuster reflects CMS's own estimate of the error rate in risk factors and diagnosis codes submitted by healthcare providers and paid by CMS for its traditional Medicare participants; applied to the results of a RADV audit of a Medicare Advantage insurer, it is designed to achieve actuarial equivalence between the two. Thus, Medicare Advantage providers must return to CMS any audited

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Request for Comment (Dec. 20, 2010) (RADV Methodology Request for Comment) at AR5021-22.

[5] *See generally* Aetna Inc. Comments (Jan. 21, 2011) at AR5036-71; Humana Inc.'s Comments (Jan. 21, 2011) at AR5102-16; UnitedHealthCare Comments (Jan. 21, 2011) at AR5193-5220; *see also* American Academy of Actuaries Comment on RADV Sampling and Error Calculation Methodology (Jan. 21, 2011) (Academy of Actuaries Comment) at AR5235-36.

"overpayments" to the extent that the insurer's errors exceed the estimated error rate in CMS payments under traditional Medicare. *See* Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) (RADV Final Methodology) at AR5311-15.

UnitedHealth asserts that the 2012 FFS Adjuster works to counteract the fact that per-capita payments to Medicare Advantage insurers are based on a less precise set of data—belonging to CMS—than that which is reviewed during an audit. Their argument, and CMS's eventual concurrence, are supported by the American Academy of Actuaries, which strongly advised CMS that it was not actuarially sound to compare unaudited figures to calculate per-capita payments and then audited figures to calculate overpayments. *See* Academy of Actuaries Comment at AR5236 ("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.").

The passage of the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), is also directly relevant here. The ACA imposed an obligation on Medicare Advantage insurers to report and return any overpayments that an insurer discovers on its own. *See* 42 U.S.C. § 1320a-7k(d)(1) (2012). This section of the ACA defined "overpayment" as "any funds that a person receives or retains under [Medicare Advantage] to which the person, after applicable reconciliation, is not entitled." *Id.* § 1320a-7k(d)(4)(B). The law further required that any "overpayment . . . be

reported and returned [within] 60 days after the date on which the overpayment was identified." *Id.* § 1320a-7k(d)(2). If an insurer in the Medicare Advantage program fails to return such a discovered overpayment within 60 days of identifying it, that failure renders the insurer's initial but faulty claim for payment a violation of the False Claims Act (FCA). *Id.* § 1320a-7k(d)(3) ("Any overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation (as defined in section 3729 (b)(3) of title 31) for purposes of section 3729 of such title."); *cf.* False Claims Act, 31 U.S.C. § 3729(b)(3). Claims for overpayments under the False Claims Act carry the potential for treble damages, civil penalties, and debarment from Medicare. *See* 31 U.S.C. § 3729(a)(1)(G) (providing for civil penalties and treble damages); 42 C.F.R. § 424.535(a) (describing grounds for revocation of enrollment in the Medicare program). Further, non-government *qui tam* plaintiffs may bring FCA claims in federal court. *See* 31 U.S.C. § 3730(b).

The Affordable Care Act established a basic statutory framework but left several crucial terms undefined. It did not define at what point an insurer might be said to have "identified" an overpayment, thus triggering the 60-day clock; nor did it outline the scope of "applicable reconciliation" or state how "overpayments" and "actuarial equivalence" in payments are related.

We come to the 2014 Final Rule at issue here. CMS issued a notice of proposed rulemaking in January 2014 and sought comments.[6] CMS proposed

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[6] *See* Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug

to "clarify the statutory definition of overpayment" with a new regulation titled "Reporting and Returning Overpayments," to be codified at 42 C.F.R. § 422.326. *See* 79 Fed. Reg. at 1996, 2055-56 (June 29, 2000) (AR80 at AR139-40).

CMS published its Final Rule on May 23, 2014, and in so doing finalized 42 C.F.R. § 422.326 concerning overpayments.[7] Under the 2014 Overpayment Rule, *any* diagnostic code that is inadequately documented in a patient's medical chart results in an "overpayment." *Id.* at 29,921 (AR1313). Further, an overpayment is "identified" whenever a Medicare Advantage insurer determines, "or should have determined through the exercise of reasonable diligence," that it had received an overpayment. *Id.* at 29,923 (AR1315). CMS further defined reasonable diligence as requiring "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." *Id.* UnitedHealth alleges that these obligations apply a simple negligence standard for purposes of False Claims Act liability, which is contrary to the standards in the False Claims Act itself. *See* 31 U.S.C. § 3729(b)(1) (defining "knowing" and "knowingly" to include "actual knowledge," "deliberate ignorance," or "reckless disregard of the truth or falsity of the information"). At oral argument, CMS essentially conceded that the 2014

Benefit Programs, 79 Fed. Reg. 1918, 1918-2073 (Jan. 10, 2014) (2014 Proposed Rule) at AR1 *et seq*.

[7] *See* Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,844-968 (May 23, 2014) (2014 Overpayment Rule) at AR1235 *et seq*.

Overpayment Rule imposed a negligence standard with a purported False Claims Act enforcement mechanism:

> The Court: It's a negligence standard, knew or should have known?
>
> [Defense Counsel]: . . . . [T]he rule does interpret the statutory language identified to mean not only literally knew about the overpayment, but also if you for instance have an entirely deficient compliance program and that is the reason, and your failure to have the appropriate compliance program is the reason you didn't learn of an overpayment that you should have learned of, then we will also begin the clock on that . . . .
>
> The Court: . . . . The definition of identified doesn't mean knew, it means knew or with reasonable diligence should have known or maybe didn't care to look.
>
> [Counsel]: Yes, your Honor.
>
> The Court: That's all negligence.
>
> [Counsel]: It bears some similarities to negligence, your Honor.
>
> The Court: Right. So it's not a knowledge based thing?
>
> [Counsel]: Not as it has been interpreted in the overpayment rule.

Hearing Tr. at 34-36.

Most critically for the present challenge, the 2014 Overpayment Rule did not adopt something like an "FFS Adjuster" to recognize that the sources of data

are not compatible, *i.e.*, unaudited traditional Medicare records to determine payments to Medicare Advantage insurers and audited medical charts to determine overpayments. UnitedHealth argues that the 2014 Overpayment Rule thus fails to ensure "actuarial equivalence" between CMS's own costs and what CMS pays Medicare Advantage insurers to provide the same coverage. Rather, it subjects the insurers to a more searching form of scrutiny than CMS applies to its own enrollee data, thus resulting in a false appearance of better health among Medicare Advantage beneficiaries compared to traditional Medicare participants and systemic underpayments for healthcare costs to Medicare Advantage insurers. UnitedHealth also argues that the "negligence" standard of liability imposed by the 2014 Overpayment Rule constitutes an unlawful departure from the standard for liability under the False Claims Act.

The original Complaint in this matter was filed January 29, 2016, and CMS filed a motion to dismiss, which the Court denied on March 31, 2017. *See* 3/31/2017 Order [Dkt. 26]; Mem. Op. [Dkt. 25]. The parties proceeded to summary judgment briefing. Defendants filed the Administrative Record on July 14, 2017, *see* Notice of Filing and Serv. of Admin. Record [Dkt. 40], and UnitedHealth moved to supplement it. *See* Mot. for Leave to File Suppl. to the Admin. Record [Dkt. 44]. After full briefing, the Court granted the motion to supplement with two documents related to the FFS Adjuster for RADV Audits, *see* Mem. Op. [Dkt. 68]; 8/1/18 Order [Dkt. 69]; the parties filed a joint appendix to the administrative record including the additional documents. *See* Notice of Submission of Suppl. Joint Appx. [Dkt. 70];

Joint Mot. for Leave to File Corrected Joint Appx. Vol. 2 [Dkt. 71]; 8/7/18 Minute Order (granting motion to file corrected volume). Summary judgment is now fully briefed,[8] with the addition of a brief *amicus curiae* in support of Plaintiffs, without objection from CMS, by America's Health Insurance Plans. *See* Amicus Brief [Dkt. 62]. The Court heard oral argument from the parties on August 8, 2018. *See* Hearing Tr.

III. LEGAL STANDARD

Summary judgment is available when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it is capable of affecting the outcome of litigation. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Id.*

Summary judgment is the proper stage for determining whether, as a matter of law, an agency action is supported by the administrative record and is consistent with the Administrative Procedure Act (APA). *Richards v. INS*, 554 F.2d 1173, 1177 (D.C. Cir. 1977). The APA provides that "[t]he reviewing court shall . . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of

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[8] *See* Pls.' Mot. for Summary J. (United Mot.) [Dkt. 47]; CMS Mot.; Mem. in Opp'n to Mot. for Summ. J. [Dkt. 58]; Pls.' Mem. in Opp'n to Cross-Mot. for Summ. J. (Pls.' Opp'n & Reply) [Dkt. 60]; Reply to Opp'n to Mot. for Summ. J. [Dkt. 61]; Defs.' Reply to Opp'n to Cross-Mot. for Summ. J. (Defs.' Reply) [Dkt. 64].

discretion, or otherwise not in accordance with law," or that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). Arbitrary and capricious review is "narrow." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971). The Court is not to "substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). Rather, the Court must determine whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action, including a 'rational connection between the facts found and the choice made.' " *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S.Ct. 239, 9 L.Ed.2d 207 (1962)). The Court's review is limited to the administrative record, *Holy Land Found. For Relief and Dev. v. Ashcroft*, 333 F.3d 156, 160 (D.C. Cir. 2003), and the party challenging an agency's action bears the burden of proof, *City of Olmsted Falls v. FAA*, 292 F.3d 261, 271 (D.C. Cir. 2002).

III. ANALYSIS

A. Statutory Requirement of "Actuarial Equivalence"

The statutory provision at issue states that "the Secretary shall adjust the payment amount" of fixed monthly payments to Medicare Advantage insurers "for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-

23(a)(1)(C)(i). A traditional rule of statutory interpretation renders the use of "shall" a mandatory obligation. *See Anglers Conserv. Network v. Pritzker*, 809 F.3d 664, 671 (D.C. Cir. 2016) (citing Antonin Scalia & Bryan A. Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 112 (2012)).

UnitedHealth argues that the 2014 Overpayment Rule violates the statutory mandate of "actuarial equivalence." CMS responds that Medicare Advantage insurers are paid "a sum equal to the cost that CMS would expect to bear in providing traditional Medicare benefits to a given beneficiary" and there is thus "equivalence between an expected cost, on the one hand, and a known payment, on the other." CMS Mot. at 36.

In its briefs, CMS fails adequately to address the actuarial problem posed by the 2014 Overpayment Rule because of the different data sources on which it rests; the same actuarial problem was recognized and mitigated by CMS in 2012 with the FFS Adjuster for RADV audits but, surprisingly, omitted in 2014. The record is clear that payments for care under traditional Medicare and Medicare Advantage are both set annually based on costs from unaudited traditional Medicare records, but the 2014 Overpayment Rule systemically devalues payments to Medicare Advantage insurers by measuring "overpayments" based on audited patient records. This distinction makes an actuarial difference.

In plain English, doctors treating patients under traditional Medicare bill CMS by the procedure involved and not by diagnosis code(s). While the doctors are required to enter diagnosis codes, that information is irrelevant to payment. As far as the record reveals, the diagnosis codes in traditional

Medicare are never verified because they do not matter to payment. "[T]he risk adjustment model is built on unaudited data about traditional, fee-for-service Medicare beneficiaries, which must contain errors." CMS Mot. at 37. However, those very same diagnosis codes are presumed to have been accurate when CMS inputs all the data concerning beneficiaries of traditional Medicare into its regression model, which ultimately computes a value for each diagnosis. In consequence, the rates at which CMS pays Medicare Advantage insurers are based on flawed data across the millions of people in traditional Medicare. Yet the 2014 Overpayment Rule ignores those flaws when defining an "overpayment."

It is critical to appreciate that CMS does not claim that it audits traditional Medicare patient records; to the contrary, it accepts their diagnosis codes as given. *See* CMS Mot. at 7 (agreeing that traditional Medicare payments to doctors "depend only on the services . . . and not in any way on the diagnoses submitted"). It is also critical to appreciate that CMS does not show more errors or fraud in the charts of Medicare Advantage beneficiaries than in the charts of traditional Medicare beneficiaries. But the effect of the 2014 Overpayment Rule, without some kind of adjustment, is that Medicare Advantage insurers will be paid less to provide the same healthcare coverage to their beneficiaries than CMS itself pays for comparable patients. This inequity is inevitable because CMS sets Medicare Advantage rates based on costs that are presumed, based on traditional Medicare diagnosis codes, to be associated with particular health status information that is not verified in underlying patient records. The same unverified diagnosis is, under the 2014 Overpayment

Rule, treated as an overpayment that must be repaid, thus reducing the reimbursement to a Medicare Advantage insurer while requiring no such reduction in payment under traditional Medicare. Similarly auditing CMS records for errors or fraud could resolve the difference, if the audits were timely and if CMS were able to construct a legitimate program to carry out such audits. *See* Hearing Tr. at 26 (Plaintiffs' counsel explaining that CMS data is not audited prior to determining risk coefficients). This statement is not made to denigrate CMS but to recognize the difficulty involved.

Neither party cites, and the Court has not located, any case in which a court has defined the precise meaning of "actuarial equivalence" as used in 42 U.S.C. § 1395w-23(a)(1)(C)(i). Congress used the same language in the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1054(b)((1)(H)(iii)(I), (c)(3); and the D.C. Circuit has construed its meaning in that context. In *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437 (D.C. Cir. 2011), the Circuit "assume[d]" that "Congress intended that term of art to have its established meaning," that "[t]wo modes of payment are actuarially equivalent when their present values are equal *under a given set of actuarial assumptions*." *Id.* at 440 (emphasis added). The Seventh Circuit has found that ERISA requires "actuarial equivalence between a lump sum and an accrued pension benefit," and determined that this comparison was comparable to equivalence "between a present and a future value." *Berger v. Xerox Corp. Ret. Income Guar. Plan*, 338 F.3d 755, 759 (7th Cir. 2003).

The term also appears in the Medicare Part D statute, which provides that certain prescription-drug

coverage is subject to an "actuarial equivalence requirement" that is described in implementing regulations as "a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with . . . CMS actuarial guidelines." 42 C.F.R. § 423.4; *see also* 42 U.S.C. § 1395w-113(b)(5). According to CMS, the Medicare Part D provision requires "actuarial equivalence to compare the expected value [of covered prescription drugs] to the beneficiary (or, seen differently, the expected cost to the insurer) of different benefit plans." CMS Mot. at 29.

Based on these references to actuarial equivalence, CMS argues that the term "means to equate either an expected value with a known value (as in the case of an annuity and a lump sum payment) or two expected values (as in the case of benefit plans)." *Id.* at 30. In particular, CMS insists that the risk adjustment model for determining Medicare Advantage payment rates for each diagnostic code results in actuarial equivalence between the per capita payments to the insurers and payments for services by traditional Medicare. In this argument, CMS happily ignores the requirements of the 2014 Overpayment Rule that an insurer repay within 60 days *any* overpayment, no matter its degree, about which it knew or "should have determined through the exercise of reasonable diligence." 42 C.F.R. § 422.326(c).

Of particular assistance here, the D.C. Circuit specifically noted that two figures are actuarially equivalent only when they share "a given set of actuarial assumptions." *Stephens*, 644 F.3d at 440. In the *Stephens* context and here, this Court interprets "given" to mean "the same," as in two

figures are actuarially equivalent when they share the same set of actuarial assumptions. Different assumptions behind the elements of a calculation would, necessarily, result in actuarially non-equivalent results.

CMS is the insurer for traditional Medicare. Under the 2014 Overpayment Rule, however, the "expected cost" to the government insurer for traditional Medicare, *i.e.*, CMS, would be less than the "expected cost" to a private insurance company offering Medicare Advantage coverage. The problem would immediately arise when a Medicare Advantage insurer found its payments from CMS lower than traditional Medicare payments for comparable patients, due to reductions for *any* "overpayments" as defined by the 2014 Overpayment Rule. The use of unaudited CMS data, with its known and unknown errors, to set the rates by which Medicare Advantage insurers are paid and then the use of audited data to define "overpayments" will lead to this result. *See* Academy of Actuaries Comment at AR5235 ("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 [model's] risk-adjustment factors were developed with FFS data that, to the best of our knowledge, were not validated or audited for accuracy.").

RADV audits, of course, are conducted for the same purpose as the 2014 Overpayment Rule: to identify those claims for medical care that are not supported by medical diagnoses. In the context of an RADV audit, a contract-wide "error rate" is extrapolated from a sample and extended to an entire contract; a Medicare Advantage insurer may be required to return monies to CMS based on the

extrapolated error rate. In that context, CMS heeded the advice of actuaries and adopted the FFS Adjuster to achieve actuarial equivalence between Medicare Advantage and traditional Medicare. Under an RADV audit, therefore, an "overpayment" is shown when, and only when, the error rate for a Medicare Advantage contract is greater than the CMS error rate. *See* RADV Final Methodology at AR5314 ("[T]o determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster . . . as an offset to the preliminary recovery amount.").

The base rate for the "average Medicare beneficiary" and specific rates for diagnosis codes are determined using unverified CMS data. From this uncontested fact, UnitedHealth argues that relying on audited data to identify alleged overpayments to Medicare Advantage insurers is actuarially unsound and violates the statute. It contends that the statutory mandate of actuarial equivalence requires CMS to use the "same methodology" for each. *See* 42 U.S.C. § 1395w-23(b)(4)(D). According to the argument, CMS cannot subject the diagnosis codes underlying Medicare Advantage payments to a different level of scrutiny than it applies to its own payments under traditional Medicare without impermissibly skewing the calculus: by doing so, it ensures that there will *not* be actuarial equivalence between traditional Medicare payments and Medicare Advantage payments for comparable patients.

CMS fails to respond adequately. The agency has been explicit that the 2014 Overpayment Rule requires "proactive compliance activities" and other measures to ensure that overpayments, defined as any unsupported diagnosis, are identified and repaid

promptly. 79 Fed. Reg. at 29,923 (AR1315). Given its definitions and this proactive obligation, the "expected" value of payments from CMS for healthcare costs under Medicare Advantage plans will be lower than the "expected" payments CMS itself will make under traditional Medicare, since CMS does not audit or engage in similar self-examination for accuracy of its own records. The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed. *See* Academy of Actuaries Comment at AR5235. The Court finds that the 2014 Overpayment Rule establishes a system where "actuarial equivalence" cannot be achieved.

B. Statutory Requirement of "Same Methodology"

UnitedHealth argues that the 2014 Overpayment Rule violates other statutory requirements as well. In computing expenditures for traditional Medicare (information that determines patient risk scores and Medicare Advantage payment rates), CMS must "us[e] the same methodology as is expected to be applied in making payments" to Medicare Advantage plans. 42 U.S.C. § 1395w-23(b)(4)(D). UnitedHealth insists that CMS fails to comply with this mandate because the "methodology" applied in "making payments" to the insurers involves reconciliation based strictly on audited diagnosis codes for Medicare Advantage patients, in sharp contrast to unverified diagnosis codes for traditional Medicare patients from which payment rates were set. The argument also raises the question of the meaning of "applicable

reconciliation" contemplated by the statute. *Id.* § 1320a-7k(d)(4)(B). The logic of the earlier discussion of "actuarial equivalence" commands the results here.[9]

For present purposes, the fly in the ointment is that CMS recognized the actuarial need to apply an FFS Adjuster to the RADV audit program because of its failure, as proposed, to maintain actuarial equivalence in payments between traditional Medicare and Medicare Advantage but CMS refused to maintain such actuarial equivalence in the 2014 Overpayment Rule. Yet without some adjustment, the entire Rule would fail. Whether analyzed as a direct question of the statutory requirement of actuarial equivalence or an indirect question of the requirements of explicit statutory language concerning "same methodology," the result is the same: the 2014 Overpayment Rule fails to recognize a crucial data mismatch and, without correction, it fails to satisfy 42 U.S.C. § 1395w-23(b)(4)(D).

C. Arbitrary and Capricious

It is established law that an agency must provide a legitimate reason for departing from or rejecting a previous rule. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29,

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[9] The parties argue about the validity of CMS risk factors and risk scores, which, as stated, form the basis for (unaudited) CMS payments to traditional Medicare beneficiaries and payments to Medicare Advantage plans (subject to RADV audits and to the 2014 Overpayment Rule). Going back to these basics and redefining all the risk factors and all the diagnostic codes to account, within that structure, for actuarial equivalence may be the preferred approach but the very heart quakes at the thought, if one or more actuarially-sound "adjusters" might resolve the obvious dissonance in the 2014 Overpayment Rule.

42, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). This principle also applies to changes to an agency's policy. *See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 1001, 125 S.Ct. 2688, 162 L.Ed.2d 820 (2005) ("[T]he Commission is free within the limits of reasoned interpretation to change course *if it adequately justifies the change*.") (emphasis added). UnitedHealth complains that the 2014 Overpayment Rule departs from prior CMS policies and pronouncements without rationale or justification and is therefore arbitrary and capricious. It identifies four categories of prior statements by CMS that arguably established an agency position that is contrary to the 2014 Overpayment Rule.

The first, most recent, and most apt is the stated rationale on which CMS ultimately included the FFS Adjuster in the RADV audit process, as explained in the official notice of the methodology CMS would use to extrapolate payment errors to a contract-wide error rate. *See* RADV Final Methodology at AR5311-15. After notice and comment on the proposed audit process, including from the American Academy of Actuaries, CMS explained:

> CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. . . . *The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the [MA] risk-adjustment model (FFS claims).* The actual amount of the adjuster will be calculated

> by CMS based on a RADV-like review of records submitted to support FFS claims data.

RADV Final Methodology at AR5314-15 (emphasis added). 42 U.S.C. § 1395w-23(b)(4)(D). (At oral argument, counsel for CMS stated that the anticipated audit, whose goal is to "publish[ ] a finalized FFS adjuster," is not concluded. *See* Hearing Tr. at 31-32.) UnitedHealth urges the Court to find that this CMS explanation of the need for an FFS Adjuster for audits, due to the different data sources from which pay rates and error rates are determined, is a singular and strong demonstration of the inadequacies of the 2014 Overpayment Rule, which is based on the same dissimilar data sources but lacks such an adjustment.

Second, UnitedHealth points to two notices from CMS that recognized the differences in data for traditional Medicare and Medicare Advantage healthcare coverage. It notes the CMS rationale for applying a "Coding Intensity Adjustment" to Medicare Advantage insurers. Medicare Advantage plans contain more diagnosis codes than does traditional Medicare, which could lead to overpayments relative to traditional Medicare costs for the same patient. CMS implemented a Coding Intensity Adjustment to adjust for the higher prevalence of diagnosis codes in Medicare Advantage plans. When it did so, CMS emphasized that it was concerned about the imbalance in the number of diagnosis codes between traditional Medicare and Medicare Advantage and not "improper coding." Advance Notice of Methodological Changes for CY 2009 Parts C and D Rates and Policies (Feb. 22, 2008) (2009 Advance Notice) at AR4231 ("We do not assume

that the coding pattern differences that we found in our study are the result of improper coding. . . . However, because MA coding patterns differ from FFS coding patterns, the normalization factor (which is calculated based on FFS coding) does not currently adjust for these different coding patterns."). In addition, UnitedHealth points to a CMS 2010 rate announcement for Medicare Advantage plans which recognized that because "MA payment methodology is based on fee-for-service payments" by traditional Medicare, such "plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid." Announcement of CY 2010 Parts C and D Rates and Policies (Apr. 6, 2009) at AR4335.

Third, UnitedHealth argues that an Advance Notice for 2004 defined "diagnosis" as "keyed to the presence of a diagnosis code in the claims data," which definition is contradicted by the 2014 Overpayment Rule that declares that a "diagnosis" must be supported by underlying medical charts. *See* 2004 Advance Notice at AR3903.

CMS dismisses these earlier statements as only "varied comments about the purpose of the coding difference adjuster, made in an effort to explain why insurers' search for every supportable diagnosis would lead to overpayment." CMS Mot. at 35. It insists that the agency "has always understood a certification of the 'accuracy' and 'truthfulness' of risk adjustment data to require that any reported diagnosis be substantiated" by underlying records. *Id.* at 35 (citing 42 C.F.R. § 422.31(d), (e)); *see also* 79 Fed. Reg. at 29,921-22 (AR1313-14).

The CMS argument does not misstate its regulations but misses the point. UnitedHealth does

not contend that Medicare Advantage insurers should be permitted knowingly or recklessly to bill CMS for erroneous diagnosis codes. Instead, it argues that the Medicare statute requires CMS to pay for the healthcare of Medicare Advantage beneficiaries in the same manner, and by the same standards, by which CMS pays for traditional Medicare beneficiaries. That means, for the millions of Americans covered by Medicare and Medicare Advantage, that there are error rates; UnitedHealth argues that it should not be subject to lesser payments, False Claims Act liability, or debarment for errors over these huge populations that are fewer than those errors made by CMS itself.

CMS fails to address the central issue here. The question is whether the documents cited by UnitedHealth constitute an agency policy or position from which the 2014 Overpayment Rule deviated without a reasoned explanation. More specifically, UnitedHealth argues that the analysis in the RADV Final Methodology constituted an agency decision or policy that recognized the necessity of an FFS Adjuster-type procedure to account for discrepancies between the documentation for setting payments to Medicare Advantage insurers and that used for determining whether an "overpayment" had occurred. As to this argument, CMS is essentially silent.

Agency policies and practices may take many forms and still be sufficiently established so that any change in the policy must be explained. *Republic Airline Inc. v. U.S. Dept. of Transp.*, 669 F.3d 296 (D.C. Cir. 2012), provides a good example. That case involved the transfer of "slot exemptions," by which airlines operate out of high-traffic airports. Specifically, after a corporate acquisition, the new parent corporation planned to use an existing slot

exemption exactly as it had been used before the acquisition took place. Because the corporate entity operating the flight had "ceased to exist as a carrier," the Department of Transportation (DOT) decided that the new entity's use of the predecessor's slot exemption would constitute a transfer in violation of federal law. *Id.* at 301 (quoting DOT letter). In isolation, its reasoning was not illogical but the D.C. Circuit overruled it nonetheless. Since DOT had previously permitted slot exemptions to continue in use after similar corporate changes, its decision that *Republic Air* resulted in an impermissible "transfer" was found to be arbitrary and capricious. *Id.* at 300-02.

This Court comes to the same conclusion. Having recognized that actuarial equivalence, mandated by statute, required an FFS Adjuster for purposes of defining overpayments because of dissimilar data for RADV audits, CMS provides no legitimate reason for abandoning that statutory mandate in the context of the 2014 Overpayment Rule. The Court finds that CMS was arbitrary and capricious in adopting the 2014 Overpayment Rule without explaining its departure from prior policy.[10]

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[10] UnitedHealth further urges the Court to find that "it is inherently arbitrary and irrational to calibrate a payment model using one type of data and then operate the model using a different type of data." United Mot. at 32. As discussed above, the Court recognizes and gives substantial weight to the American Academy of Actuaries' analysis of why it is actuarially unsound to "apply the risk-adjustment model in a way that is inconsistent with the way it was developed." Academy of Actuaries Comment at AR5235. Further, " 'unexplained departure from prior agency determinations' is inherently arbitrary and capricious." *Nat'l Treasury Emps. Union v. Fed. Labor Relations Auth.*, 404 F.3d 454 (D.C. Cir. 2005) (quoting

D. False Claims Act Liability

1. Negligence Standard

UnitedHealth further complains that the 2014 Overpayment Rule unlawfully imposes a negligence standard on Medicare Advantage insurers to identify and report "overpayments," which is inconsistent with the standards of the False Claims Act to which it would otherwise align enforcement. CMS objects, contending that the standard adopted in the 2014 Overpayment Rule, including its requirement of "reasonable diligence," is indistinguishable from the CMS 2000 Rule that required Medicare Advantage insurers to certify to the accuracy of risk adjustment data. *See* Medicare + Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (2000 Rule) (AR2006)). CMS insists that the 2014 Overpayment Rule only "prevents . . . willful ignorance (or reckless disregard), but no more." CMS Mot. at 44.

Back to basics. The ACA requires that "[a]n overpayment must be reported and returned" within "60 days after the date on which the overpayment was identified." 42 U.S.C. § 1320a-7k(d)(2). The 2014 Overpayment Rule provides: "The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment." 42 C.F.R. § 422.326(c). In the preamble to the 2014 Overpayment Rule, CMS

Am. Fed. of Gov't Emps., Local 2761 v. FLRA, 866 F.2d 1443, 1446 (D.C. Cir. 1989)). The Court contents itself with finding that the failure of the 2014 Overpayment Rule to ensure actuarial equivalence violates the statute and its unexplained departure from prior agency policy is arbitrary and capricious.

explained that such reasonable diligence "at a minimum . . . would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." 79 Fed. Reg. at 29,923 (AR1315). Failure to do so could place a Medicare Advantage insurer at risk of liability under the False Claims Act.

In contrast, the False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. § 1320a-7k(d)(3)—imposes liability for erroneous ("false") claims for payment submitted to the government that are submitted "knowingly." "Knowingly" is a term of art defined in the FCA to include false information about which a person "has actual knowledge," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).[11] In summary, the FCA and the ACA require actual knowledge, deliberate ignorance, or reckless disregard before liability can be found. This, indeed, is the standard CMS itself once adopted: the preamble to the 2000 Rule required certification to the "best knowledge, information, and belief" of an insurer, with a sanction only in cases of "[a]ctual knowledge of falsity," "reckless disregard," or "deliberate ignorance." *See* 2000 Rule, 65 Fed. Reg. at 40,268 (AR2006). The standard in the 2000 Rule (or the FCA or the ACA) is certainly *not* the standard in the 2014 Overpayment Rule, however much CMS might want to make it so.

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[11] The ACA does not use the term "knowingly" but defines it by cross-reference to the FCA. *See* 42 U.S.C. § 1320a-7k(d)(4)(A) ("The terms 'knowing' and 'knowingly' have the meaning given those terms in section 3729(b) of Title 31.").

"Congress clearly had no intention to turn the FCA, a law designed to punish and deter fraud, into a vehicle for either 'punish[ing] honest mistakes or incorrect claims submitted through mere negligence' or imposing 'a burdensome obligation' . . . rather than a 'limited duty to inquire.' " *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274-75 (D.C. Cir. 2010) (quoting S. Rep. No. 99-345, at 6, 19 (1986)). With these proscriptions in mind, the 2014 Overpayment Rule extends far beyond the False Claims Act and, by extension, the Affordable Care Act. Not being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation.

2. Definition of "Identified"

UnitedHealth also notes that the proposal for the 2014 Overpayment Rule stated that a Medicare Advantage insurer would have "identified" an overpayment when "it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment." 2014 Proposed Rule at 1997 (AR81). However, the final 2014 Overpayment Rule stated that a Medicare Advantage insurer would have "identified" an overpayment when "it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment." 42 C.F.R. § 422.326(c). The proposed language was consistent with the 2000 Rule, the FCA and the ACA's reference to the FCA. The CMS proposal intimated nothing about what Medicare Advantage insurers should have known, nor about "proactive compliance activities." While CMS argues that there is no new requirement, its change

of standards is obvious. *Cf.* 2000 Rule, 65 Fed. Reg. at 40,268 (AR2006) (providing for sanctions only if insurers certify information despite their "actual knowledge," "reckless disregard," or "deliberate ignorance" of its falsity).

A regulation "violates the APA, if it is not a 'logical outgrowth' of the agency's proposed regulations." *Ass'n of Private Sector Colleges and Univs. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012). In such cases, the regulated parties must be afforded "an opportunity to comment on new regulations." *Id.* "A final rule is a logical outgrowth if affected parties should have anticipated that the relevant modification was possible." *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014). In point of fact, regulated insurers apparently did not anticipate that CMS might ultimately define "identified" to include overpayments about which an insurer should have known because of "proactive compliance activities." In the position of insurance companies that do not regularly see patient medical records, but only doctor bills, Medicare Advantage insurers argued that "identified" overpayments should be identified as ones that are "known" to the insurer. UnitedHealth draws attention to its own comment on the Proposed Rule argued that "an identified overpayment should be limited to actual knowledge of an overpayment." UnitedHealth Group Comment (Mar. 7, 2014) at AR1040. Agencies may not "pull a surprise switcheroo on regulated entities" by adopting an interpretation that significantly departs from the one proposed. *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). The Court agrees that CMS did so here, and that 2014 Overpayment Rule

imposed a distinctly different and more burdensome definition of "identified" without adequate notice.

IV. CONCLUSION

For the foregoing reasons, the Court will grant UnitedHealth's Motion for Summary Judgment, Dkt. 47; deny CMS's Cross-Motion for Summary Judgment, Dkt. 57; and vacate the 2014 Overpayment Rule. A memorializing Order accompanies this Opinion.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITEDHEALTHCARE INSURANCE COMPANY, *et al.*, **Plaintiffs,** **v.** **Alex M. AZAR II, Secretary of the Department of Health and Human Services, *et al.*,** **Defendants.**	**Civil Action No. 16-157 (RMC)**

2020 WL 417867

MEMORANDUM OPINION

This Court vacated a final rule issued by the Centers for Medicare & Medicaid Services (CMS) to determine when certain private insurers were overpaid by Medicare because it did not comply with the statutory requirement of "actuarial equivalence." *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018). The government moves for reconsideration. Although the government does not ask to reinstate the rule, it does ask the Court to narrow its decision based on new empirical analysis. Because the data underlying that analysis has long been in CMS' possession but was not litigated and because the analysis does not persuade, the Court will deny the motion.

I. BACKGROUND

A more robust description of the statutory scheme, regulatory scheme, and facts of this case can be found in the Court's previous decision. *See id.* at 176-83. A brief recap is necessary for context.

Under the Medicare Advantage program, Medicare-eligible beneficiaries can elect to receive health insurance coverage through private insurance companies instead of through traditional Medicare programs administered by CMS. CMS reimburses hospitals participating in traditional Medicare a fixed amount based on each patient's diagnosis at discharge, and it reimburses doctors a fixed amount based on the specific services provided. By comparison, CMS reimburses insurers participating in Medicare Advantage a fixed amount for each patient they enroll, based in part on various risk factors including diagnosis on discharge.

Although different reimbursement schemes are at play, by statute CMS must pay Medicare Advantage insurers in a manner that ensures "actuarial equivalence" with payments to traditional Medicare providers. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). CMS accomplishes this feat by using a complex risk-adjustment model, the CMS Hierarchical Condition Category (CMS-HCC) model, to regress total traditional-Medicare expenditures onto traditional-Medicare beneficiaries' risk factors. The output of this model is a marginal dollar cost associated with each risk factor, reduced to a "normalized" risk coefficient that takes as its starting point the "average beneficiary."[1] Medicare Advantage insurers are paid

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[1] For example, the model might determine that the average beneficiary receives $10,000 per year in reimbursable

based on the cumulative risk scores of their patients.[2] The underlying logic is that developing risk coefficients from traditional Medicare data, and then adjusting a Medicare Advantage beneficiary's risk score, will render the cost to CMS under traditional Medicare and the cost to the insurer under Medicare Advantage actuarially equivalent.

As part of its oversight of the Medicare Advantage program, CMS audits a sample of reimbursement requests submitted by Medicare Advantage insurers. Costs associated with unsupported diagnoses must be reported to CMS. But reimbursement is not limited to only those audited cases. As of 2008, CMS applies a "Risk Adjustment Data Validation" (RADV) audit to extrapolate the error rate in the audited sample across an entire insurance contract, and the insurer is responsible for returning all overpayments calculated based on that extrapolated rate.

RADV audits introduce a complication in this payment scheme. RADV audits extrapolate an error rate based on audited data from a Medicare Advantage insurer, but Medicare Advantage payment rates are based on data drawn from traditional Medicare, which is itself unaudited and admittedly prone to some degree of error. This has the effect of making traditional Medicare patients appear healthier, and cost less per diagnosis code, than their

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expenses and that the marginal cost of a given risk factor is $2,000. By definition the average beneficiary has a risk score of 1.0, so the risk factor would have a normalized risk coefficient of 0.2.

[2] For example, a patient with a cumulative risk score of 1.2 costs 20% more than the average beneficiary and the Medicare Advantage insurer would be reimbursed 120% the average benchmark rate.

Medicare Advantage counterparts.[3] For years CMS counterbalanced this effect by implementing a fee-for-service adjuster (FFS Adjuster), which estimated the error rate present in traditional Medicare diagnoses; insurers were only responsible for repayment of RADV audit errors exceeding the estimated traditional Medicare error rate. In early 2014, however, CMS finalized a rule which eliminated the FFS Adjuster and upset this balance. *See* 79 Fed. Reg. 29,844 (May 23, 2014) (Overpayment Rule). UnitedHealthcare challenged the Overpayment Rule in January 2016. *See* Compl. [Dkt. 1].

This Court made three findings relevant to the instant motion when it ruled on summary judgment. First, the Court determined that "two figures are actuarially equivalent when they share the same set of actuarial assumptions." *UnitedHealthcare*, 330 F. Supp. 3d at 186 (citing *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011)). "Different assumptions behind the elements of a calculation would, necessarily, result in actuarially non-equivalent results." *Id.* Thus, an "inevitable" result of relying on unaudited data to set payment rates but audited data to determine overpayment is that CMS "will pay less for Medicare Advantage coverage because," unlike traditional Medicare settings, "essentially no errors would be reimbursed." *Id.* at 187. This violates the actuarial equivalence requirement of 42 U.S.C. § 1395w-23(a)(1)(C)(i).

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[3] This is because the CMS regresses total Medicare expenditures onto both audited and unaudited diagnosis codes. Put another way, costs are spread out among a larger set of diagnoses, such that each individual diagnosis takes up a smaller share of the costs.

Second, the statutory scheme requires CMS to establish risk factors for Medicare Advantage patients "using the same methodology as is expected to be applied in making payments under" traditional Medicare. 42 U.S.C. § 1395w-23(b)(4)(D). However, beneficiary risk factors in traditional Medicare were developed using unaudited diagnoses. So, for the same reason, the Court determined that CMS failed to use the "same methodology" and violated this statutory requirement when it subsequently applied RADV audits to Medicare Advantage payments without accounting for the "crucial data mismatch" between audited and unaudited data. *UnitedHealthcare*, 330 F. Supp. 3d at 187.

Third, CMS stated as part of prior rulemaking that the FFS Adjuster was necessary 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 [Medicare Advantage] risk-adjustment model (FFS claims)." *Id.* at 188 (quoting RADV Final Methodology at AR5314-15) (emphasis and internal quotations omitted). Although "Medicare Advantage insurers should [not] be permitted knowingly or recklessly to bill CMS for erroneous diagnosis codes," *id.* at 189, the Court determined that this concern did not adequately explain why, as a technical matter, the FFS Adjuster was no longer necessary and why the agency had changed its position. This absence of adequate explanation rendered the Overpayment Rule arbitrary and capricious. *Id.* (citing *Republic Airline Inc. v. U.S. Dept. of Transp.*, 669 F.3d 296 (D.C. Cir. 2012)).

For each of these three reasons, the Court vacated the Overpayment Rule. *Id.* at 192. Sixty days later, the government moved for partial reconsideration under Federal Rule of Civil Procedure 60(b). *See* Defs.' Rule 60(b) Mot. for Partial Recons. (Mot.) [Dkt. 76]. The government does not dispute that the Overpayment Rule failed to explain the shift in policy, was arbitrary and capricious, and should remain vacated. *Id.* at 1. But the government notes that just weeks after the Court's decision, CMS finalized an FFS Adjuster Study which concluded that, as an empirical matter, "diagnosis error in FFS claims data does not lead to systematic payment error" in the Medicare Advantage program. CMS, *Fee for Service Adjuster & Payment Recovery for Contract Level Risk Adjustment Data Validation Audits* at 6 (Oct. 26, 2018) (FFS Adjuster Study), *available at* https://tinyurl.com/ve3737d; *see also* 83 Fed. Reg. 54,982 (Nov. 1, 2018) (publishing FFS Adjuster Study and soliciting comments on its conclusions). The government contends that this conclusion calls into question the Court's own findings regarding the "inevitable" consequences of a data mismatch between audited and unaudited records, and further asks the Court, as a matter of judicial prudence, to reconsider its opinion and reserve a decision on the necessity of the FFS Adjuster until CMS has an opportunity to further investigate the issue through regular rulemaking processes.

UnitedHealthcare signaled its intent to oppose, but briefing was stayed pending the release of the data underlying the FFS Adjuster Study. *See* 12/20/2018 Minute Order. CMS publicly released some data on April 25, 2019. Shortly thereafter, CMS noticed its intentions to release "[a]dditional data . . .

to all parties who have entered in an applicable data use agreement" and to "replicate" the FFS Adjuster Study and publish the results. 84 Fed. Reg. 18,215, 18,216 (Apr. 30, 2019). CMS published that replicated study—which explained certain methodological decisions and confirmed the FFS Adjuster Study's conclusions—on June 28, 2019, and further extended the comment period for the FFS Adjuster Study. *See* Defs.' Reply in Supp. of Their Rule 60(b) Mot. for Partial Recons. (Reply), Ex. A, FFS Adjuster Study Addendum [Dkt. 97-1]; *see also* 84 Fed. Reg. 30,983 (June 28, 2019) (2019 FFS Adjuster Study Rule). Although that rulemaking process has not yet completed, briefing resumed and the motion is now ripe for review.[4]

II. LEGAL STANDARD

The government asks the Court for relief pursuant to Federal Rule of Civil Procedure 60(b). Rule 60(b) provides as follows:

> On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:
>
> > (1) mistake, inadvertence, surprise, or excusable neglect;
> >
> > (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);

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[4] *See* Mot.; United's Brief in Opp'n to Defs.' Rule 60(b) Mot. for Partial Recons. (Opp'n) [Dkt. 91]; Reply [Dkt. 97].

> (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
>
> (4) the judgment is void;
>
> (5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
>
> (6) any other reason that justifies relief.

Fed. R. Civ. P. 60(b). The government specifically moves for relief under provisions (b)(2) and (b)(6).

"In considering a Rule 60(b) motion, the district court 'must strike a delicate balance between the sanctity of final judgments . . . and the incessant command of a court's conscience that justice be done in light of *all* the facts.' " *PETA v. HHS*, 901 F.3d 343, 354-55 (D.C. Cir. 2018) (quoting *Twelve John Does v. District of Columbia*, 841 F.2d 1133, 1138 (D.C. Cir. 1988)) (internal quotations omitted). To that end, a district court considering a Rule 60(b) motion "is vested with a large measure of discretion." *Id.* at 355. Notwithstanding, "[m]otions for reconsideration are 'disfavored,' " *Walsh v. Hagee*, 10 F. Supp. 3d 15, 18 (D.D.C. 2013) (citation omitted), and the D.C. Circuit has cautioned that Rule 60(b) "should be only sparingly used." *PETA*, 901 F.3d at 355.

III. ANALYSIS

A. Rule 60(b)(2)

The government first argues that its Rule 60(b) motion is appropriate because the FFS Adjuster Study constitutes "new evidence" that would

have been relevant to the Court's decision. UnitedHealthcare responds that the data underlying the FFS Adjuster Study has been in CMS' possession for many years now and that the agency has not shown that with "reasonable diligence" the study "could not have been discovered" before judgment. In turn, the government does not contest the age of the data but asserts that the study is the culmination of an extended review, that it is commonplace for agencies to review previous decisions, and further that the agency is entitled to a presumption of regularity when performing such a review. *See Allied Mech. Servs., Inc. v. NLRB*, 668 F.3d 758, 770-71 (D.C. Cir. 2012).

The government's response misses the mark. Although CMS is entitled to a presumption of regularity in its review of prior decisions, the development of facts central to this litigation does not call merely for regularity—it calls for the exercise of "reasonable diligence." *Compare Reasonable Diligence*, Black's Law Dictionary (11th ed. 2019) ("A fair degree of diligence expected from someone of ordinary prudence under the circumstances like those at issue."), *with Ordinary Diligence*, Black's Law Dictionary (11th ed. 2019) ("The diligence that a person of average prudence would exercise in handling his or her own affairs."). Here, CMS was aware of actuarial criticisms of the Overpayment Rule when it first responded to comments. *See* Overpayment Rule at 29,844. It was similarly aware that those criticisms were at the heart of this lawsuit when the Complaint was filed in early 2016. *See generally* Compl. And it remained aware of the importance of this issue through over two years of litigation in this Court.

By contrast, the underlying data sets CMS used for its FFS Adjuster Study were developed in 2004, 2005, 2008, and 2011, respectively. *See* 2019 FFS Adjuster Study Rule at 30,983. The FFS Adjuster Study itself is only sixteen pages long. There is no indication in the record or from the government that the timeline for completion of the FFS Adjuster Study was informed in any way by its potential evidentiary value in this litigation. After CMS received criticisms of the FFS Adjuster Study, it only took some four months for the agency to replicate that study. *See* 2019 FFS Adjuster Study Rule. Given the years available to CMS, the Court cannot conclude that the completion of the FFS Adjuster Study after the 11th hour is the result of "reasonable diligence" under the circumstances. *See In re Neurontin Mkg. & Sales Practices Litig.*, 799 F. Supp. 2d 110, 114-15 (D. Mass. 2011) (holding a new meta-analysis of existing scientific studies was not new evidence because the defendant "could have performed a similar meta-analysis prior to the trial"); *see also Good Luck Nursing Home, Inc. v. Harris*, 636 F.2d 572, 577 (D.C. Cir. 1980) ("[A] party that . . . has not presented known facts helpful to its cause when it had the chance cannot ordinarily avail itself on [R]ule 60(b) after an adverse judgment has been handed down."); *cf. Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596-97 (1993) ("Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual

revision. Law, on the other hand, must resolve disputes finally and quickly.").[5]

B. Rule 60(b)(6)

The government argues that relief is nonetheless warranted under Rule 60(b)(6), which permits relief from judgment for "any other reason that justifies relief." Fed. R. Civ. P. 60(b)(6). But not just any reason will do; such relief is reserved for "extraordinary circumstances." *Ackermann v. United States*, 340 U.S. 193, 199 (1950). This is a weighty burden that is best satisfied when "the interest that litigation must someday end [is] only slightly impinged, while the countervailing interest that justice be done [is] seriously at stake." *Good Luck Nursing Home*, 636 F.2d at 577-78. For example, "[w]hen a party timely presents a previously undisclosed fact so central to the litigation that it shows the initial judgment to have been *manifestly unjust*, reconsideration under [R]ule 60(b)(6) is proper even though the original failure to present that information was inexcusable." *Id.* at 577 (emphasis added). And for the reasons below, the Court finds these criteria are not satisfied.

1. Unjust Outcome

In response to the government's motion, UnitedHealthcare has gone to great lengths to explain why the conclusions of the FFS Adjuster Study are incorrect. For its part, the government has done little to substantiate the findings of the FFS

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[5] As the government suggests, provision (b)(2) is an odd fit with the administrative record and rulemaking process because there is no "evidence"; analysis under provision (b)(6) may be more appropriate. *See* Reply at 10-11.

Adjuster Study to the Court. Without getting too much into the weeds, UnitedHealthcare argues:

First, that the FFS Adjuster Study answers the wrong question. The FFS Adjuster Study concluded that "errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to [Medicare Advantage] organizations." FFS Adjuster Study at 5. But problems with the Overpayment Rule arise because it operates in two steps: (1) payment to insurers; and (2) recoupment of overpayment by CMS. The Court determined that the Overpayment Rule created a "crucial data mismatch" between the first step and the second. *UnitedHealthcare*, 330 F. Supp. 3d at 187. That is, unaudited data was used to develop risk coefficients for the first step, but audited data was used to determine when insurers had been overpaid. The FFS Adjuster Study addresses only the effect of audited data on the development of risk factor coefficients for payments, *i.e.*, only the first step. It does not examine the effect of using only audited data to determine overpayment amounts to Medicare Advantage insurers, *i.e.*, the second step, and so does not speak to the "crucial data mismatch" identified by the Court.

Second, and more fundamentally, that the FFS Adjuster Study mixes audited and unaudited data when analyzing payments to insurers and so actually negates its authors' conclusions. Simplified, the CMS-HCC risk model also proceeds in two steps: (1) regression of total Medicare Parts A and B expenditures for each beneficiary onto all risk factors, producing a marginal dollar cost for each risk factor;

and (2) normalization of those marginal costs against the average beneficiary cost, producing a risk coefficient. While the FFS Adjuster Study used audited data to generate the marginal dollar costs in step one, it then normalized those coefficients against unaudited data. *See* CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Validation Audits - Technical Appendix* at 13 (Oct. 26, 2018), *available at* https://tinyurl.com/rte2b6l ("In the next step, we take the new coefficients and apply them on the original FFS data set."). This was accomplished by mathematically correcting—*i.e.*, adjusting downwards—the results using audited data to conform to the results using unaudited data. Without this correction, the coefficients *over* predict total Medicare costs, which is exactly what one would expect if higher marginal dollar costs generated from only audited diagnoses were applied to a beneficiary population that includes both audited and unaudited diagnoses. But this correction plays the same role as the FFS Adjuster, only proving the FFS Adjuster's necessity in the payment scheme. *See* Opp'n, Ex. 7, Decl. of Julia Lambert [Dkt. 91-7] ¶¶ 40-42.

The Court need not linger on the details of these arguments. On a motion to reconsider, it is sufficient to say that the arguments are fully explained and the government does not adequately respond. Indeed, the government asserts that it would be improper to "fully address United's criticisms outside of the rulemaking process." Reply at 23. Instead, the government offers the FFS Adjuster Study not "for the validity of its conclusions, which are still tentative, but rather as evidence that the Court's conclusions may not necessarily be accurate, [and] to demonstrate the

technical complexity of the questions that the study addresses." *Id.* at 24.

In the regular course of rulemaking pending comments, the government is entitled to withhold its final conclusions until its review process is completed. But the government cannot be coy when it seeks extraordinary relief. Having already argued and lost its case after two years of litigation and careful consideration by the Court, merely hinting at possible inaccuracies and suggesting technical complexity is not enough to now convince the Court that the interests of justice are "seriously at stake" or that the outcome was "manifestly unjust." True, this case is technically complex, but it did not somehow become *more* technically complex after the Court's decision than it was before. In the face of robust argument that the Court's initial decision was correct—which itself followed only after extensive briefing from both parties—the government's new arguments to the contrary must be both convincing and definitive.

2. Interest of Finality

On the other hand, the stakes for Plaintiffs are high. As the government itself previously argued, merely vacating the Overpayment Rule without addressing the merits of the CMS methodology "would provide plaintiffs no relief" because it "would not necessitate any change to the Secretary's risk adjustment methodology." Defs.' Mem. of P. & A. in Supp. of Their Mot. to Dismiss for Lack of Subject Matter Jurisdiction [Dkt. 12-1] at 19. The government motion for reconsideration demonstrates the problem: without the finality of a decision, the government seems intent on re-litigating the Court's findings.

C. Deference to the Regulatory Process

The government nonetheless counsels deference to the CMS administrative process and asks the Court to give UnitedHealthcare "time . . . to 'convince the agency to alter a tentative position' " and provide the agency " 'an opportunity to correct its own mistakes and to apply its expertise,' potentially eliminating the need for (and costs of) judicial review." *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 387 (D.C. Cir. 2012) (quoting *Pub. Citizen Health Research Grp. v. FDA*, 740 F.2d 21, 30-31 (D.C. Cir. 1984)). But the factors discussed in *American Petroleum Institute* do not support reconsideration when applied to this case.

In *American Petroleum Institute*, EPA promulgated a final rule that exempted some hazardous materials from regulation, but not others. The petitioners argued that the final rule should have exempted a broader range of materials. During the pendency of litigation, however, EPA backtracked and proposed a rule eliminating the exemption entirely which, if adopted, would have mooted the petitioners' claims. Alternatively, the comment process on the proposed rule gave the petitioners another avenue to argue their case to the agency, before any judgment by the court. Accordingly, the D.C. Circuit held the case in abeyance, reasoning that "waiting to resolve this case allows EPA to apply its expertise and correct any errors, preserves the integrity of the administrative process, and prevents piecemeal and unnecessary judicial review." *Id.* at 388.

Essentially all those facts cut in the opposite direction here. For one, CMS is no longer writing on a blank slate: UnitedHealthcare had plenty of time to

convince CMS and the Court of its position; CMS had plenty of time to consider and finalize its interpretation; and whatever the costs of judicial review, after two years of litigation, multiple rounds of briefing, and three decisions by the Court, they have already been expended. For another, if the Court modifies its decision and CMS adopts its proposed rule, the effect would be to expand the scope of litigation, not contract it. That is, the proposed rule is not a "complete reversal of course" by the agency that might otherwise end this litigation. *Id.* To the contrary, CMS is doubling down on its position. Thus, instead of mooting UnitedHealthcare's claims, CMS seeks to *re-open* a matter which has already been decided. Further, this expansion would occur even if the Court modifies its decision and CMS does *not* adopt the proposed rule. Under those circumstances, the most that could be said is that the regulatory landscape would revert to the same condition as before any of this litigation began, setting the parties up for another four years of conflict.

"Put simply, the doctrine of prudential ripeness ensures that Article III courts make decisions only when they have to, and then, only once." *Id.* at 387. The government does not contest that this matter was properly ripe when it was litigated or when it was decided. The Court carefully considered the matter and issued its decision, and that decision was crafted to give practical, not merely nominal, relief to the prevailing party. Having lost, the government now seeks to reset the process. But "an agency [cannot] stave off judicial review of a challenged rule simply by initiating a new proposed rulemaking that would amend the rule in a significant way." *Id.* at 388. By that same token, an agency clearly cannot *undo*

judicial review of a challenged rule by initiating proposed rulemaking after an adverse decision has already been handed down.

IV. CONCLUSION

For the reasons stated, the Court will deny the government's Rule 60(b) Motion for Partial Reconsideration, Dkt. 76. A memorializing Order accompanies this Memorandum Opinion.

Date: January 27, 2020

ROSEMARY M. COLLYER
United States District Judge

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 18-5326 **September Term, 2021**
1:16-cv-00157-RMC
Filed On: November 1, 2021

UnitedHealthcare Insurance Company, et al.,
Appellees,

v.

Xavier Becerra, in his official capacity as
Secretary of Health and Human Services, et al.,
Appellants.

2021 WL 5045254

BEFORE: Rogers, Pillard, and Walker, Circuit Judges

ORDER

Upon consideration of appellees' petition for panel rehearing filed September 27, 2021, and the response thereto, it is

ORDERED that the petition be denied. It is

FURTHER ORDERED that the opinion issued August 13, 2021, be amended as follows:

(1) Slip Op., p. 7, lines 1-5: Delete: "We therefore reverse the district court's grant of summary judgment to UnitedHealth and its resulting vacatur of the Overpayment Rule and remand for the district court to enter judgment in favor of CMS." and

Insert in lieu thereof: "We therefore reverse the judgment of the district court vacating the Overpayment Rule and remand this case with orders to enter judgment in favor of Appellants, except with

respect to the Overpayment Rule's definition of 'identified.' "

(2) Slip Op., p. 49, lines 5-7: Delete: "We accordingly reverse the judgment of the district court and remand this case with orders to enter judgment in favor of Appellants." and

Insert in lieu thereof: "We accordingly reverse the judgment of the district court vacating the Overpayment Rule and remand this case with orders to enter judgment in favor of Appellants, except with respect to the Overpayment Rule's definition of 'identified.' "

The Clerk is directed to issue the amended opinion and to amend the judgment issued August 13, 2021. The Clerk is further directed to issue the mandate forthwith.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk
BY: /s/
Daniel J. Reidy
Deputy Clerk

42 U.S.C. § 1320a-7k(d)

§ 1320a-7k. Medicare and Medicaid program integrity provisions

* * *

(d) Reporting and returning of overpayments

(1) In general

If a person has received an overpayment, the person shall—

(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) Deadline for reporting and returning overpayments

An overpayment must be reported and returned under paragraph (1) by the later of—

(A) the date which is 60 days after the date on which the overpayment was identified; or

(B) the date any corresponding cost report is due, if applicable.

(3) Enforcement

Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of Title 31) for purposes of section 3729 of such title.

(4) Definitions

In this subsection:

(A) Knowing and knowingly

The terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of Title 31.

(B) Overpayment

The term "overpayment" means any funds that a person receives or retains under subchapter XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such subchapter.

(C) Person

(i) In general

The term "person" means a provider of services, supplier, medicaid managed care organization (as defined in section 1396b(m)(1)(A) of this title), Medicare Advantage organization (as defined in section 1395w-28(a)(1) of this title), or PDP sponsor (as defined in section 1395w-151(a)(13) of this title).

(ii) Exclusion

Such term does not include a beneficiary.

* * *

42 U.S.C. § 1395w-23(a)(1)(A), (B)(i)-(iii), (C)(i)-(ii), (b), (c)(1)(D)(i)-(ii), (j), (n)

§ 1395w-23. Payments to Medicare+Choice organizations

(a) Payments to organizations

(1) Monthly payments

(A) In general

Under a contract under section 1395w-27 of this title and subject to subsections (e), (g), (i), and (l) and section 1395w-28(e)(4) of this title, the Secretary shall make monthly payments under this section in advance to each Medicare+Choice organization, with respect to coverage of an individual under this part in a Medicare+Choice payment area for a month, in an amount determined as follows:

(i) Payment before 2006

For years before 2006, the payment amount shall be equal to 1/12 of the annual MA capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, adjusted under subparagraph (C) and reduced by the amount of any reduction elected under section 1395w-24(f)(1)(E) of this title.

(ii) Payment for original fee-for-service benefits beginning with 2006

For years beginning with 2006, the amount specified in subparagraph (B).

(B) Payment amount for original fee-for-service benefits beginning with 2006

(i) Payment of bid for plans with bids below benchmark

In the case of a plan for which there are average per capita monthly savings described in section 1395w-24(b)(3)(C) or 1395w-24(b)(4)(C) of this title, as the case may be, the amount specified in this subparagraph is equal to the unadjusted MA statutory non-drug monthly bid amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G), plus the amount (if any) of any rebate under subparagraph (E).

(ii) Payment of benchmark for plans with bids at or above benchmark

In the case of a plan for which there are no average per capita monthly savings described in section 1395w-24(b)(3)(C) or 1395w-24(b)(4)(C) of this title, as the case may be, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G).

(iii) Payment of benchmark for MSA plans

Notwithstanding clauses (i) and (ii), in the case of an MSA plan, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C).

* * *

(C) Demographic adjustment, including adjustment for health status

(i) In general

Subject to subparagraph (I), the Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

(ii) Application of coding adjustment

For 2006 and each subsequent year:

(I) In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part1 A and B to the extent that the Secretary has identified such differences.

(II) In order to ensure payment accuracy, the Secretary shall annually conduct an

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1 So in original. Probably should be "parts".

analysis of the differences described in subclause (I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(III) In calculating each year's adjustment, the adjustment factor shall be for 2014, not less than the adjustment factor applied for 2010, plus 1.5 percentage points; for each of years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage point; and for 2019 and each subsequent year, not less than 5.9 percent.

(IV) Such adjustment shall be applied to risk scores until the Secretary implements risk adjustment using Medicare Advantage diagnostic, cost, and use data.

* * *

(b) Annual announcement of payment rates

(1) Annual announcements

(A) For 2005

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the second Monday in May of 2004, with respect to each MA payment area, the following:

(i) MA capitation rates

The annual MA capitation rate for each MA payment area for 2005.

(ii) Adjustment factors

The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in 2005.

(B) For 2006 and subsequent years

For a year after 2005—

(i) Initial announcement

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the first Monday in April before the calendar year concerned, with respect to each MA payment area, the following:

(I) MA capitation rates; MA local area benchmark

The annual MA capitation rate for each MA payment area for the year.

(II) Adjustment factors

The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in such year.

(ii) Regional benchmark announcement

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned,

with respect to each MA region and each MA regional plan for which a bid was submitted under section 1395w-24 of this title, the MA region-specific non-drug monthly benchmark amount for that region for the year involved.

(iii) Benchmark announcement for CCA local areas

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each CCA area (as defined in section 1395w-29(b)(1)(A)[3] of this title), the CCA non-drug monthly benchmark amount under section 1395w-29(e)(1)[3] of this title for that area for the year involved.

(2) Advance notice of methodological changes

At least 45 days (or, in 2017 and each subsequent year, at least 60 days) before making the announcement under paragraph (1) for a year, the Secretary shall provide for notice to Medicare+Choice 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 (in 2017 and each subsequent year, of no less than 30 days) to comment on such proposed changes.

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[3] See Reference in Text note below.

(3) Explanation of assumptions

In each announcement made under paragraph (1), the Secretary shall include an explanation of the assumptions and changes in methodology used in such announcement.

(4) Continued computation and publication of county-specific per capita fee-for-service expenditure information

The Secretary, through the Chief Actuary of the Centers for Medicare & Medicaid Services, shall provide for the computation and publication, on an annual basis beginning with 2001 at the time of publication of the annual Medicare+Choice capitation rates under paragraph (1), of the following information for the original medicare fee-for-service program under parts A and B (exclusive of individuals eligible for coverage under section 426-1 of this title) for each Medicare+Choice payment area for the second calendar year ending before the date of publication:

(A) Total expenditures per capita per month, computed separately for part A and for part B.

(B) The expenditures described in subparagraph (A) reduced by the best estimate of the expenditures (such as graduate medical education and disproportionate share hospital payments) not related to the payment of claims.

(C) The 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 payments under subsection (a).

(D) Such average risk factor based on diagnoses for inpatient and other sites of service, using the same methodology as is expected to be applied in making payments under subsection (a).

* * *

(c) Calculation of annual Medicare+Choice capitation rates

(1) In general

For purposes of this part, subject to paragraphs (6)(C) and (7), each annual Medicare+Choice capitation rate, for a Medicare+Choice payment area that is an MA local area for a contract year consisting of a calendar year, is equal to the largest of the amounts specified in the following subparagraph (A), (B), (C), or (D):

* * *

(D) 100 percent of fee-for-service costs

(i) In general

For each year specified in clause (ii), the adjusted average per capita cost for the year involved, determined under section 1395mm(a)(4) of this title and adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments

under sections,[4] 1395w-4(*o*), and[4] 1395ww(n) and 1395ww(h) of this title.

(ii) Periodic rebasing

The provisions of clause (i) shall apply for 2004 and for subsequent years as the Secretary shall specify (but not less than once every 3 years).

* * *

(j) Computation of benchmark amounts

For purposes of this part, subject to subsection (*o*), the term "MA area-specific non-drug monthly benchmark amount" means for a month in a year—

(1) with respect to—

(A) a service area that is entirely within an MA local area, subject to section 1395w-29(d)(2)(A)[6] of this title, an amount equal to 1/12 of the annual MA capitation rate under subsection (c)(1) for the area for the year (or, for 2007, 2008, 2009, and 2010, 1/12 of the applicable amount determined under subsection (k)(1) for the area for the year; for 2011, 1/12 of the applicable amount determined under subsection (k)(1) for the area for 2010; and, beginning with 2012, 1/12 of the blended benchmark amount determined under subsection (n)(1) for the area for the year), adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

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4 So in original.

6 See References in Text note below.

(B) a service area that includes more than one MA local area, an amount equal to the average of the amounts described in subparagraph (A) for each such local MA area, weighted by the projected number of enrollees in the plan residing in the respective local MA areas (as used by the plan for purposes of the bid and disclosed to the Secretary under section 1395w-24(a)(6)(A)(iii) of this title), adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

(2) with respect to an MA region for a month in a year, the MA region-specific non-drug monthly benchmark amount, as defined in section 1395w-27a(f) of this title for the region for the year.

* * *

(n) Determination of blended benchmark amount

(1) In general

For purposes of subsection (j), subject to paragraphs (3), (4), and (5), the term "blended benchmark amount" means for an area—

(A) for 2012 the sum of—

(i) 1/2 of the applicable amount for the area and year; and

(ii) 1/2 of the amount specified in paragraph (2)(A) for the area and year; and

(B) for a subsequent year the amount specified in paragraph (2)(A) for the area and year.

(2) Specified amount

(A) In general

The amount specified in this subparagraph for an area and year is the product of—

(i) the base payment amount specified in subparagraph (E) for the area and year adjusted to take into account the phase-out in the indirect costs of medical education from capitation rates described in subsection (k)(4) and, for 2021 and subsequent years, the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate as described in subsection (k)(5); and

(ii) the applicable percentage for the area for the year specified under subparagraph (B).

(B) Applicable percentage

Subject to subparagraph (D), the applicable percentage specified in this subparagraph for an area for a year in the case of an area that is ranked—

(i) in the highest quartile under subparagraph (C) for the previous year is 95 percent;

(ii) in the second highest quartile under such subparagraph for the previous year is 100 percent;

(iii) in the third highest quartile under such subparagraph for the previous year is 107.5 percent; or

(iv) in the lowest quartile under such subparagraph for the previous year is 115 percent.

(C) Periodic ranking

For purposes of this paragraph in the case of an area located—

(i) in 1 of the 50 States or the District of Columbia, the Secretary shall rank such area in each year specified under subsection (c)(1)(D)(ii) based upon the level of the amount specified in subparagraph (A)(i) for such areas; or

(ii) in a territory, the Secretary shall rank such areas in each such year based upon the level of the amount specified in subparagraph (A)(i) for such area relative to quartile rankings computed under clause (i).

(D) 1-year transition for changes in applicable percentage

If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year, the applicable percentage for the area in the year shall be the average of--

(i) the applicable percentage for the area for the previous year; and

(ii) the applicable percentage that would otherwise apply for the area for the year.

(E) Base payment amount

Subject to subparagraphs (F) and (G), the base payment amount specified in this subparagraph—

(i) for 2012 is the amount specified in subsection (c)(1)(D) for the area for the year; or

(ii) for a subsequent year that—

(I) is not specified under subsection (c)(1)(D)(ii), is the base amount specified in this subparagraph for the area for the previous year, 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; and

(II) is specified under subsection (c)(1)(D)(ii), is the amount specified in subsection (c)(1)(D) for the area for the year.

(F) Application of indirect medical education phase-out

The base payment amount specified in subparagraph (E) for a year shall be adjusted in the same manner under paragraph (4) of subsection (k) as the applicable amount is adjusted under such subsection.

(G) Application of kidney acquisitions adjustment

The base payment amount specified in subparagraph (E) for a year (beginning with 2021) shall be adjusted in the same manner under paragraph (5) of subsection (k) as the applicable amount is adjusted under such subsection.

(3) Alternative phase-ins

(A) 4-year phase-in for certain areas

If the difference between the applicable amount (as defined in subsection (k)) for an area for 2010 and the projected 2010 benchmark amount (as defined in subparagraph (C)) for the area is at least $30 but less than $50, the blended benchmark amount for the area is—

(i) for 2012 the sum of—

(I) 3/4 of the applicable amount for the area and year; and

(II) 1/4 of the amount specified in paragraph (2)(A) for the area and year;

(ii) for 2013 the sum of—

(I) 1/2 of the applicable amount for the area and year; and

(II) 1/2 of the amount specified in paragraph (2)(A) for the area and year;

(iii) for 2014 the sum of—

(I) 1/4 of the applicable amount for the area and year; and

(II) ¾ of the amount specified in paragraph (2)(A) for the area and year; and

(iv) for a subsequent year the amount specified in paragraph (2)(A) for the area and year.

(B) 6-year phase-in for certain areas

If the difference between the applicable amount (as defined in subsection (k)) for an area for 2010 and the projected 2010 benchmark amount (as defined in subparagraph (C)) for the area is at least $50, the blended benchmark amount for the area is—

(i) for 2012 the sum of—

(I) 5/6 of the applicable amount for the area and year; and

(II) 1/6 of the amount specified in paragraph (2)(A) for the area and year;

(ii) for 2013 the sum of—

(I) 2/3 of the applicable amount for the area and year; and

(II) 1/3 of the amount specified in paragraph (2)(A) for the area and year;

(iii) for 2014 the sum of—

(I) 1/2 of the applicable amount for the area and year; and

(II) 1/2 of the amount specified in paragraph (2)(A) for the area and year;

(iv) for 2015 the sum of—

(I) 1/3 of the applicable amount for the area and year; and

(II) 2/3 of the amount specified in paragraph (2)(A) for the area and year; and

(v) for 2016 the sum of—

(I) 1/6 of the applicable amount for the area and year; and

(II) 5/6 of the amount specified in paragraph (2)(A) for the area and year; and

(vi) for a subsequent year the amount specified in paragraph (2)(A) for the area and year.

(C) Projected 2010 benchmark amount

The projected 2010 benchmark amount described in this subparagraph for an area is equal to the sum of—

(i) 1/2 of the applicable amount (as defined in subsection (k)) for the area for 2010; and

(ii) 1/2 of the amount specified in paragraph (2)(A) for the area for 2010 but determined as if there were substituted for the applicable percentage specified in clause (ii) of such paragraph the sum of—

(I) the applicable percent that would be specified under subparagraph (B) of paragraph (2) (determined without regard to subparagraph (D) of such paragraph) for the area for 2010 if any reference in such paragraph to "the previous year" were deemed a reference to 2010; and

(II) the applicable percentage increase that would apply to a qualifying plan in the area under subsection (o) as if any reference in such subsection to 2012 were deemed a

reference to 2010 and as if the determination of a qualifying county under paragraph (3)(B) of such subsection were made for 2010.

(4) Cap on benchmark amount

In no case shall the blended benchmark amount for an area for a year (determined taking into account subsection (o)) be greater than the applicable amount that would (but for the application of this subsection) be determined under subsection (k)(1) for the area for the year.

(5) Non-application to PACE plans

This subsection shall not apply to payments to a PACE program under section 1395eee of this title.

* * *

42 U.S.C. § 1395w-24(a)(1)(A), (6)(A)

§ 1395w-24. Premiums and bid amounts

(a) Submission of proposed premiums, bid amounts, and related information.

(1) In general

(A) Initial submission

Not later than the second Monday in September of 2002, 2003, and 2004 (or the first Monday in June of each subsequent year), each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary and for each MA plan for the service area (or segment of such an area if permitted under subsection (h)) in which it intends to be offered in the following year the following:

(i) The information described in paragraph (2), (3), (4), or (6)(A) for the type of plan and year involved.

(ii) The plan type for each plan.

(iii) The enrollment capacity (if any) in relation to the plan and area.

* * *

(6) Submission of bid amounts by MA organizations beginning in 2006.

(A) Information to be submitted

For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this subparagraph is as follows:

(i) 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 (as used for purposes of section 300e-1(8) of this title) in the payment area for an enrollee with a national average risk profile for the factors described in section 1395w-23(a)(1)(C) of this title (as specified by the Secretary).

(ii) The proportions of such bid amount that are attributable to—

(I) the provision of benefits under the original medicare fee-for-service program option (as defined in section 1395w-22(a)(1)(B) of this title), including, for plan year 2020 and subsequent plan years, the provision of additional telehealth benefits as described in section 1395w-22(m) of this title;

(II) the provision of basic prescription drug coverage; and

(III) the provision of supplemental health care benefits.

(iii) The actuarial basis for determining the amount under clause (i) and the proportions described in clause (ii) and such additional information as the Secretary may require to verify such actuarial bases and the projected number of enrollees in each MA local area.

(iv) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such

deductibles, coinsurance, and copayments, described in subsection (e)(4)(A).

(v) With respect to qualified prescription drug coverage, the information required under section 1395w-104 of this title, as incorporated under section 1395w-111(b)(2) of this title, with respect to such coverage.

In the case of a specialized MA plan for special needs individuals, the information described in this subparagraph is such information as the Secretary shall specify.

* * *

42 C.F.R. § 422.254(b)(1), (5)

§ 422.254. Submission of bids.

* * *

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

* * *

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

* * *

42 C.F.R. § 422.326

§ 422.326 Reporting and returning of overpayments.

(a) *Terminology*. For purposes of this section—

Applicable reconciliation occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g), which is announced by CMS each year.

Funds means any payment that an MA organization has received that is based on data submitted by the MA organization to CMS for payment purposes, including § 422.308(f) and § 422.310.

Overpayment means any funds that an MA organization has received or retained under title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment*. The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.

(d) *Reporting and returning of an overpayment*. An MA organization must report and return any overpayment it received no later than 60 days after

the date on which it identified it received an overpayment, unless otherwise directed by CMS for purposes of § 422.311.

(1) *Reporting*. An MA organization must notify CMS, of the amount and reason for the overpayment, using a notification process determined by CMS.

(2) *Returning*. An MA organization must return identified overpayments in a manner specified by CMS.

(e) *Enforcement*. Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period*. An MA organization must report and return any overpayment identified for the 6 most recent completed payment years.