

No. _____

In the
Supreme Court of the United States

UNITEDHEALTHCARE INSURANCE COMPANY, ET AL.,
Applicants,

v.

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

**APPLICATION DIRECTED TO THE HONORABLE JOHN G. ROBERTS, JR.
FOR AN EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT**

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January 12, 2022

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Applicant UnitedHealthcare Insurance Company states that it is the indirect parent of each Applicant. No other publicly held company owns 10% or more of stock.

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To the Honorable John G. Roberts, Jr., Chief Justice of the Supreme Court of the United States and Circuit Justice for the United States Court of Appeals for the District of Columbia Circuit:

Pursuant to 28 U.S.C. § 2101(c) and Rules 13.5, 22, and 30.2 of the Rules of this Court, Applicants UnitedHealthcare Insurance Company, et al., respectfully request a 14-day extension of time, to and including February 14, 2022, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case. The D.C. Circuit entered its decision on August 13, 2021. Applicants timely filed a petition for rehearing. On November 1, 2021, the D.C. Circuit issued an amended decision and denied the petition for rehearing. A copy of the court’s decision, which is also reported at 16 F.4th 867, is attached hereto as Attachment 1. A copy of the order denying rehearing is attached hereto as Attachment 2. Unless extended, the time for filing a petition for a writ of certiorari will expire on January 31, 2022. This application is filed more than 10 days before the date the petition would be due. *See* Sup. Ct. R. 13.5. This Court has jurisdiction under 28 U.S.C. § 1254(1).

This case presents questions of exceptional importance to a critical government program, including whether and how the Medicare statute’s “actuarial equivalence” provision—which requires the government to pay private Medicare Advantage plans on an equivalent basis with the amounts the government expends in traditional Medicare—must be effectuated in determining what counts as an “overpayment” under the Medicare Advantage program. In the decision below, the D.C. Circuit held

that the statute’s “actuarial equivalence” provision is irrelevant to assessing whether a Medicare Advantage plan has received an overpayment. That conclusion—which was not advanced by the government or briefed by the parties—flies in the face of the statutory text, and destroys the comparative payment model underlying the Medicare Advantage program. The D.C. Circuit’s sweeping ruling threatens to destabilize the Medicare Advantage program by subjecting industry participants like Applicants to potentially billions of dollars in reduced payments never intended by Congress and, ultimately, harming millions of Americans who participate in this hugely successful program. Applicants seek a two-week extension of time to prepare a petition for certiorari to the Court to grant review of that erroneous decision.

BACKGROUND

1. Millions of senior and disabled Americans receive health insurance under Medicare. As amended, the Medicare statute not only authorizes the Centers for Medicare & Medicaid Services (CMS) to provide health insurance directly to eligible individuals (so-called “traditional Medicare”), but also allows such individuals to elect to receive health insurance through private insurance companies instead. This latter program, known as “Medicare Advantage,” is enormously popular because it allows individuals to keep their insurance coverage and healthcare providers and frequently offers expanded care.

Traditional Medicare and Medicare Advantage use difference payment models. In traditional Medicare, CMS reimburses physicians for the services they provide to patients during visits. During such visits, physicians may assign diagnosis codes that reflect their patients’ medical conditions. In the Medicare Advantage program, by

contrast, CMS pays private insurance plans a fixed amount to cover beneficiaries' future healthcare costs. CMS calculates those payments to plans by relying on plan beneficiaries' diagnosis codes to estimate beneficiaries' expected future healthcare costs. Of course, providers may, on occasion, inaccurately assign or enter diagnosis codes, which, in turn, may affect the amount paid under the programs.

The Medicare statute requires “actuarial equivalence” between the payments CMS makes to Medicare Advantage plans and the payments CMS makes under traditional Medicare. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Among other things, the statute’s “actuarial equivalence” requirement ensures that CMS’s payments in both programs will be calculated on an apples-to-apples basis, using the same set of actuarial assumptions. The Medicare statute likewise requires CMS to compute and publish “risk scores”—the numerical measure of the risk of providing health insurance—for both traditional and Medicare Advantage beneficiaries using the “same methodology.” *Id.* § 1395w-23(b)(4)(D).

For many years, CMS recognized that it needed to use diagnosis codes in a consistent manner across *both* programs in order to calculate Medicare Advantage payments, in compliance with those two statutory commands. But in 2014, CMS departed from that understanding. Implementing a provision of the Affordable Care Act that amended the Medicare statute to obligate Medicare Advantage plans to return any identified “overpayment[s],” *see id.* § 1320a-7k(d)(1), CMS promulgated a new rule to “clarify” when a Medicare Advantage plan’s overpayment obligation is triggered. *See* 79 Fed. Reg. 29,844, 29,918-25 (May 23, 2014), *codified at* 42 C.F.R.

§ 422.326 (Overpayment Rule). This Overpayment Rule, in effect, established different assumptions for how to calculate the health and costliness of the traditional Medicare and Medicare Advantage populations.

In particular, the Overpayment Rule fundamentally differentiated the criteria by which CMS calculates the health of its own population and the criteria CMS uses to assess the health of a Medicare Advantage plan's population (through the use of diagnosis codes), imposing stricter validation requirements on plans than it imposes on itself. That mismatch in this key baseline assumption results in CMS calculating Medicare Advantage payment rates based on a fundamentally different dataset of diagnosis codes than the dataset for which Medicare Advantage plans may collect payment. CMS's rule change destroys the equivalence mandated by Congress between the traditional Medicare and Medicare Advantage programs—creating an apples-to-oranges payment scheme, in which CMS reaps the benefits—and imposes potentially billions of dollars of losses on private insurers in the form of alleged “overpayments.”

2. Applicants are Medicare Advantage plans that insure healthcare for millions of Americans who participate in the Medicare Advantage program. They brought this action in the United States District Court for the District of Columbia challenging the Overpayment Rule under the Administrative Procedure Act (APA) on the grounds that the Rule contravenes the Medicare statute's “actuarial equivalence” and “same methodology” mandates, represents an unexplained departure from CMS's prior statements on payment accuracy, and is otherwise unlawful.

On cross-motions for summary judgment, the district court (Collyer, J.) held the Overpayment Rule unlawful. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. 2018). The district court concluded that the Overpayment Rule violates the Medicare statute’s “actuarial equivalence” and “same methodology” mandates by establishing different requirements for traditional Medicare and Medicare Advantage plans. *Id.* at 187. As the court explained, the Overpayment Rule imposes a stringent definition on the validity of diagnosis codes in the Medicare Advantage program, while CMS calculates the value of those diagnosis codes based on its own unaudited data. *See id.* at 184. “[T]he 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 beneficiaries than CMS itself pays for comparable patients.” *Id.* at 184-85. This different treatment in payment, the district court concluded, “is inevitable” and “system[atic].” *Id.*; *see also id.* at 187 (reiterating that because “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”).

The district court also concluded that “CMS was arbitrary and capricious in adopting the 2014 Overpayment Rule without explaining its departure from prior policy.” *Id.* at 190. In a prior rulemaking concerning audits of Medicare Advantage plans, CMS had recognized that requiring Medicare Advantage plans to return *all* payments associated with erroneous diagnostic codes would result in unequal rates, because CMS does not audit traditional Medicare patient records in the same way.

Id. at 180. For this reason, CMS proposed an “adjuster” that accounted for this discrepancy and reduced Medicare Advantage insurers’ overpayment obligations. *Id.* at 180-81. The district court agreed with Applicants that CMS’s unexplained disregard of this same principle in promulgating the Overpayment Rule violated the APA. *Id.* at 189-90.

CMS sought reconsideration, which the district court denied. *See UnitedHealthcare Ins. Co. v. Azar*, Civil Action No. 16-157 (RMC), 2020 WL 417867 (D.D.C. Jan. 27, 2020).

3. A panel of the D.C. Circuit reversed. *See UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021) (Pillard, Rogers & Walker, JJ.) (Attachment 1). Adopting a position never advocated by CMS in this litigation or otherwise, the court concluded that the statutory requirement of “actuarial equivalence” has no relevance to the overpayment provision at all. *Id.* at 884. In so holding, the panel reasoned that the Medicare statute’s “actuarial equivalence” provision did not “cross-reference” or otherwise apply to the overpayment provision—that the former was “a directive to CMS” in how to develop its risk-adjustment model, without speaking to the kinds of overpayments CMS may collect from Medicare Advantage plans. *Id.* at 870-71; *see id.* at 886. But the court’s decision overlooked key language in the statute expressly connecting these provisions. *See infra* at 7-8.

And that core statutory error infected the rest of the court’s opinion. For “much the same reasons,” the court concluded that the Medicare statute’s “same methodology” requirement was also not relevant to the Overpayment Rule’s legality.

16 F.4th at 871-82. And this same lack of a statutory connection, the court reasoned, eliminated any need for CMS “to provide further explanation of its decision” to adopt the Overpayment Rule. *Id.* at 892. At bottom, the D.C. Circuit concluded that CMS was free to obligate Medicare Advantage insurers to return *all* payments linked to identified diagnostic-coding errors—even if that error rate did not exceed the rate of coding errors in traditional Medicare, and even if that resulted in CMS paying plans much less than the costs CMS itself would expect to incur in insuring its own population—thus violating the government’s own acknowledged understanding of what “actuarial equivalence” requires.

Applicants sought panel rehearing to correct a mistake in the court’s opinion regarding the directive to the district court on remand. On November 1, 2021, the panel issued an amended opinion correcting the mistake. *See* Attachment 2. But it denied rehearing—thus precluding Applicants from seeking rehearing on any other issues—and took the extraordinary step of immediately issuing its mandate. *See id.*

REASONS FOR GRANTING THE APPLICATION

1. The decision below adopts a reading of the Medicare statute that is egregiously wrong, eliminates the statute’s fundamental “actuarial equivalence” requirement, and threatens grave harm to the Medicare Advantage program—even beyond the present dispute regarding the Overpayment Rule. The D.C. Circuit’s reasoning conflicts with the Medicare statute’s plain text, which explicitly links the actuarial equivalence requirement with the overpayment obligation through the statutory definition of an “overpayment.” *See* 42 U.S.C. § 1320a-7k(d)(4)(B). Congress defined “overpayment” as “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*”; “subchapter XVIII” includes the actuarial equivalence requirement. *Id.* (emphasis added). The definition of “overpayment” is therefore expressly conditioned on the actuarial equivalence requirement in two respects: (1) by the express cross-reference to the chapter containing the requirement, and (2) because one cannot determine whether a plan has retained an overpayment without first determining the amount to which the plan *is* “entitled” under the Medicare Act (subchapter XVIII).

Given the straightforward text, CMS has never attempted to argue that actuarial equivalence was irrelevant to the Overpayment Rule’s legality; instead, CMS argued (erroneously) that the Rule *complied* with that requirement. In other words, the decision below reached out to fundamentally reorder a complex Medicare reimbursement scheme—and jeopardize the highly popular Medicare Advantage program—based on an understanding of the statute’s operation that had never been advanced by any party, ever, and is obviously wrong.

By relieving CMS of its obligation to pay Medicare Advantage plans the same amount CMS itself would spend to insure an equivalent patient population under traditional Medicare, the D.C. Circuit’s ruling undercuts the viability of an important healthcare program serving millions of Americans. And by obligating Medicare Advantage companies to identify and return *all* payments connected to diagnostic-coding errors—even when the plan’s error rate does not exceed the rate present in traditional Medicare—the rule also exposes companies like Applicants to billions of

dollars in False Claims Act liability (that is, liability the government has asserted against these companies in pending litigation in other courts). In addition, because of this statutory error, the D.C. Circuit simply excused CMS from having to comply with its basic APA obligation to explain its departure from the agency's prior position on this issue—a critical check on arbitrary administrative action. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016).

The D.C. Circuit's blatant misreading of the Medicare statute alone warrants review. But the undeniable importance of this case bolsters the need for this Court's intervention. The D.C. Circuit's decision effectively threatens insurers like Applicants that participate in the Medicare Advantage program with billions of dollars of additional costs (in the form of returned payments) never intended by Congress. This will disrupt the provision of services under Medicare Advantage, and ultimately harm the millions of Americans who chose to participate in this program.

2. A short, 14-day extension of time is warranted so that undersigned counsel may evaluate, prepare, and file a petition for certiorari. Counsel of record has had several significant commitments in other matters during the months of January and February, including presenting oral argument to the Ninth Circuit in *Lara v. First National Insurance Co.* (No. 21-35126) on January 10, 2022; preparing a petition for certiorari to this Court in *Oracle Corp. v. Hewlett-Packard Co.* due January 27, 2022; and preparing a response brief to the Seventh Circuit in *CCC Intelligent Solutions Inc. v. Tractable Inc.* (No. 19-1997) due February 18, 2022. An extension of time would enable counsel to frame and present the issues for review in the most direct

and effective manner for this Court's consideration. In addition, an extension would permit potential amici to evaluate the important issues presented by this case and consider how they might assist the Court in their filings.

The extension will not impact the Court's consideration of this case this term or the calendaring of this case for oral argument next term, should the Court grant review. Nor would this short extension work any meaningful prejudice on any party.

CONCLUSION

For the foregoing reasons, Applicants respectfully request that the time for filing a petition for a writ of certiorari in this case be extended by 14 days to and including February 14, 2022.

Respectfully submitted,



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January 12, 2022

ATTACHMENT 1

16 F.4th 867
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

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Reissued November 1, 2021

Synopsis

Background: Medicare Advantage insurers brought action against Centers for Medicare and Medicaid Services (CMS), challenging rule requiring insurers to return overpayments and asserting that rule failed to ensure actuarial equivalence between CMS's own costs and what CMS paid Medicare Advantage insurers to provide same coverage. The United States District Court for the District of Columbia, Rosemary M. Collyer, Senior District Judge, 330 F.Supp.3d 173, granted summary judgment for insurers, and denied reconsideration, 2020 WL 417867. CMS appealed.

Holdings: The Court of Appeals, Pillard, Circuit Judge, held that:

on issue of first impression, Medicare statute's actuarial-equivalence requirement did not apply to overpayment-refund obligation or overpayment rule promulgated by CMS to comply with that provision;

overpayment rule was not violation of Medicare statute's "actuarial equivalence";

overpayment rule was not violation of Medicare statute's requirement of "same methodology"; and

overpayment rule was not unexplained departure from prior policy, and therefore CMS was not required to provide further explanation of its decision.

Reversed and remanded.

Opinion, 9 F.4th 868, superseded.

Procedural Posture(s): On Appeal; Motion for Summary Judgment.

West Codenotes

Negative Treatment Reconsidered

42 C.F.R. §§ 422.326, 422.504, 423.1, 423.360, 423.505

*869 Appeal from the United States District Court for the District of Columbia (No. 1:16-cv-00157)

Attorneys and Law Firms

Weili J. Shaw, Attorney, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were Ethan P. Davis, Acting Assistant Attorney General, and Mark B. Stern, Attorney. Michael S. Raab, Attorney, entered an appearance.

Daniel Meron argued the cause for appellees. With him on the brief was Matthew M. Shors.

David W. Ogden, Brian M. Boynton, and Kevin M. Lamb were on the brief for amicus curiae America's Health Insurance Plans in support of appellees.

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 *870 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 *871 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 *872 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 *873 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, *874 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. *875 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>; *876 *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(I); *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(I) (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(I)(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 *877 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, *878 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.

*879 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] *880 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, ***881** 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 ***882** 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 ***883** 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 *884 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 ***885** 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 ***886** 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 *887 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 *888 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.” *889 *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.

***890** 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 *891 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 *892 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 *893 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

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 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.

* * *

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."

All Citations

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So ordered.

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ATTACHMENT 2

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

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.'"

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 18-5326

September Term, 2021

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