

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

HUMANA INC., et al.,)
)
 Plaintiffs,)
)
 v.) Case No. 4:23-cv-909-O
)
 XAVIER BECERRA, et al.,)
)
 Defendants.)
 _____)

**DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT AND
IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Last year, the federal government paid private insurers more than \$450 billion through the Medicare Advantage program.¹ That sum was nearly seven percent of the entire federal budget. A large fraction of those payments depended on data submitted by the insurers themselves, concerning the medical conditions with which their beneficiaries had been diagnosed. When a Medicare Advantage insurer submits a relevant diagnosis, it automatically triggers additional payments to the insurer. This case concerns the government's efforts to ensure that the diagnoses for which insurers claim many billions of dollars of payment each year are documented in the medical records of their beneficiaries. Studies suggest that a concerning number of those payments are based on diagnoses that lack medical record support. The Centers for Medicare & Medicaid Services (CMS) estimate that the Medicare Advantage program has recently made more than \$10 billion in such overpayments each year.²

Because insurers are paid more for covering beneficiaries with certain medical conditions, the federal government conducts audits to confirm the accuracy of some reported diagnoses. Any payments based on diagnoses that are not documented in the beneficiary's medical record are then recovered. Historically, the recoveries made through this audit program have been a tiny fraction of the estimated overpayments to Medicare Advantage insurers. But for many years, CMS has considered the use of statistical sampling and extrapolation in Medicare Advantage audits, to allow the government to recover a larger portion of its overpayments. Last year, CMS published a rule

¹ 2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds at 162 (“2024 Annual Report”), <https://www.cms.gov/oact/tr/2024>.

² CMS, Part C Improper Payment Measure Fiscal Year 2022 Payment Error Rate Results at 1 (Gov't Appx. 263); *see* CMS, Medicare Part C Improper Payment Measurement (reporting figures for FY 2023 and 2024), <https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/medicare-part-c-ipm>.

concerning those audits. 88 Fed. Reg. 6,643 (Feb. 1, 2023) (“RADV Rule”).³ Under that rule, the agency may use statistical sampling and extrapolation in Medicare Advantage audits, beginning with payment year 2018. Humana brings a facial challenge to the rule, in which CMS decided not to alter the program-wide payment rates or documentation standards for the subset of Medicare Advantage contracts that are subject to audit each year.

Humana advances several arguments against the rule, all of them meritless. First, Humana points to the statutory actuarial-equivalence provision, 42 U.S.C. § 1395w-23(a)(1)(C)(i), and suggests that it limits the government’s ability to conduct audits that seek to recover all of the overpayments on a Medicare Advantage contract. But the challenged rule does not commit the government to seek such “population-level” recoveries, and the government is not seeking them in any of the more than sixty pending Medicare Advantage audits. Humana’s facial challenge therefore fails: the insurer must show that there is “no set of circumstances” in which the rule’s statutory interpretation could be lawfully applied, and Humana does not challenge the lawfulness of its application to the pending audits. *United States v. Salerno*, 481 U.S. 739, 745 (1987); *Associated Builders & Contractors of Tex., Inc. v. NLRB*, 826 F.3d 215, 220 (5th Cir. 2016).

Humana’s interpretation is also wrong as a matter of law because, as an interrelated set of statutory provisions makes clear, the actuarial-equivalence provision is exclusively concerned with the establishment of payment rates, and does not limit the recovery of overpayments. *See UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 884–85 (D.C. Cir. 2021) (“*United*”) (holding that “the text of section 1395w-23(a)(1)(C)(i) limits the scope of the actuarial-equivalence requirement” to the “specified context of CMS’s calculation and disbursement of monthly

³ The RADV Rule appears at page 56 of the government’s appendix (henceforth “GA”), but for ease of reference the government will cite to its appearance in the Federal Register.

payments in the first instance”), *cert. denied*, 142 S. Ct. 2851 (2022). A neighboring provision confirms the government’s interpretation of the actuarial-equivalence provision, and provides an independent statutory basis for its decision not to increase payment rates or lower documentation standards when conducting extrapolated audits. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(ii). The government’s decision not to do so was also reasonable, since any concern with the accuracy of Medicare Advantage payments—which the government vigorously contests—should be dealt with by correcting the payment rates that apply to all Medicare Advantage contracts, and not through the audit program. Interested parties had adequate notice of this potential rationale for the government’s decision, and the rule was properly applied to audits beginning with payment year 2018. The government is therefore entitled to summary judgment on all of Humana’s claims.

BACKGROUND

A. The Medicare Program

The federal government provides health insurance to the elderly and disabled through the Medicare program. Medicare covers hospitalizations under Part A of the statute, 42 U.S.C. §§ 1395c to 1395i-6, outpatient medical care under Part B, *id.* §§ 1395j to 1395w-6, and prescription drugs under Part D, *id.* §§ 1395w-101 to 1395w-154. This case concerns Medicare Advantage, which Congress established in Part C of the statute, *id.* §§ 1395w-21 to 1395w-28.⁴ Under Medicare Advantage, the federal government pays private insurers to provide the coverage that participating beneficiaries would otherwise receive through Medicare Parts A and B. *Id.* § 1395w-22(a). Roughly half of all Medicare beneficiaries now choose to receive their benefits through a Medicare Advantage plan. 2024 Annual Report at 22.

⁴ Medicare Advantage is sometimes referred to as “MA,” was previously known as “Medicare+Choice” (or “M+C”), and has also been called “Part C” for short.

B. Payment in Medicare Parts A and B

The government pays differently for each of the Medicare programs. Under Part A, Medicare reimburses hospitals depending on the “diagnosis-related group” (DRG) to which a patient is assigned upon discharge. 42 U.S.C. § 1395ww(d)(1)–(4); 42 C.F.R. § 412.60. “The classification of a particular discharge” into the appropriate DRG “is based . . . on the patient’s age, sex, *principal diagnosis* . . . , *secondary diagnoses*, procedures performed, and discharge status.” 42 C.F.R. § 412.60(c)(1) (emphases added). Correctly identifying the principal and secondary diagnoses is therefore important to proper payment under Part A.⁵ Under Medicare Part B, “[d]octors who provide medical services to Part B beneficiaries” receive “compensation in accordance with fee schedules that limit the amount they may charge and be paid.” *United Seniors Ass’n v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999) (citing 42 U.S.C. § 1395w-4(g)(2)(C), (D)).

Hospitals, doctors, and other service providers seeking payment under Medicare Parts A and B submit patient diagnoses to support their claims. In Medicare Part A, as discussed above, the amount that a hospital is paid for treating a patient depends on the diagnoses that it reports for him or her. *See* 42 C.F.R. § 412.60(c)(1). In Medicare Part B, the amount of payment does not depend on reported diagnoses, but the validity of a claim often does, because a service is

⁵ Initially, Medicare Part A payments “were based on the ‘reasonable costs’ of [the] services furnished.” *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994) (quoting 42 U.S.C. § 1395f(b) (1988)). Under this “fee-for-service” regime, “providers were reimbursed for the actual costs that they incurred, provided they fell within certain cost limits.” *Id.* But in 1983, “Congress . . . completely revised the scheme for reimbursing Medicare hospitals.” *Id.* (citing Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 149). Under the new DRG-based payment system, “the amount that hospitals receive from the Medicare program for treating patients” generally “does not vary with the cost of treating the patient.” *U.S. ex. rel. Lam v. Tenet Healthcare Corp.*, 2007 WL 9702505, at *1 (W.D. Tex. July 20, 2007); *see Appalachian Reg’l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1051 (D.C. Cir. 1997) (“Reimbursement depends on the DRG to which a patient is assigned and the average cost of treating such a diagnosis, ‘regardless of the [actual] number of conditions treated or services furnished during the patient’s stay.’” (quoting 42 C.F.R. § 412.60(c)(2) (1996))).

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). Part B covers chemotherapy and dialysis, for example, but only if a patient has been diagnosed with cancer or kidney disease. For that reason, physicians must often report diagnoses to obtain reimbursement under Medicare Part B. *See id.* § 1395u(p)(1) (“Each request for payment . . . shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.”); 42 C.F.R. § 424.32(a)(2) (“A claim for physician services . . . must include appropriate diagnostic coding for those services. . .”).

Diagnosis reporting in Parts A and B is governed by the International Classification of Diseases, Tenth Edition, Clinical Modification (ICD-10-CM), which applies throughout the Medicare program. 45 C.F.R. § 162.1002(c). Under the ICD-10-CM Guidelines for Coding and Reporting, the assignment of a diagnosis code must be based upon medical record documentation.⁶ *See* 45 C.F.R. § 162.1002(c)(2), (3) (explicitly adopting these Guidelines). Diagnosis codes are only validly “reported when they are supported by the available medical record documentation,” and it “would be inappropriate” to report a diagnosis “code that is not supported by the medical record documentation.” ICD Guidelines at 17.

Reported diagnoses that bear on payment in Medicare Parts A and B must therefore be supported by the medical record. *See, e.g.*, 42 C.F.R. §§ 412.46(a)(1) (diagnoses must be “evidenced by the physician’s entries in the patient’s medical record”), 412.508(b), 405.968(a)(1). If a relevant diagnosis code is unsupported by the medical record, CMS will correct (in Part A) or deny (in Part B) the associated payment.⁷ Moreover, the Medicare statute and CMS regulations

⁶ CMS, ICD-10-CM Official Guidelines for Coding and Reporting at 15 (Oct. 1, 2024) (“ICD Guidelines”), <https://www.cms.gov/files/document/fy-2025-icd-10-cm-coding-guidelines.pdf>.

⁷ *See, e.g., In re Desert Valley Hosp., Inc.*, No. M-20-40, at 4 (HHS Dec. 27, 2019) (GA 279) (recouping some of a Part A payment because the “principal diagnosis reflected in the beneficiary’s medical records” did not “match the principal diagnosis reported on the claim form”); *In re Zoll*

require Part A and B providers who identify funds to which they are “not entitled” to return those funds within 60 days. *See* 42 U.S.C. § 1320a-7k(d); 42 C.F.R. §§ 401.303, .305(a)(1), (b)(1). A provider that identifies an unsupported diagnosis is therefore expected to return any resulting overpayment.

Because the size of payments (in Part A) and the validity of claims (in Part B) depends on the reporting of diagnoses, which themselves are valid only if they are documented in the beneficiary’s medical records, the government directs various contractors to conduct medical record review of Part A and B claims. *See, e.g.*, Medicare Program Integrity Manual §§ 1.1 (GA 100), 3.1 (GA 116), 3.3.1 (GA 146). Different contractors perform different types of medical record reviews. For example, CMS directs Medicare Administrative Contractors (MACs) reviewing inpatient hospital claims to “utilize the medical record to determine whether procedures and diagnoses were coded correctly.” *Id.* § 6.5.2 (GA 251). “If the medical record supports that they were not,” CMS directs MACs, as relevant here, to “utilize . . . ICD-10-CM coding guidelines to adjust the claim and pay at the appropriate DRG.” *Id.* CMS further directs contractors to “[d]elete any incorrect diagnoses,” including “diagnoses relating to an earlier episode that have no bearing on the current hospital stay.” *Id.* § 6.5.3 (GA 253). Medical record reviews for Medicare Part B also entail “evaluat[ing] medical record documentation” “for the purpose of determining [a service’s] medical necessity.” *Id.* § 3.3.1.1 (GA 146). For example, because “[a] beneficiary is eligible for immunosuppressant drugs only if they received an organ transplant,” a contractor may use “medical documentation” or other sources “to validate the transplant occurred.” *Id.* § 3.2.4 (GA 141).

Lifecor Corp., No. M-15-8503, at 3 (HHS Dec. 6, 2018) (GA 274) (denying claim for lack of “information in the medical record that substantiates” the diagnoses required for a piece of medical equipment to be covered by Part B).

Because of the tremendous volume of Medicare claims, Medicare contractors can only review a small fraction of claims submitted every year. *Id.* § 3.2.1 (GA 119) (“[T]he claims volume of the Medicare Program doesn’t allow for review of every claim.”). CMS therefore directs many (but not all) contractors to “target their efforts at error prevention to those services and items that pose the greatest financial risk to the Medicare program and that represent the best investment of resources,” including those “where the services billed have significant potential to be non-covered or incorrectly coded.” *Id.* (GA 119–20). Moreover, many review activities are intended to encourage compliance beyond the specific claims being audited. For example, MACs provide “[t]argeted provider education,” use “extrapolation reviews” to “encourage providers to submit claims correctly,” and provide guidance to “assist providers in understanding how to correctly submit claims and under what circumstances the services will be considered reasonable and necessary.” *Id.* § 1.3.1 (GA 101). As a result of these efforts, Medicare contractors collectively recoup hundreds of millions of dollars of Part A and B overpayments each year.⁸

C. Payment in Medicare Part C

Payments to Medicare Advantage insurers also depend on the diagnoses that the insurers submit for their covered beneficiaries. As in Parts A and B, those diagnoses must be reported in compliance with the ICD-10-CM Guidelines for Coding and Reporting, 45 C.F.R. § 162.1002(c)(2), (3), which require each diagnosis to be “supported by the available medical record documentation.” ICD Guidelines at 17. *See* 42 C.F.R. § 422.310(d)(1) (requiring Medicare Advantage insurers to “submit data that conform to CMS’ requirements for data equivalent to Medicare [Part A and B] data . . . and to all relevant national standards”). A high-level official

⁸ CMS, Medicare & Medicaid Program Integrity: Annual Report to Congress FY 2022 § 1.3.2, <https://www.cms.gov/files/document/fy2022-medicare-and-medicare-report-congress.pdf>; CMS, Medicare & Medicaid Program Integrity: Annual Report to Congress FY 2019 at 8 (GA 306).

from each insurer “must certify (based on best knowledge, information, and belief) that the data it submits under § 422.310,” including diagnosis data, “are accurate . . . and truthful.” *Id.* § 422.504(l)(2). Contractors, subcontractors, and other entities that generate diagnosis data reported by Medicare Advantage insurers must make the same certification. *Id.* § 422.504(l)(3). These certifications reflect the fact that, when a Medicare Advantage insurer submits diagnosis data, “it is making a ‘claim’ for . . . payment in the amount dictated by the data submitted.” 63 Fed. Reg. 34,968, 35,017 (June 26, 1998). As in Parts A and B, Medicare Advantage insurers who identify funds to which they are “not entitled” must return those funds within 60 days. 42 U.S.C. § 1320a-7k(d); *see* 42 C.F.R. § 422.326. An insurer that identifies a diagnosis unsupported by the medical record must therefore return any associated payment. 79 Fed. Reg. 29,844, 29,921–22 (May 23, 2014) (noting the “long-standing . . . requirement that a diagnosis submitted . . . by an MA organization for payment purposes must be supported by medical record documentation,” and explaining that an “invalid” diagnosis would “result in an overpayment”).

Medicare Advantage insurers are subject to medical record review of their claims, just like doctors and hospitals claiming payment under Parts A and B. *See* 42 C.F.R. § 422.310(e) (requiring insurers “to submit a sample of medical records for the validation of” the diagnoses submitted for payment). The purpose of this review is to “validat[e] that a particular Medicare beneficiary indeed has the medical condition for which the [insurer] has been paid.” 75 Fed. Reg. 19,678, 19,748 (Apr. 15, 2010) (“2010 Rule”). The validation of reported diagnoses “that result in additional payment” is achieved by confirming “the existence of clear, unambiguous diagnostic information in a beneficiary’s medical record” that “provides the written support for the diagnosis that was made.” *Id.* at 19,749. Unfortunately, this medical record review program—known as the risk adjustment data validation or “RADV” audit program—has been much less effective than its

analogues in Medicare Parts A and B. For many payment years, CMS has not conducted any RADV audits. *See* RADV Rule, 88 Fed. Reg. at 6,646; Dupee Decl. ¶ 5 (GA 651). And since its inception more than 20 years ago, the RADV audit program has recouped less than \$20 million in Medicare Advantage overpayments. RADV Rule, 88 Fed. Reg. at 6,646.

Although the requirements for diagnosis reporting and the medical record review procedures in Medicare Advantage are similar to their analogues in Parts A and B, the payment model is quite different. In Medicare Advantage, the government pays private insurers a predetermined sum for each beneficiary they cover. The size of the payment depends on the characteristics of each covered individual. Insurers receive larger payments for covering people expected to incur greater medical expenses (because they are older or more seriously ill) and smaller payments for covering younger or healthier beneficiaries, who will usually have lower medical costs. *See id.* at 6,644.

To achieve this variation in payments, the government computes a “risk score” for each beneficiary covered by a Medicare Advantage insurer. A risk score of 1.0 indicates average risk of medical expenses; a score of 2.0 indicates twice as much risk, and triggers twice as large a payment to the Medicare Advantage insurer. Every beneficiary is given an initial risk score based on their age, sex, and certain other characteristics. Reported diagnoses add to the beneficiary’s score, and increase the insurer’s payment for covering him or her. For example, in 2023, an 80-year-old man who was previously enrolled in Medicare Advantage, and neither institutionalized nor eligible for Medicaid, received an initial risk score of 0.556. CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates at 74 (Apr. 1, 2019), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/>

Announcement2020.pdf. A diagnosis of diabetes without complication would add another 0.105, for a total score of $0.556 + 0.105 = 0.661$. *Id.* at 75. And a diagnosis of rheumatoid arthritis would add another 0.421, for a risk score of $0.556 + 0.105 + 0.421 = 1.082$. *Id.* at 76. An insurer would therefore be paid 8.2% more for covering this beneficiary than it would receive for covering a beneficiary of average risk (*i.e.*, 108.2% of the payment for covering that average beneficiary).

CMS periodically publishes tables of these “risk factors” (also called “relative factors” or “risk coefficients”), which are added together to make up a beneficiary’s risk score, through a special statutory notice-and-comment process outside of the Federal Register. *See* 42 U.S.C. § 1395w-23(b)(1)–(2). The agency calculates the coefficients with its Hierarchical Condition Category (or CMS-HCC) model. The CMS-HCC model is a complex regression model that uses medical expenditure and diagnosis data from individuals who receive their benefits through Medicare Parts A and B to estimate the costs associated with certain characteristics of Medicare beneficiaries.⁹ The basic design of the model has been constant since it was first adopted in 2004. *See* Gregory C. Pope, et al., *Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model*, 25 Health Care Fin. Rev. 119 (Summer 2004) (GA 596).

To determine the payment owed to a Medicare Advantage insurer, the government first determines its “benchmark” (or “capitation rate”). The benchmark is based on the per capita cost of covering Medicare beneficiaries under Parts A and B in the relevant geographic area. 42 U.S.C. § 1395w-23(n); 42 C.F.R. § 422.258. Each participating insurer then submits a “bid,” telling the government what payment the insurer will accept to cover a beneficiary with an average risk

⁹ The Medicare statute also authorizes the government to “implement[] risk adjustment using Medicare Advantage diagnostic, cost, and use data,” rather than using cost and diagnosis data from Parts A and B, but the government has not yet exercised this authority. 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(IV).

profile in that area. 42 C.F.R. § 422.254. If the insurer’s bid is less than the benchmark, the bid becomes its “base payment”—the amount it is paid for covering a beneficiary of average risk—and the insurer receives a portion of the difference between its bid and the benchmark as a “rebate” that funds supplemental benefits otherwise unavailable to Medicare beneficiaries, or reduces the premiums that beneficiaries would otherwise owe. 42 U.S.C. § 1395w-24(b)(1)(C); 42 C.F.R. §§ 422.260, .266. If the insurer’s bid is greater than the benchmark or equal to it, then the benchmark becomes its base payment and the insurer must charge beneficiaries a premium to make up the difference. *See* 42 U.S.C. §§ 1395w-23(a)(1)(B)(ii), 1395w-24(b)(2)(A).

For each covered beneficiary, the government pays the Medicare Advantage insurer a sum equal to the insurer’s base payment times the beneficiary’s risk score—subject to two further adjustments. First, the statutory coding pattern adjustment further reduces an insurer’s payment by at least 5.9%. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III). Second, because the Part A and B data used to calibrate the Medicare Advantage payment model is always several years old, the normalization factor accounts for intervening changes in treatment and diagnostic coding patterns. *Id.* § 1395w-23(a)(1)(C)(ii)(I). In 2023, the combined effect of the two adjustments reduced each insurer’s payment by approximately 16.5%. An insurer therefore did not receive its full base payment multiplied by the beneficiary’s risk score, but rather 83.5% of that amount. *See* CMS, Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates at 55, 59 (Apr. 4, 2022), <https://www.cms.gov/files/document/2023-announcement.pdf>.

D. Actuarial Equivalence and the Overpayment Rule

By calculating risk scores as described above, and using those scores to vary payments to Medicare Advantage insurers, the government complies with the statutory requirement that it “adjust the . . . amount” of the payments to account “for such risk factors . . . as the Secretary

determines to be appropriate,” such as the “age, disability status, gender, institutional status, and . . . health status” of each beneficiary being covered, “so as to ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). As relevant here, when Congress instructs an agency “to ensure actuarial equivalence,” it means to equate an expected value (such as future medical costs) with a known value (such as present monthly payments). *Berger v. Xerox Corp. Ret. Income Guar. Plan*, 338 F.3d 755, 759 (7th Cir. 2003) (explaining that “actuarial equivalence” implies the comparison of “a present and a future value”); see *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011). Using the risk coefficients calculated by the CMS-HCC model and the diagnoses reported by Medicare Advantage insurers, the government pays those insurers a sum equal to the cost that it would expect to bear in providing Medicare benefits to a given beneficiary.

As the D.C. Circuit explained in *UnitedHealthcare Insurance Co. v. Becerra*, “[a]ctuarial equivalence is a directive to CMS” which “describes the goal of the risk-adjustment model Congress directed CMS to develop” for the Medicare Advantage program. 16 F.4th 867, 871 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (2022). “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.” *Id.* at 886. “It calls on CMS to use its expert judgment to identify cost-predictive risk factors in the Medicare population and to analyze . . . data . . . to determine average costs associated with those factors.” *Id.*

The *United* case was a challenge to the Medicare Advantage Overpayment Rule, which applied the “long-standing . . . requirement that a diagnosis submitted . . . by an MA organization for payment purposes must be supported by medical record documentation” to a new statutory provision about the return of overpayments. 79 Fed. Reg. at 29,921–22. The Overpayment Rule explained that, because insurers are “not entitled” to payments based on diagnoses that lack

medical record support, 42 U.S.C. § 1320a-7k(d)(4)(B), such payments are overpayments which insurers must return within sixty days of identifying them, *id.* § 1320a-7k(d)(2)(A). *See United*, 16 F.4th at 869 (“[T]he 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.”).

An insurer challenged the rule, arguing that the statutory “actuarial-equivalence principle” “impose[d] an implied—and functionally prohibitive—legal precondition on the requirement to return known overpayments.” *Id.* at 870. The insurer’s argument rested on imperfections in the medical cost and diagnosis data from Parts A and B, which the CMS-HCC model uses to calculate the risk factors that adjust Medicare Advantage payments. Despite the government’s efforts to enforce compliance with the requirement of medical record support for all diagnoses reported in Parts A and B, *see supra* at 6–7, some diagnoses reported in those programs lack medical record support. The insurer challenging the Overpayment Rule argued that, under the actuarial-equivalence provision, the presence of unsupported diagnoses in Part A and B data prevented the government from demanding the return of known overpayments in the Medicare Advantage program, “unless [it] first shows that the rate of payment errors to healthcare providers in traditional . . . 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 . . . that predicts the cost to insure Medicare Advantage beneficiaries.” *United*, 16 F.4th at 870. Under the insurer’s “view of actuarial equivalence as a defense against its obligation to reimburse CMS for known overpayments,” the insurer was “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.” *Id.* at 886. Taken to its logical conclusion, the insurer’s argument would have allowed it to “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.” *Id.*

The *United* court rejected this interpretation of the actuarial-equivalence provision, concluding that an insurer’s obligation to return overpayments did not “depend on a prior determination of actuarial equivalence.” *Id.* at 870. The D.C. Circuit held that “the actuarial-equivalence requirement is not broadly applicable” throughout the Medicare Advantage program, “but instead limited to the . . . context of CMS’s calculation and disbursement of monthly payments in the first instance,” and that it “is satisfied . . . so long as CMS reasonably concluded when it set its monthly payments to [the insurer] 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 [the insurer] ‘so as to ensure actuarial equivalence.’” *Id.* at 885 (citation omitted).

The insurer argued that unsupported diagnoses in the Part A and B data deflated the risk factors calculated by the CMS-HCC model, systematically reducing the payments to Medicare Advantage insurers. But the insurer “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,” which was “fatal to [its] claim,” because the actuarial-equivalence provision did not allow it to “belatedly do so in the guise of a challenge to the Overpayment Rule.” *Id.* at 871. CMS was therefore within its statutory authority to “recover overpayments for diagnosis codes [that the insurer] 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.” *Id.* at 885. The D.C. Circuit went on to conclude that “[e]ven if the Medicare statute could theoretically support” the insurer’s interpretation of the actuarial-equivalence provision, the court would still “lack the necessary grounds . . . to invalidate the Overpayment Rule as a violation of actuarial equivalence,” because the insurer had failed to demonstrate “that the obligation to refund overpayments . . . leads to systematic underpayment of Medicare Advantage insurers relative to traditional Medicare.” *Id.* at 887.¹⁰

E. Extrapolated RADV Audits and the Challenged Rule

Since the beginning of the Medicare Advantage program, CMS has conducted medical record review of some diagnoses that insurers submit for payment. *See, e.g.*, 2010 Rule, 75 Fed. Reg. at 19,746 (noting that “the process of independently reviewing medical records to validate [diagnosis] data submitted . . . for payment purposes has been established and operational for more than 10 years”); 42 C.F.R. § 422.310(e) (2005); 42 C.F.R. § 422.257(e) (1999). The agency refers to such reviews as risk adjustment data validation (RADV) audits. *See supra* at 8–9. At its core, the RADV audit process is quite simple. First, the government chooses a Medicare Advantage contract to audit. Then it selects particular individuals receiving benefits under that contract. Next,

¹⁰ As the D.C. Circuit explained, the insurer had “identifie[d] 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,” nor had it “established . . . that the unsupported codes it posits in traditional Medicare would both be materially analogous to those the Overpayment Rule targets, and would cause [it] to be underpaid.” *Id.* at 888; *see id.* at 890 (explaining that the insurer had “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”); *id.* at 891 (“In the absence of . . . proof—or even persuasive logic in [the insurer’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.”).

the insurer submits medical records to substantiate the diagnoses that it reported for those beneficiaries. The government then compares the reported diagnoses—which are “risk adjustment data”—to the submitted medical records, against which the diagnoses are “validated.” *See* 2010 Rule, 75 Fed. Reg. at 19,749 (explaining that reported diagnoses which “result in additional payment” are validated by identifying “clear, unambiguous diagnostic information in a beneficiary’s medical record” that “provides the written support for the diagnosis that was made”). Any payment based on an unsupported diagnosis is identified as an overpayment that must be returned to the government.¹¹

Since 2008, CMS has discussed the possibility of collecting not only the particular overpayments identified through RADV audits, but also using the audited sample as the basis for a statistical extrapolation. *See* CMS, Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates at 22 (Apr. 7, 2008), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2009.pdf>. “[R]ecouping overpayments” through sampling and extrapolation “is a long-standing practice” in Medicare Parts A and B, where it has been “utilized at least since 1972.” *Chaves Cnty. Home Health Serv. v. Sullivan*, 931 F.2d 914, 922 (D.C. Cir. 1991); *see* 42 U.S.C. § 1395ddd(f)(3); HCFA Ruling 86-1 (GA 282). The use of sampling and extrapolation in RADV audits would allow the government to recoup more of the overpayments made to Medicare Advantage insurers, without having to inspect an unmanageably large volume of beneficiary medical records. *See United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005) (noting that “sampling of similar claims and

¹¹ Exercising its independent oversight function, *see* 5 U.S.C. § 402, the HHS Office of Inspector General (OIG) also performs analogous audits. Although OIG lacks the authority to demand repayment from insurers, it can recommend that insurers voluntarily return overpayments. Only CMS, exercising the Secretary’s authority, can demand the return of overpayments on the basis of factual findings made by OIG. *See* RADV Rule, 88 Fed. Reg. at 6,645 n.6.

extrapolation from the sample is a recognized method of proof” when the government seeks to recoup overpayments); *Ratanasen v. Cal. Dep’t of Health Servs.*, 11 F.3d 1467, 1469–71 (9th Cir. 1993) (collecting cases in which sampling and extrapolation have been approved and “join[ing] other circuits in approving the use of sampling and extrapolation as part of audits in connection with Medicare and other similar programs”).

At first, CMS focused its efforts on developing a sampling and extrapolation methodology that would apply to all of the reported diagnoses for as many beneficiaries as possible on a given Medicare Advantage contract. *See* 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009) (discussing the agency’s “plans to make contract-level payment adjustments using payment error findings from a sample of enrollees from each of the selected contracts”). CMS said that it would publish its methodology “in some type of public document . . . so that the public can review and provide comment as it deems necessary.” 2010 Rule, 75 Fed. Reg. at 19,746. The agency did so in 2010, and solicited informal public feedback. Medicare Advantage RADV Notice of Payment Error Calculation Methodology (Dec. 20, 2010) (GA 79). In response, one commenter argued that CMS should not recover the full amount suggested by the draft methodology without accounting for the “the underlying error in the Medicare fee-for-service^[12] (FFS) data used to calibrate the MA risk adjustment model.” Comment of America’s Health Insurance Plans at 4 (Jan. 21, 2011) (GA 85). *See* 2010 Rule, 75 Fed. Reg. at 19,749 (discussing this issue). Others made similar comments.

In 2012, CMS published a Notice of Final Payment Error Calculation Methodology on its website. GA 94. Under the methodology described in that guidance document, CMS would select a sample of up to 201 beneficiaries for each audit, calculate the overall payment error for the

¹² Medicare Parts A and B are sometimes called “fee-for-service” (or “FFS”) Medicare, although Part A has not relied on a fee-for-service compensation model in nearly 40 years. *See supra* at 4 n.5. The *United* court referred to them as “traditional Medicare.” 16 F.4th at 872.

sample by reviewing medical records for all of the relevant diagnoses for the sample beneficiaries, and extrapolate that result to the entire pool of audit-eligible beneficiaries on the contract. CMS said that it would then “apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset” to the extrapolated recovery, to “account[] for the fact that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).” GA 97–98. CMS said that this FFS Adjuster would “be calculated . . . based on a RADV-like review of records submitted to support FFS claims data.” GA 98.

In 2018, CMS published a notice of proposed rulemaking concerning the agency’s use of sampling and extrapolation in RADV audits. 83 Fed. Reg. 54,982, 55,037–41 (Nov. 1, 2018) (“NPRM”).¹³ The agency noted that it had conducted audits for three payment years according to its posted methodology, at a cost of \$150 million, the results of which had “not yet been finalized.” *Id.* at 55,038. CMS sought further comment on that methodology, as well as the possibility of using “other potential methodologies for sampling and extrapolation, which would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts in a given payment year.” *Id.* at 55,039. Such a “sub-cohort” methodology would identify a group of beneficiaries on a given contract with shared characteristics, audit the reported diagnoses (or perhaps only the diagnoses of interest) for a sample of that group, and then extrapolate the results to the rest of the group. For example, CMS might select a group of beneficiaries for whom a particular diagnosis was reported and then, through sampling and extrapolation, determine the

¹³ The NPRM appears at page 2 of the government’s appendix, but for ease of reference the government will generally cite to its appearance in the Federal Register.

overpayments attributable to that diagnosis on the audited contract. CMS also sought comment on when it should begin collecting extrapolated recoveries from RADV audits.

In addition, CMS sought further comment on whether its sampling and extrapolation methodologies should include an FFS Adjuster. The agency proposed not to utilize such an adjustment factor for two reasons. First, the FFS Adjuster was premised on the same argument advanced by the insurer in *United*, that unsupported diagnoses in the Part A and B data deflated the risk factors calculated by the CMS-HCC model, systematically reducing the payments made to all Medicare Advantage insurers for the reported diagnoses of their beneficiaries. But RADV audits do not review the accuracy of the relative factors calculated by the risk adjustment model; they only “recover payments based on diagnoses that are not supported by medical record documentation.” *Id.* at 55,041. An FFS Adjuster that addressed “issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation” was therefore outside the scope of the audit program. *Id.* (emphasis added). If inaccuracies in the risk factors led to “systematic payment error” throughout Medicare Advantage, then CMS suggested that all Medicare Advantage payments should be corrected (presumably by revising the risk factors themselves). *Id.* The agency provisionally concluded that “correcting the payments made to audited plans,” without doing the same for all Medicare Advantage insurers, “would not be appropriate,” and sought public comment. *Id.*

CMS also offered a second explanation for its proposal not to include an FFS Adjuster in its RADV audit sampling and extrapolation methodologies. CMS said that it had “conducted an extensive study regarding the presence and impact of diagnosis error in FFS claims data,” which suggested that “errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic

effect on the payments made to MA organizations.” *Id.* at 55,040. CMS sought comment on this study as well, and held the public comment period open for nearly ten months as it released related documents and data.

In 2019, two months before the comment period closed, CMS sought comment on the question of “whether 42 U.S.C. 1395w-23—and in particular clause (a)(1)(C), which requires risk adjustment in subclause (a)(1)(C)(i), mandates a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C) (iii)—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.” 84 Fed. Reg. 30,983, 30,983 (June 28, 2019).

CMS issued a final rule in 2023, which Humana challenges here. The agency declined to “adopt[] either the . . . sampling and extrapolation technique described in the 2012 methodology or a specific extrapolated audit methodology based on sub-cohorts of enrollees.” RADV Rule, 88 Fed. Reg. at 6,651. Instead, CMS announced that “for future RADV audits” the agency would “rely on any statistically valid method for sampling and extrapolation that it determines to be well-suited to a particular audit.” *Id.*; *see id.* at 6,654 (“We are not adopting any particular statistical sampling methodology in the final rule.”). In doing so, CMS effectively withdrew the 2012 guidance document. *See id.* at 6,658 (“This rule, rather than the 2012 methodology, will govern CMS’ conduct of RADV audits.”). The agency also decided not to collect extrapolated overpayments for payment years 2011 through 2017—despite having performed several years of pending audits designed to support such extrapolated recoveries—but only to recoup the particular overpayments identified through medical record review for those years, as it had done previously. CMS announced that it intended to use sampling and extrapolation to support overpayment

recoveries beginning with its payment year 2018 audits. *Id.* at 6,650; *see* 42 C.F.R. § 422.311(a)(2) (“CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.”).

CMS decided that it would not include an FFS Adjuster in its sampling and extrapolation methodologies. Some commenters suggested that, in light of the actuarial-equivalence provision, 42 U.S.C. § 1395w-23(a)(1)(C)(i), “CMS cannot lawfully enforce the requirement of medical record documentation for diagnosis codes while making payments at the . . . rates” calculated through its published risk factors, because the “presence of erroneous diagnoses in the [Part A and B] claims data used to calibrate the [CMS-HCC] payment model” will cause the risk factors to systematically “understate the cost of treating various conditions.” RADV Rule, 88 Fed. Reg. at 6,655. These commenters argued that any sampling and extrapolation methodology for RADV audits must therefore “adjust payment rates (by raising them) or adjust documentation standards (by loosening them) to resolve the alleged incompatibility between the current rates and current documentation standards.” *Id.*

CMS declined to make such an adjustment in its audit methodologies, for two reasons. First, the agency concluded that “the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to [Medicare Advantage insurers]” in the first instance, “and not to the obligation to return improper payments for diagnosis codes . . . lacking medical record support.” *Id.* at 6,656. CMS noted that this statutory interpretation was “consistent with the D.C. Circuit’s decision” in *United* and explained that “[t]he RADV program enforces the longstanding medical record documentation . . . requirement” for diagnoses reported for payment, but does not reevaluate “the risk adjustment coefficients used to calculate risk scores, and thus risk-adjusted payments.” *Id.* at 6,658.

Second, CMS pointed to the statutory coding pattern adjustment, which is adjacent to the actuarial-equivalence provision and requires the agency to reduce payments to Medicare Advantage insurers by at least a specific amount. 42 U.S.C. 1395w-23(a)(1)(C)(ii)(III). The agency has made the statutory minimum reduction in every year that a reduction has been required. The agency concluded that because (1) “the Act requires CMS to reduce payments to [Medicare Advantage insurers] by at least a specific minimum percentage,” and (2) “CMS has, each year, implemented the minimum . . . reduction required by statute,” then (3) “the only reasonable interpretation of the Act is that CMS would pay [Medicare Advantage insurers] at those reduced rates, under the existing payment model, and enforce the longstanding documentation requirements through CMS’ audits,” without employing an FFS Adjuster that would offset the effect of this required minimum reduction in payments. RADV Rule, 88 Fed. Reg. at 6,657; *see id.* at 6,658. In other words, the statutorily mandated reduction in payments reflected Congress’s understanding that Medicare Advantage payment rates are too high, but an FFS Adjuster would be based on the opposite and inconsistent premise that those payment rates are too low.

CMS did not rest its “decision not to apply an FFS Adjuster” on “the empirical findings of [its] study,” which it acknowledged had “inherent limitations.” *Id.* at 6,659. But the agency nonetheless made clear that it did “not agree with those commenters who claim that our study or their counter-studies provide evidence that FFS errors systematically reduce payments to [Medicare Advantage insurers].” *Id.* CMS explained that (1) there were many fewer “diagnosis codes unsupported by medical records . . . in the Medicare [Part A and B] data . . . than some commenters have suggested”; (2) the Part A and B data are missing a “significant” number of “unreported diagnosis codes that have medical record support,” the absence of which would tend to “offset” the effect of unsupported diagnoses in the data, “to the extent that any such effects

exist”; (3) any such effects would also be “offset” by the presence of improper Part A and B expenditures, which should have been recovered or adjusted because they were based on unsupported diagnoses; and (4) the counter-studies submitted by commenters “employed widely differing methodologies and arrived at widely varying estimates for their FFS Adjuster,” which demonstrated “the complexity of the issues” involved in any attempt to calculate such an adjustment factor, and “the fact that any related study must rely on assumptions, estimates, and projections, and will, therefore, have inherent limitations.” *Id.* at 6,659–60.

F. Procedural Background

Humana Inc. and its Texas subsidiary brought this case several months after the RADV Rule was published. Their complaint asserts three claims. First, Humana alleges that the decision not to apply an FFS Adjuster in extrapolated RADV audits is unlawful, either because it rests on an impermissible statutory interpretation or because it is an arbitrary reversal of policy. Compl. ¶¶ 72–77. Second, the insurer asserts that the application of that decision to RADV audits for payment years 2018 through 2023 is impermissibly retroactive. *Id.* ¶¶ 78–87. Third, and finally, Humana alleges that the challenged rule is invalid on procedural grounds, because CMS did not offer adequate notice of the policies and rationales adopted in the RADV Rule. *Id.* ¶¶ 88–91. The government moved to dismiss or transfer venue, but that motion was denied.

LEGAL STANDARD

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In challenges to agency action under the Administrative Procedure Act (“APA”), “[s]ummary judgment is the proper mechanism for deciding, as a matter of law, whether an agency’s action is supported by the administrative record and consistent with the APA standard of

review.” *Am. Stewards of Liberty v. Dep’t. of Interior*, 370 F. Supp. 3d 711, 723 (W.D. Tex. 2019) (citation omitted); *see Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993) (“The entire case on review is a question of law, and only a question of law.”).

ARGUMENT

Medicare Advantage is a very large program, and quite profitable for the insurers that participate in it. Last year, the federal government paid Medicare Advantage insurers more than \$450 billion—nearly seven percent of the entire federal budget. *See supra* at 1 n.1. On average, those insurers received almost \$2,000 more in payments than they paid out in claims for each covered beneficiary—more than twice the difference between payments and claims for the group health insurance market, which Humana recently left to focus its business on Medicare Advantage and other government-funded programs.¹⁴ The government, for its part, pays substantially more for Medicare Advantage enrollees than it would spend if those same beneficiaries were enrolled in traditional Medicare—22 percent more, according to the most recent estimates of the Medicare Payment Advisory Commission (MedPAC).¹⁵ And CMS has estimated that, in recent years, the government has made more than \$10 billion in annual overpayments through the Medicare Advantage program. *See supra* at 1 n.2. The challenged rule is one part of the government’s ongoing effort to address the significant waste of tax dollars through overpayments.

¹⁴ *See* Jared Ortaliza, *Health Insurer Financial Performance in 2023*, KFF (July 2, 2024), <https://www.kff.org/medicare/issue-brief/health-insurer-financial-performance/>; Humana, *Press Release: Humana to Exit Employer Group Commercial Medical Products Business* (Feb. 23, 2023), <https://press.humana.com/news/news-details/2023/Humana-to-Exit-Employer-Group-Commercial-Medical-Products-Business> (explaining Humana’s “strategy to focus our health plan offerings primarily on Government-funded programs (Medicare, Medicaid and Military) and Specialty businesses”).

¹⁵ MedPAC Report to the Congress: Medicare Payment Policy at 358 (Mar. 2024), https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-3.pdf; *see* RADV Rule, 88 Fed. Reg. 6659 n. 41 (collecting studies).

Humana argues that the rule is contrary to law, arbitrarily adopted, procedurally invalid, and impermissibly retroactive. But its arguments are meritless, for the reasons set forth below, and the government is therefore entitled to summary judgment on all of the claims against it.

A. The government had the statutory authority to promulgate the RADV Rule.

RADV audits confirm the accuracy of diagnoses reported by Medicare Advantage insurers, and recover payments that were based on diagnoses not documented in the beneficiary's medical record. Under the challenged rule, CMS will use sampling and extrapolation to estimate and recover such overpayments, without first assessing the effect of those recoveries under the actuarial-equivalence provision of the Medicare statute, 42 U.S.C. § 1395w-23(a)(1)(C)(i). Humana brings a facial challenge to the government's statutory authority to do so. Brief in Support of Pls.' Mot. for Summ. J. at 22–36, ECF No. 44 (“MSJ”).

i. CMS satisfies the statute's actuarial-equivalence provision when it establishes payment rates, and that provision does not provide a defense against an insurer's obligation to return overpayments.

There is no question that payments based on diagnoses absent from a beneficiary's medical record are overpayments, because Medicare Advantage insurers may only claim payment on the basis of documented diagnoses. 42 C.F.R. § 422.310(d)(1); 45 C.F.R. § 162.1002(c)(2), (3). *See United*, 16 F.4th at 869 (“Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer.”); *United States ex rel. Swoben v. United Health Ins. Co.*, 848 F.3d 1161, 1176 (9th Cir. 2016) (noting that “CMS requires medical diagnosis codes to be supported by a medical record”). Medicare Advantage insurers must certify the “accuracy” of the diagnoses they submit. 42 C.F.R. § 422.504(l). And because insurers are “not entitled” to payments based on diagnoses that lack medical record

support, 42 U.S.C. § 1320a-7k(d)(4)(B), such payments are overpayments that insurers must return within sixty days of identifying them, *id.* § 1320a-7k(d)(2)(A). *See* 79 Fed. Reg. at 29,921–22.

In the *United* litigation, another Medicare Advantage insurer invoked the actuarial-equivalence provision “as a defense against its obligation to reimburse CMS for known overpayments.” *Id.* at 886. The insurer argued that the provision required CMS to make a “prior determination” that recovering a particular overpayment would not upset the overall accuracy of the payment model. *Id.* at 870. The D.C. Circuit held that the actuarial-equivalence provision only applies in the “context of CMS’s calculation and disbursement of monthly payments in the first instance,” and is not “broadly applicable” throughout the Medicare Advantage program. *Id.* at 885. When CMS publishes the risk factors that it uses to vary payments to Medicare Advantage insurers—when it determines that an insurer will be paid 41.2% of its base rate for each beneficiary diagnosed with rheumatoid arthritis, and so forth—the agency concludes that payment at those published rates for those documented diagnoses will satisfy the statutory command that it “adjust the . . . amount” of each payment to account for the “health status” of the covered beneficiary, “so as to ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Any insurer that believes the published risk factors do not “ensure actuarial equivalence” is free to challenge them. But no insurer ever has. In *United*, the D.C. Circuit held that the insurer’s failure to “challenge[] the values CMS assigned to the risk factors it identified or the level of the capitation payments resulting from CMS’s risk adjustment model” was “fatal to [its] claim.” 16 F.4th at 871. Because the insurer had “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,” it could not “use actuarial equivalence to litigate belated objections to the risk-adjustment model or the level of its monthly

payments” when CMS attempted to enforce the requirement that diagnoses submitted for payment be supported by medical record documentation. *Id.* at 887. In the absence of a timely challenge to the Medicare Advantage risk adjustment model or payment rates, CMS did not have to “remak[e]” or “re-defend[]” its “actuarial-equivalence calculation” before recovering overpayments. *Id.* at 885.

In the challenged rule, CMS responded similarly to arguments that it had to reassess its actuarial-equivalence calculation before it could use sampling and extrapolation to recoup overpayments through RADV audits. The agency explained that “[t]he RADV program enforces the longstanding medical record documentation . . . requirement” for diagnoses reported for payment, but does not reevaluate “the risk adjustment coefficients used to calculate risk scores, and thus risk-adjusted payments.” RADV Rule, 88 Fed. Reg. at 6,658. And the agency concluded that the RADV program was not required to include such a reevaluation of the published risk factors, because “the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to [Medicare Advantage insurers]” in the first instance, “and not to the obligation to return improper payments for diagnosis codes . . . lacking medical record support,” which RADV audits enforce. *Id.* at 6,656. In other words, any payment that depends on an undocumented diagnosis is an overpayment, and the government’s ability to recover such overpayments is not limited by allegations of error in the payment rates that apply throughout the Medicare Advantage program. If insurers believe that errors in Part A and B data cause the payment rates (or more precisely, the risk factors) for various diagnoses to be too low, then their remedy is to challenge those payment rates directly, and not to retain payments based on undocumented diagnoses.

- ii. **Humana’s facial challenge to the government’s statutory authority fails, because it only asserts that “population-level” audit recoveries are subject to an actuarial-equivalence analysis, and many extrapolated RADV audits do not seek such recoveries.**

Humana now challenges the government’s conclusion that the RADV program was not required to include a reevaluation of the published risk factors. The insurer apparently believes that *United* was wrongly decided, *see* MSJ at 29, and that the actuarial-equivalence provision provides a valid “defense against [an insurer’s] obligation to reimburse CMS” for individual overpayments identified by the insurer, 16 F. 4th at 886. But Humana has waived that argument by choosing not to press it here.

Instead, Humana contends that extrapolated RADV audit recoveries are distinguishable from the obligation to return known overpayments. On Humana’s account, the difference arises whenever an extrapolated audit seeks to make “population-level” recoveries. MSJ at 23–24. Although Humana never defines that phrase, it seems to mean audits that, in the words of the *United* decision, “would effectively eliminate—and require repayment for—all unsupported [diagnosis] codes in a Medicare Advantage insurer’s data,” 16 F.4th at 892. Humana says that, under the RADV Rule, CMS “will statistically extrapolate the results of audit samples across an entire Medicare Advantage contract and thereby reduce contract-wide payments to [Medicare Advantage insurers].” MSJ at 1. But it offers no support for that claim, and for good reason: the Rule expressly declines to “adopt[] any particular statistical sampling methodology,” RADV Rule, 88 Fed. Reg. at 6,654, and instead reserves the agency’s discretion to “rely on any statistically valid method for sampling and extrapolation that it determines to be well-suited to a particular audit,” *id.* at 6651.

The challenged rule does not commit CMS to seek “population-level” recoveries in its extrapolated audits. To the contrary, the rulemaking expressly contemplated that the government

might identify a group of beneficiaries on a given contract with shared characteristics (which it called a “sub-cohort”), audit the diagnoses of interest for a sample of that group, and then extrapolate the results of its audit *to the rest of the group* rather than the contract population as a whole. *See* NPRM, 83 Fed. Reg. at 55,039. And that is precisely what CMS and OIG are doing in their first audits under the RADV Rule.

CMS has chosen 60 Medicare Advantage contracts to audit for payment year 2018. For each audit, the agency will identify a group of beneficiaries on the contract to be the subject of the audit (the “group of interest”). *Dupee Decl.* ¶¶ 9–10, 13–14 (GA 652–54). When the group of interest is smaller than 35 beneficiaries—as it is on six of the audited contracts—CMS will not use sampling and extrapolation to calculate overpayments. Instead, the agency will review the medical records of each beneficiary in the group of interest and recoup any overpayments that it specifically identifies, just as it has done in previous RADV audits. *Id.* ¶ 19 (GA 655).

For the other 54 audits, CMS will select a sample of 35 beneficiaries from the group of interest, review their medical records, and then extrapolate the results of that review to estimate overpayments for the entire group. *Id.* ¶¶ 11, 15 (GA 653–54). The smallest group of interest for an extrapolated audit will contain 43 beneficiaries: in that audit, CMS will review the medical records of 35 beneficiaries, and then extrapolate an overpayment amount for the group of 43. *Id.* ¶ 20 (GA 655). Five groups of interest will be smaller than 100 beneficiaries; more than one quarter will be smaller than 400 beneficiaries. *Id.* ¶ 21 (GA 656). And as these absolute numbers suggest, the groups of interest for these audits will usually be a small fraction of the contract’s beneficiary population. Three audits will extrapolate an overpayment amount for less than 2% of the contract’s beneficiaries; nine will extrapolate out to less than 5% of the beneficiary population; and twenty-three will extrapolate out to less than 10% of the beneficiaries on the audited contract.

Id. Thirty-nine out of fifty-four extrapolated audits will calculate an overpayment amount for less than 20% of the beneficiary population; all but two will extrapolate out to less than 30% of the beneficiaries on the audited contract. *Id.* ¶ 22 (GA 656). And all of the audits will calculate extrapolated overpayments for less than 45% of the beneficiary population. *Id.*

The Medicare Advantage audits being conducted by OIG are similarly targeted. OIG recently published the results of a payment year 2018 audit of a Humana subsidiary, which exemplifies its current approach. HHS OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Humana Health Plan, Inc. (Contract H2649) Submitted to CMS (Sept. 2024), <https://oig.hhs.gov/documents/audit/10008/A-02-22-01001.pdf>. Humana covered approximately 250,000 beneficiaries on the audited contract, and received payments of approximately \$2.5 billion per year. *Id.* at 5. For the audit, OIG identified eight beneficiary groups of interest; for each group, Humana had reported a diagnosis indicating an acute medical event, but the beneficiary had not received the medical care that would usually accompany such a diagnosis. *Id.* at 4–5. Seven of the eight groups of interest were smaller than 600 beneficiaries, and the other group was smaller than 1,500. *Id.* at 41. OIG chose a random sample of approximately fifteen beneficiaries for each of the eight groups of interest, reviewed only the single diagnosis of interest that characterized each group for each sampled beneficiary, and then calculated the extrapolated overpayments associated with that particular diagnosis for the entire group of interest. The total of the extrapolated overpayments calculated for the eight groups of interest was approximately \$6.5 million for payment year 2018—less than three-tenths of one percent of the payments initially made on that contract. *Id.* at 7.

Humana argues that the RADV Rule’s interpretation of the actuarial-equivalence provision is unlawful as applied to audits that make “population-level” recoveries. But none of the

extrapolated audits currently being conducted by CMS or OIG will make “population-level” recoveries on any plausible definition of that term, and neither entity has said that it will seek such recoveries in the future. At most, then, Humana’s argument seeks to prove that the RADV Rule allows for some potentially unlawful applications.

But even if that were true, it would not be enough for Humana to prevail on its facial challenge. In the Fifth Circuit, facial challenges are evaluated under the test first articulated in *United States v. Salerno*: they can succeed only if there is “no set of circumstances” in which the challenged rule could be lawfully applied, 481 U.S. 739, 745 (1987). *See Associated Builders*, 826 F.3d at 220 (“Because [plaintiffs] bring a facial challenge, they must establish that no set of circumstances exists under which the Rule would be valid.”) (cleaned up); *accord Scherer v. U.S. Forest Serv.*, 653 F.3d 1241, 1243 (10th Cir. 2011) (“To prevail in this and any facial challenge to an agency’s regulation, the plaintiffs must show that there is ‘no set of circumstances’ in which the challenged regulation might be applied consistent with the agency’s statutory authority.”); *Sherley v. Sebelius*, 644 F.3d 388, 397 (D.C. Cir. 2011) (applying the “no set of circumstances” test to a facial statutory challenge, and noting that “it is not enough for the plaintiffs to show [that the challenged agency action] could be applied unlawfully”) (citation omitted).

Under the *Salerno* “no set of circumstances” test, as the Supreme Court has recently emphasized, “the Government need only demonstrate that” the RADV Rule is lawful “in some of its applications.” *United States v. Rahimi*, 144 S. Ct. 1889, 1898 (2024). Even if Humana was correct to argue that extrapolated RADV audits seeking “population-level” recoveries require a reassessment of actuarial equivalence, the RADV Rule would still be lawful as applied to audits that do not seek “population-level” recoveries, such as those currently being conducted by CMS and OIG. That is enough for the Court to resolve Humana’s facial statutory challenge in favor of

the government, and proceed to its arbitrary and capricious challenge. None of the pending Medicare Advantage audits seek “population-level” recoveries, and if the government were to conduct such audits in the future, they could be challenged on an as-applied basis.

iii. Humana’s facial statutory challenge also fails as applied to RADV audits seeking “population-level” recoveries.

Humana’s statutory challenge also fails as applied to any future RADV audits that may seek “population-level” recoveries, because (1) the actuarial-equivalence provision governs the establishment of payment rates, not the recovery of overpayments, and (2) an adjacent statutory provision provides further support for the government’s interpretation of the actuarial-equivalence provision, as well as an independent basis for affirming the RADV Rule’s decision not to include an FFS Adjuster in any sampling and extrapolation methodology.

a. Actuarial Equivalence

Humana contends that the Medicare statute limits the government’s ability to recover overpayments through RADV audits, by requiring the government to first assess the effect of any “population-level” recoveries under the actuarial-equivalence provision of the Medicare statute, 42 U.S.C. § 1395w-23(a)(1)(C)(i). Humana’s interpretation is wrong, because the actuarial-equivalence provision is exclusively concerned with the establishment of payment rates, and does not limit the recovery of overpayments.

The Medicare statute provides that “the Secretary shall make monthly payments . . . in advance to each [Medicare Advantage insurer] . . . in an amount determined as follows” 42 U.S.C. § 1395w-23(a)(1)(A). The next subsection describes the establishment of each insurer’s base payment rate. *Id.* § 1395w-23(a)(1)(B); *see supra* at 10–11. And then the following subsection says that:

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

Id. § 1395w-23(a)(1)(C)(i) (emphasis added).

Reading the statute as a whole, it is clear that (in the words of the RADV Rule), “the actuarial equivalence provision . . . applies only to how CMS risk adjusts the payments it makes to [Medicare Advantage insurers], and not to the obligation to return improper payments for diagnosis codes . . . lacking medical record support.” 88 Fed. Reg. at 6,656. To begin with, § 1395w-23 describes how the “amount” of the “monthly payments” made “in advance” to Medicare Advantage organizations is “determined.” 42 U.S.C. § 1395w-23(a)(1)(A). The Secretary is then required to “adjust” the amount of those payments “for health status under paragraph (3), so as to ensure actuarial equivalence.” *Id.* § 1395w-23(a)(1)(C)(i). Paragraph (3) governs the “Establishment of risk adjustment factors,” *id.* § 1395w-23(a)(3), which are the means by which the Secretary “makes adjustments to capitation rates for health status,” *id.* § 1395w-23(a)(3)(C)(ii). The Secretary must annually “determine” and “announce” the “[a]djustment factors” that are “to be used in adjusting such rates [*i.e.*, capitation rates] under subsection (a)(1)(C) for payments for months in such year.” *Id.* § 1395w-23(b)(1)(B)(i)(II).

In sum, the statute itself explains that “adjusting [capitation] rates under subsection (a)(1)(C),” *id.*, is accomplished through the “Establishment of risk adjustment factors,” *id.* § 1395w-23(a)(3), which “make[] adjustments to capitation rates for health status,” *id.* § 1395w-23(a)(3)(C)(ii). When subsection (a)(1)(C) instructs the government to “adjust the payment amount . . . for health status under paragraph (3), so as to ensure actuarial equivalence,” *id.*

§ 1395w-23(a)(1)(C)(i), it therefore means to require nothing more than the establishment of such risk factors. *See United*, 16 F.4th at 886 (“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.”).

Humana’s competing interpretation is unpersuasive. Humana argues that, by recovering overpayments, “extrapolated RADV audits ‘adjust the payment amount’ to [a Medicare Advantage insurer] based on the ‘health status’” of the beneficiaries being insured. MSJ at 23 (citation omitted). But the statute does not make a free-floating reference to all adjustments “for health status.” Instead, it specifically applies the actuarial-equivalence provision to adjustments “for health status under paragraph (3),” 42 U.S.C. § 1395w-23(a)(1)(C)(i)—that is, payment adjustments made through the “Establishment of risk adjustment factors,” *id.* § 1395w-23(a)(3). Because RADV audits do not involve the establishment of risk adjustment factors, audit recoveries do not constitute a payment “adjustment for health status under paragraph (3),” and are not subject to the actuarial-equivalence provision that immediately follows that phrase. *See RADV Rule*, 88 Fed. Reg. at 6,658 (noting that RADV audits do not reevaluate “the risk adjustment coefficients used to calculate risk scores, and thus risk-adjusted payments”).¹⁶

Humana’s argument from statutory and regulatory structure ignores this web of cross-references, and insists that RADV audits should not be permitted to “negate . . . actuarial equivalence” by recovering too many overpayments. MSJ at 27. But the insurer’s suggestion that

¹⁶ The government’s argument does not depend on the “timing” of a payment adjustment, as Humana suggests, MSJ at 24, but rather on whether the adjustment is made through the establishment of risk factors as described in paragraph (3). A “temporal limitation” would not be entirely “atextual,” *id.* at 25, however: the statute concerns itself with how the “amount” of a “monthly payment[]” made “in advance” should be “determined.” 42 U.S.C. § 1395w-23(a)(1)(A) (emphasis added).

the actuarial-equivalence provision applies differently to RADV audits seeking “population-level” recoveries finds no support in the statutory text. If the population-level recovery of overpayments is an “adjustment for health status” requiring a reevaluation of actuarial equivalence under § 1395w-23(a)(1)(C)(i), then so too is the recovery of individual overpayments, and indeed the making of individual payments to insurers on the basis of the diagnoses they report, all of which make the insurer’s payment conform more closely to the risk associated with the health status of one or more covered beneficiaries. *See* MSJ at 23–24. A payment system that required such constant reassessment of actuarial equivalence could not function.

Nothing in the text or statutory structure of the actuarial-equivalence provision supports Humana’s interpretation, nor does the D.C. Circuit’s *United* opinion. Although the D.C. Circuit was careful not to extend its holding beyond the recovery of known overpayments, its conclusion that “the text of section 1395w-23(a)(1)(C)(i) limits the scope of the actuarial-equivalence requirement,” so that “the actuarial-equivalence requirement is not broadly applicable” throughout the Medicare Advantage program, “but instead limited to the . . . context of CMS’s calculation and disbursement of monthly payments in the first instance,” *United*, 16 F.4th at 884–85, did not rest on any distinction between known and extrapolated overpayments, or individual and “population-level” recoveries.

Even if the recovery of overpayments through RADV audits would leave Medicare Advantage insurers underpaid (which CMS strongly disputes, *see supra* at 1, 22–24 and *infra* at 41–43) that does not justify stretching the actuarial-equivalence provision to prevent the government from recovering payment for unsupported diagnoses. Humana’s theory is that errors in Part A and B data cause the risk factors for diagnoses to be too low, so that it will be underpaid

if it cannot collect payment for unsupported diagnoses.¹⁷ If that were true, the insurer’s remedy would be a challenge to the risk adjustment factors that established its payment rates on the ground that they violate actuarial equivalence. The government agrees that the actuarial equivalence of the Medicare Advantage payment model is central to the operation of the statute, but it does not follow that the statute seeks to achieve actuarial equivalence by limiting the government’s ability to recover payments that should never have been made in the first place. The actuarial-equivalence provision simply does not limit the government’s ability to recoup payments based on the reporting of diagnoses that lack medical record support.

And finally, even if the actuarial-equivalence provision could be read as Humana suggests, it would only require that an insurer’s payments remain sufficiently accurate after a “population-level” audit. Humana has not shown that “population-level” audit recoveries would necessarily produce inaccurate payments, as explained more fully below, and it has explicitly waived any argument that the Court should reach that conclusion. MSJ at 3 (“Humana does not ask the Court to” conclude “that the Final Rule violates actuarial equivalence.”); *see infra* at 41–43.

b. Coding Pattern Adjustment.

An adjacent statutory provision provides further support for the government’s interpretation, as well as an independent basis for affirming the RADV Rule’s decision not to include an FFS Adjuster in any sampling and extrapolation methodology. As discussed above, “actuarial equivalence” in payments to insurers means the calculation of the expected cost of covering a given beneficiary through the establishment of payment rates. To claim that Medicare Advantage payment rates violate actuarial equivalence is thus to say that they fall short of the

¹⁷ This is illustrated by the example Humana presents in its motion, arguing that alleged errors in the initial payment rates are causing it to receive “depress[ed]” payments for other enrollees that do have supported codes. MSJ at 14–16.

standard of accuracy demanded by Congress in the Medicare statute. But Congress itself has evaluated the accuracy of the payments made to Medicare Advantage insurers under the CMS-HCC model, and has twice enacted its evaluation into law. Contrary to some insurers' suggestion that Medicare Advantage payment rates are too low given the medical record documentation standard for diagnosis reporting (which has been in place for the life of the program), Congress found that Medicare Advantage payment rates were too high, and mandated their reduction.

In 2006, "to ensure payment accuracy," Congress required CMS to evaluate any "differences in coding patterns between Medicare Advantage plans and providers under part A and part B," and to incorporate "the results of such analysis . . . into the risk scores . . . for 2008, 2009, and 2010." Pub. L. No. 109-171, § 5301(b)(2), 120 Stat. 4, 51, (codified at 42 U.S.C. § 1395w-23(a)(1)(C)(i) (2006)). CMS did not make any adjustment for 2008 or 2009, but for 2010 it announced a reduction of risk scores by 3.41%.¹⁸ In 2010, Congress extended CMS's authority to make this adjustment in its own best judgment until 2013. Pub. L. No. 111-152, tit. I, subtit. B, § 1102(e), 124 Stat. 1029, 1046 (amending 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(II)).

But for 2014 and each subsequent year, Congress made its own judgment. Congress determined that mandatory reductions in risk scores—which produce mandatory reductions in payments to Medicare Advantage insurers—were necessary, beginning at 4.71% in 2014 and rising to 5.7% in 2019. *Id.* (adding 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III)). CMS retained its authority to apply a larger reduction as necessary, but it was no longer free to determine that a smaller reduction (or no reduction at all) was appropriate. Several years later, Congress decided that these mandatory payment reductions were not steep enough to ensure payment accuracy. Instead, it

¹⁸ CMS, Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates at 19 (Apr. 6, 2009), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2010.pdf>.

required CMS to make a reduction of at least 4.91% in 2014, rising to at least 5.9% by 2019. Pub. L. No. 112-240, tit. VI, subtit. C, § 639, 126 Stat. 2313, 2357 (amending 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III)). That mandatory payment reduction remains in effect today.

In 2010, and then again in 2013, Congress thus determined that the payments calculated by the CMS-HCC model were too high, and required CMS to lower them by at least a fixed percentage. CMS has made the minimum reduction allowed by statute every year since 2014. In the RADV Rule, CMS concluded that because (1) “the Act requires CMS to reduce payments to [Medicare Advantage insurers] by at least a specific minimum percentage,” and (2) “CMS has, each year, implemented the minimum . . . reduction required by statute,” then (3) “the only reasonable interpretation of the Act is that CMS would pay [Medicare Advantage insurers] at those reduced rates, under the existing payment model, and enforce the longstanding documentation requirements through CMS’ audits,” without employing an FFS Adjuster that would offset the effect of this required minimum reduction in payments. 88 Fed. Reg. at 6,657; *see id.* at 6,658. In other words, the statutorily mandated reduction in payments reflected Congress’s understanding that Medicare Advantage payment rates are too high, but an FFS Adjuster would be based on the opposite and inconsistent premise that those payment rates are too low.

Humana disputes that conclusion, and points to the text of this coding adjustment provision, which currently begins:

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

42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I). As an initial matter, this provision’s reference to “the adjustment under clause (i) for health status to payment amounts” reinforces the government’s

interpretation of “clause (i),” which contains the actuarial-equivalence provision, as applying only to the establishment of risk adjustment factors. *See id.* § 1395w-23(a)(1)(C)(i). Humana’s argument that overpayment recoveries constitute an “adjustment for health status” within the meaning of clause (i)—*i.e.*, § 1395w-23(a)(1)(C)(i)—cannot be squared with the instruction in § 1395w-23(a)(1)(C)(ii)(I) to make a coding adjustment “[i]n applying the adjustment under clause (i) for health status to payment amounts.” The coding adjustment reduces risk scores, and does not reduce audit recoveries, because the risk scores (and the risk factors that comprise them) make an “adjustment under clause (i) for health status to payment amounts,” and audit recoveries do not.

But even if the actuarial-equivalence provision could generally be read to require the government to assess the effect of any “population-level” audit recoveries on payment accuracy, that obligation is limited by Congress’s own determination in § 1395w-23(a)(1)(C)(ii)(III) that Medicare Advantage payments were inaccurately high and had to be reduced by at least a fixed percentage. It would be inconsistent with that congressional determination for CMS to make an offsetting adjustment that would wholly or partially negate the mandatory payment reduction.

In resisting that conclusion, Humana first points to an agency statement from April 2010. *See* MSJ at 33. But that statement did not address the mandatory payment reduction, which had become law less than a week before and would not take effect for several years. Humana then suggests that the RADV Rule’s interpretation of this provision is impermissibly “conclusory,” *id.* at 34, but the agency’s reasoning was adequately laid out in the preamble, *see* RADV Rule, 88 Fed. Reg. at 6,657–58.

The coding adjustment described in § 1395w-23(a)(1)(C)(ii)(I) confirms the government’s interpretation of the actuarial-equivalence provision in the preceding statutory subsection, and the mandatory payment reductions established in § 1395w-23(a)(1)(C)(ii)(III) represent a holistic

congressional assessment of the accuracy of Medicare Advantage payments. As the RADV Rule correctly concluded, “the only reasonable interpretation” of the statute is that Congress expected the government to pay Medicare Advantage insurers “at those reduced rates, under the existing payment model, and enforce the longstanding documentation requirements through CMS’ audits,” without introducing an offsetting adjustment. 88 Fed. Reg. at 6,657.

B. The RADV Rule was not arbitrarily adopted.

Humana also raises an arbitrary and capricious challenge to the RADV Rule. “Judicial review under [the arbitrary and capricious] standard is deferential, and a court may not substitute its own policy judgment for that of the agency.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). In evaluating whether an agency action is arbitrary and capricious, “[a] court is not to ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives.” *Fed. Energy Regul. Comm’n v. Elec. Power Supply Ass’n*, 577 U.S. 260, 292 (2016). Rather, the Court must ensure “that the agency has acted within a zone of reasonableness.” *Prometheus Radio*, 592 U.S. at 423. Plaintiffs have “the burden of proving that the [Departments’] determination was arbitrary and capricious.” *Medina Cnty. Env’t Action Ass’n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). But Humana cannot do so.

To begin with, even if valid, Humana’s arbitrary-and-capricious argument against the decision not to apply an FFS Adjuster to extrapolated audits seeking “population-level” recoveries would not support a facial challenge to the RADV Rule, which does not commit the government to seek such recoveries. *See supra* at 28–32. And the argument is not valid.

Humana argues that, even if the government has correctly interpreted the actuarial-equivalence provision to be exclusively concerned with the establishment of payment rates, and not the recovery of overpayments, it “did not meaningfully engage with the possibility that

applying an FFS Adjuster” to reduce population-level RADV audit recoveries, “even if not required as a statutory matter,” “would constitute sound policy promoting the continued health of the Medicare Advantage program.” MSJ at 37. Not so. The government responded directly to comments in that vein: if the presence of unsupported diagnoses in the Part A and B data is systematically lowering the Medicare Advantage risk factors in a way that causes insurers to be underpaid for the documented diagnoses of their beneficiaries, then the proper solution is to correct the payment rates that apply throughout the Medicare Advantage program, and not to make a payment adjustment that would only apply to audited contracts. *See* RADV Rule, 88 Fed. Reg at 6,657 (explaining that “even if systematic payment error exists, it would be inequitable to correct such errors in the payments made only to audited plans”); *id.* at 6,659 (“An adjustment factor to account for hypothetical systematic payment differences would not be appropriately applied in the RADV context, even if such systematic differences existed.”).

CMS also concluded that, if there is any adjustment to be made, it should be made through payment rates rather than documentation standards. This choice was reasonable on its own terms, and all the more so in light of the substantial risk of improper payments that many observers have noted in the Medicare Advantage program. *See id.* at 6,660. Studies have consistently found significant overpayments to Medicare Advantage insurers. CMS estimates that the government makes more than \$10 billion in overpayments annually through the Medicare Advantage program. *See supra* at 1 n.2. These findings support the government’s conclusion that the health of the Medicare Advantage program called for more robust efforts to recover these overpayments, and not for imposing limitations on those recoveries even after an audit finds payments due to unsupported diagnoses.

The core argument made by insurers in favor of an FFS Adjuster is that “because erroneous diagnoses in the FFS claims data are used to calibrate the [Medicare Advantage] payment model, CMS must either adjust payment rates (by raising them) or adjust documentation standards (by loosening them) to resolve the alleged incompatibility between the payment rates and documentation standards.” *Id.* at 6,646. But an audit-specific FFS Adjuster is essentially a conceptual error, because it would correct a purportedly program-wide payment issue through an adjustment made only to the payments of audited contracts.

Humana also questions the government’s insistence that the diagnoses reported for payment by Medicare Advantage insurers be supported by medical record documentation. MSJ at 38 (“The agency appears to have implicitly concluded that its interest in enforcing its medical-record requirement outweighs the interests of [Medicare Advantage insurers] and the public in actuarially sound administration of the Medicare Advantage program.”). The actuarially sound administration of the program is served by the recovery of overpayments, and “CMS has always required proper medical record documentation in order for any reported diagnosis code or claim to be valid.” RADV Rule, 88 Fed. Reg at 6,658; *id.* at 6,646 (“A diagnosis code that is not documented in a patient’s medical record is not a valid basis for CMS risk adjustment payments” to a Medicare Advantage insurer.); *see United*, 16 F.4th at 869 (“Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer.”). “That is the consistent policy throughout the Medicare program,” including Parts A and B. RADV Rule, 88 Fed. Reg. at 6,658.

Finally, Humana asserts that “CMS has been well aware, for many years, of . . . empirical and actuarial problems” in the Medicare Advantage program, MSJ at 37, and disparages the agency’s response to such problems as a “cursory statement of disagreement,” *id.* at 38. It was

not. Although CMS did not rest its decision on its study assessing those empirical issues, the agency said that it did not believe that commenters had offered “evidence” that “FFS errors systematically reduce payments” to Medicare Advantage insurers. RADV Rule, 88 Fed. Reg. at 6,659. In support of its view, the agency reasonably noted that (a) the rate of unsupported diagnoses in Parts A and B appeared to be relatively low; (b) supported diagnoses that were missing from the Part A and B data would tend to offset the effect of any unsupported diagnoses present in the data; (c) any such effects would also be “offset” by the presence of improper Part A and B expenditures, which should have been recovered or adjusted because they were based on unsupported diagnoses¹⁹; and (d) commenters’ estimates of payment error varied wildly. *Id.* at 6,659–60.

Presented with similar arguments to those put forward by commenters (and by Humana here), the *United* court similarly concluded that the insurer before it had “identifie[d] no reason why the traditional Medicare data that goes into the risk-adjustment model would suffer systematically from unsupported codes . . . , *i.e.*, codes lacking substantiation in medical records,” nor had it “established . . . that the unsupported codes it posits in traditional Medicare would both be materially analogous to those the Overpayment Rule targets, and would cause [it] to be underpaid.” 16 F.4th at 888; *see id.* at 890 (explaining that the insurer had “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”); *see also U.S. ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1065–67 (N.D. Cal. 2020) (finding similar arguments unpersuasive). But unlike the insurer who brought the *United* case, Humana has chosen not to

¹⁹ The purpose of the “statistically inexplicable” adjustment with which Humana takes issue, *see* MSJ at 18, was to account for this offsetting effect. RADV Rule, 88 Fed. Reg. at 6,659 n.42.

argue that the absence of an FFS Adjuster in extrapolated RADV audits necessarily “violates actuarial equivalence,” and it “does not ask the Court” to reach that conclusion. MSJ at 3. Humana therefore cannot show that the government’s conclusion to the contrary—that commenters had not shown that “FFS errors systematically reduce payments” to Medicare Advantage insurers, RADV Rule, 88 Fed. Reg. at 6,659—was arbitrary and capricious.

The agency’s decision not to make an audit-specific payment adjustment in response to claims of program-wide payment error was reasonable, and its change in policy from 2012 was adequately explained: CMS decided that it had erred in accepting an audit-specific FFS Adjuster in its earlier guidance document, and therefore reversed course. That reversal was the product of reasoned decision-making (and also more modest than Humana suggests, *see infra* at 47).

C. The RADV Rule was a logical outgrowth of the notice of proposed rulemaking and subsequent request for comment.

Humana next contends that the RADV Rule was adopted without adequate notice and opportunity for comment. The Administrative Procedure Act only requires that a notice of proposed rulemaking “adequately frame the subjects for discussion such that the affected party should have anticipated the agency’s final course in light of the initial notice.” *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021) (citation omitted). The Fifth Circuit has discussed this requirement in terms of “fair notice” of the possibility of the final rule. *Tex. Ass’n of Mfrs. v. U.S. Consumer Prod. Safety Comm’n*, 989 F.3d 368, 381 (5th Cir. 2021). And it has said that “[t]he agency’s rationale for the rule must be made clear and subjected to public comment.” *Id.* at 382.

The RADV Rule easily meets that test. The notice of proposed rulemaking offered two rationales for its proposal not to include an FFS Adjuster in any sampling and extrapolation methodology: (1) an empirical analysis, and (2) the proposition that “a RADV-specific payment

adjustment” would not be an “appropriate” response to “systematic payment error,” because “RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation.” NPRM, 83 Fed. Reg. at 55,041; *see id.* (suggesting that “it would be inequitable to correct any systematic errors in the payments made to audited plans only”). And then, while the comment period was still open, CMS sought “comment on whether 42 U.S.C. 1395w-23—and in particular clause (a)(1)(C),” which contains both the actuarial-equivalence provision and the mandatory coding adjustment—“mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.” 84 Fed. Reg. at 30,983.

CMS then adopted its second proposed rationale as a basis for the final rule, and pointed to 42 U.S.C. § 1395w-23(a)(1)(C) in support of its decision. *See* RADV Rule, 88 Fed. Reg. at 6,660 (discussing the agency’s “conclusion that, even if systematic payment error exists, an adjustment factor would not be appropriately applied in the RADV context”). Because the agency’s “rationale for the rule” was “made clear and subjected to public comment,” and the agency “ma[d]e clear it was inviting comments on” the applicability of the statutory provision that it relied on in support of its decision, it easily satisfied its notice-and-comment obligations. *Tex. Ass’n of Mfrs.*, 989 F.3d at 382–83.

Moreover, even if it had not done so, any procedural error was harmless. Under the APA, plaintiffs “must demonstrate that the agency’s violation” has “resulted in ‘prejudice.’” *Am. Coke & Coal Chems. Inst. v. EPA*, 452 F.3d 930, 939 (D.C. Cir. 2006) (quoting 5 U.S.C. § 706(2)). Where, as here, the agency has conducted notice and comment, plaintiffs claiming that notice was inadequate must show that “had proper notice been provided, they would have submitted additional, different comments that could have invalidated the [agency’s] rationale.” *City of*

Waukesha v. EPA, 320 F.3d 228, 246 (D.C. Cir. 2003). But Humana fails to identify any specific comment it was allegedly prevented from submitting, and freely acknowledges that other commenters understood CMS to be seeking comment on the applicability of the actuarial-equivalence provision to extrapolated RADV audits. *See* MSJ at 41; *e.g.*, Comment of America’s Health Insurance Plans (AHIP) at 15–16 (Aug. 27, 2019) (GA 29–30) (responding to CMS’s June 2019 call for comments on 42 U.S.C. § 1395w-23). And there is no “likelihood that the result would have been different” if Humana had submitted additional comments objecting to the RADV Rule’s interpretation of the actuarial-equivalence provision, because that interpretation is correct as a matter of law for the reasons explained above. *Shinseki v. Sanders*, 556 U.S. 396, 411 (2009). Humana’s procedural challenge fails for this reason, as well.

D. The RADV Rule is not retroactive, much less impermissibly so.

Finally, Humana argues that the RADV Rule is impermissibly retroactive as applied to the six payment years from 2018 through 2023. But the rule does not “attach[] new legal consequences to events completed” in those payment years. *Germain v. U.S. Bank Nat’l Ass’n*, 920 F.3d 269, 275 (5th Cir. 2019) (citation omitted). In each of those years, Medicare Advantage insurers could only claim payment for diagnoses supported by the medical records of their beneficiaries, and any payments based on diagnoses unsupported by a beneficiary’s medical record were overpayments. *See supra* at 7–8. In each of those years, insurers were subject to medical record audits of the diagnoses they submitted for payment, and understood that they would be required to return any payments based on unsupported diagnoses. *See* RADV Rule, 88 Fed. Reg. at 6,653 (explaining that Medicare Advantage insurers “have never been entitled to receive or retain payments associated with [diagnoses] that cannot be validated by medical records”). And in each of those years, statistical sampling and extrapolation was a recognized means of calculating overpayments

in the Medicare program. *See Lahey Clinic Hosp.*, 399 F.3d at 18 n.19; *Ratanasen*, 11 F.3d at 1469–71. That is why CMS expressly denied that its rule would have retroactive effect, notwithstanding Humana’s suggestion to the contrary. RADV Rule, 88 Fed. Reg. at 6,653; *see* MSJ at 43.

Humana argues that “[b]efore the Final Rule, the agency’s policy was that any extrapolated RADV audit affecting Humana’s existing Medicare Advantage contracts would incorporate an FFS Adjuster.” MSJ at 44. But the 2012 guidance document to which Humana points says only that it “will be applied to the next round of RADV . . . audits, which will be conducted” under the particular sampling and extrapolation methodology described in that document. GA 94. CMS did not make a broad representation that “any extrapolated RADV audit . . . would incorporate an FFS Adjuster,” as Humana suggests, but only said that audits conducted according to one broad sampling and extrapolation methodology would do so.²⁰

CMS never took a position on whether it would apply an FFS Adjuster to RADV audits using a significantly more modest form of sampling and extrapolation, such as those now being conducted for payment year 2018, which do not “insist[] on perfect medical-record documentation in audited contracts” under any reasonable interpretation, *id.* at 45. The agency’s decision not to use an FFS Adjuster for extrapolated audits of payment years 2018 through 2023 therefore was not retroactive—and certainly not as applied to audits using a less powerful sampling and extrapolation methodology than the one in which CMS originally said that it would make such an adjustment.

²⁰ MSJ at 44. As discussed above, the methodology laid out in the 2012 guidance document aimed to estimate a much larger fraction of potential overpayments than the extrapolation methodologies that are currently in use, *see supra* at 17–18, 29–30; CMS has never attempted to recover extrapolated overpayments under the 2012 methodology, and may never do so.

And even if the RADV Rule were retroactive, that retroactive application would be authorized by 42 U.S.C. § 1395hh(e)(1)(A). Retroactive application of a Medicare regulation is permitted when it “is necessary to comply with statutory requirements,” *id.*, and Congress has instructed CMS to “conduct recovery audits . . . in a manner designed to ensure the greatest financial benefit to the Federal Government,” 31 U.S.C. § 3352(i)(1)(A)–(B). *See* RADV Rule, 88 Fed. Reg. at 6,653 (explaining that CMS has “a statutory mandate . . . to reduce improper payments”). Retroactive application is also authorized when the “failure to apply” a regulation “retroactively would be contrary to the public interest.” 42 U.S.C. § 1395hh(e)(1)(A)(ii). CMS reasonably determined that enforcing the RADV Rule retroactively would “serve[] the public interest by reducing the improper allocation of taxpayer dollars” to Medicare Advantage insurers that have been paid for reported diagnoses that were not supported by the medical records of their beneficiaries. RADV Rule, 88 Fed. Reg. at 6,653. This determination was eminently reasonable, and should be upheld if the Court concludes that the RADV Rule does apply retroactively.

E. Any relief should be limited to the parties before the Court.

If the Court concludes that the RADV Rule was unlawfully adopted, and even if the APA authorizes vacatur of agency action,²¹ the Court should decline, as a matter of equitable discretion, to enter a universal vacatur of the Rule. Text and precedent both make clear that whether to enter vacatur—and the scope of any such relief—is constrained by equitable principles. And those principles limit proper relief to redressing the injuries of the named parties, thus foreclosing universal vacatur in this case.

²¹ The government preserves for further review the argument that the APA’s provision for the courts to “set aside” unlawful agency actions, 5 U.S.C. § 706(2), does not authorize the universal vacatur that Humana seeks. *But see Tex. Med. Ass’n v. U.S. Dep’t of Health & Human Servs.*, 110 F.4th 762, 779–80 (5th Cir. 2024) (rejecting argument that the APA does not authorize vacatur).

The APA is not properly read to require vacatur—much less universal vacatur—of challenged action, in light of traditional equitable principles generally restricting relief beyond the parties. Congress enacted the APA against a background rule that statutory remedies must be construed in accordance with “traditions of equity practice.” *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). The Supreme Court has recently reinforced this principle of interpretation, instructing that, “[w]hen Congress empowers courts to grant equitable relief, there is a strong presumption that courts will exercise that authority in a manner consistent with traditional principles of equity.” *Starbucks Corp. v. McKinney*, 144 S. Ct. 1570, 1576 (2024). And the Court explained that even seemingly mandatory statutory language—such as a directive “that an injunction ‘shall be granted’ if” certain conditions are met—will not “supplant the traditional equitable principles” governing relief. *Id.* at 1577. “[S]uch an abrupt departure from traditional equity practice” as requiring relief no matter the equities requires “plain[er]” language than that. *Id.* (citation omitted); *see also Hecht Co.*, 321 U.S. at 329 (Congress’s authorization for courts to issue a remedy “hardly suggests an absolute duty” to grant such relief “under any and all circumstances.”).

So too with the APA. As an initial matter, the APA itself provides for traditional forms of equitable actions and relief, such as “declaratory judgments or writs of prohibition or mandatory injunction,” 5 U.S.C. § 703, and explicitly preserves “the power or duty of the court to ... deny relief on any ... equitable ground,” *id.* § 702. In light of the traditional equitable principles against which the statute was enacted—and which are explicitly incorporated into the statute—there is no sound reason to conclude that Congress did not merely authorize but compelled courts to abandon the “bedrock practice of case-by-case judgments with respect to the parties in each case” by adopting the unremarkable “set aside” language in § 706. *United States v. Texas*, 599 U.S. 670, 695 (2023) (Gorsuch, J., concurring in the judgment) (quotation omitted).

Finally, this construction of the APA—as permitting, but not requiring, universal vacatur—is consistent with Fifth Circuit precedent. The Fifth Circuit has treated universal vacatur as a discretionary equitable remedy, not one that is automatic or compelled in every case. *See Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (en banc) (plurality opinion) (concluding without contradiction from any other member of the Court that the district court could consider on remand “a more limited remedy” than universal vacatur, and instructing the district court to “determine what remedy ... is appropriate to effectuate” the judgment), *aff’d*, 602 U.S. 406 (2024); *see Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 952 n.102 (5th Cir. 2024) (noting that the en banc *Cargill* court remanded the case to district court for briefing on the appropriate scope of any relief under the APA). And the Fifth Circuit has sometimes declined to enter vacatur in favor of a remedy termed “remand without vacatur” when equitable principles so directed. *E.g., Cent. & Sw. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).²²

In this case, the Court could afford complete relief to Humana through an injunction prohibiting the enforcement of the RADV Rule against it. In light of the traditional equitable principles incorporated by the APA, the Court should therefore limit any relief to Humana.

CONCLUSION

Summary judgment should be entered in favor of the government on all claims.

Respectfully submitted,

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²² In addressing the scope of relief under 5 U.S.C. § 705, the Fifth Circuit recently observed that, “[w]hen a reviewing court determines that agency regulations are unlawful, the *ordinary* result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Career Colls. & Schs. of Tex. v. U.S. Dep’t of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) (emphasis added) (citation omitted). But “ordinary,” of course, does not mean “mandatory.”

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