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
	)	
ROBERT F. KENNEDY, JR., et al.,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' REPLY IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Medicare Advantage is one of the largest federal programs, paying private insurers more than $450 billion in one recent year. A large fraction of those payments depend on diagnosis data submitted by insurers, which must be supported by medical record documentation to constitute a valid claim. The government estimates that Medicare Advantage has recently made more than $10 billion in overpayments each year. *See* Gov't MSJ at 24, ECF No. 62. But because it is labor-intensive to review diagnosis data for medical record support, Medicare Advantage audits conducted without the use of sampling and extrapolation often fail to recover their costs. One recent year of audits cost $50 million to recover $4 million in overpayments. *See infra* at 7 n.4.

The government first broached the subject of using extrapolation in Medicare Advantage audits almost twenty years ago. *See* Gov't MSJ at 16. Now, under the rule challenged here, it is finally conducting audits that will lead to extrapolated recoveries, providing a cost-effective way to enforce compliance with the requirement of medical record documentation of diagnoses submitted for payment. Humana asks the Court to vacate the rule and send the government back to where it started more than six years ago. But Humana's arguments do not support its claims for relief. The Court should therefore allow the challenged rule to stand and the government's extrapolated audits to proceed.

ARGUMENT

I. Humana's statutory challenge to the RADV Rule fails.

A. Humana does not contend that it is entitled to retain Medicare Advantage payments based on diagnoses unsupported by a beneficiary's medical records.

In Medicare Advantage, the government pays private insurers a predetermined sum for each beneficiary they cover, using "a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors." 42 U.S.C. § 1395w-

23(a)(3)(C)(i). To accomplish this, the government periodically publishes tables of risk adjustment factors that assign a relative value to certain diagnoses. Gov't MSJ at 9–10. The Medicare statute requires that, in establishing the risk adjustment factors, the government reasonably determine that they will "ensure actuarial equivalence" by accurately paying insurers for the risk of medical expense associated with the health status and demographic characteristics of each covered beneficiary. 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Then insurers report the health status of their beneficiaries. After an insurer reports the conditions with which a beneficiary has been diagnosed, the beneficiary's risk adjustment factors are added together to determine how much the insurer will be paid for covering that individual. Gov't MSJ at 7–9. When an insurer reports a diagnosis associated with a risk adjustment factor, it claims the payment indicated by that risk factor. And under the terms of the Medicare program, such a claim is only valid if the diagnosis is documented in the beneficiary's medical record. If an insurer receives payment for a diagnosis that is not supported by the medical record, the payment must be returned when it is identified by the insurer or by a government audit. *Id.* at 25–26.

This principle—that unsupported diagnoses lead to overpayments which must be returned when they are identified—was challenged and upheld in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021) ("*United*"), *cert. denied*, 142 S. Ct. 2851 (2022). Pointing to the actuarial-equivalence provision of the Medicare statute, an insurer argued that the government could only demand the return of overpayments after making a "prior determination" that recovering them would not upset the overall accuracy of the payment model. *Id.* at 870. The D.C. Circuit rejected that argument, holding that the actuarial-equivalence provision applies in the "context of [the] calculation and disbursement of monthly payments in the first instance," and is not "broadly applicable" throughout the Medicare Advantage program. *Id.* at 885.

Although Humana maintains that *United* was wrongly decided, the insurer has made a strategic decision not to advance that argument here. Opp. at 9, 11, ECF No. 68; *see* Humana MSJ at 29, ECF No. 44. Instead, Humana contends that this case is different from *United*. The rule challenged here concerns audits in which the government (rather than the insurer) identifies overpayments, but Humana does not rest its argument on that distinction either. For the purposes of this case, at least, Humana accepts that when an audit identifies particular Medicare Advantage payments that rest on unsupported diagnoses, those overpayments may be recovered without first reassessing the accuracy of the payment model, as RADV audits have done for many years. *See* Opp. at 16.

B. Because Humana cannot show that there is "no set of circumstances" in which the RADV Rule's interpretation can be lawfully applied, its facial statutory challenge fails.

In its opening brief, Humana contended that audits making "population-level" recoveries are different from other methods of recovering Medicare Advantage overpayments, and implicate the actuarial-equivalence provision even if other methods do not. Humana MSJ at 23–24. And the insurer insisted that extrapolated audits conducted under the RADV Rule would "recoup[] payments corresponding to the diagnosis codes that CMS" estimates to be "inadequately documented in the enrollees' medical records across the *entire contract population*." *Id.* at 23 (emphasis in original); *see United*, 16 F.4th at 892 (noting that audits "which would effectively eliminate—and require repayment for—all unsupported codes in a Medicare Advantage insurer's data, are an error-correction mechanism that is materially distinct" from the recovery of individual overpayments). In response, the government explained that the RADV Rule does not commit it to seek "population-level" recoveries "on any plausible definition of that term," Gov't MSJ at 31, and that none of the audits being conducted under the Rule were in fact seeking such recoveries,

id. at 29–30. To the contrary, the pending audits focus on a "group of interest" that is "usually . . . a small fraction of the contract's beneficiary population," and often quite small in absolute terms. *Id.* at 29. Because Humana's argument did not question these applications of the RADV Rule, the government explained, its statutory challenge fails: on a facial challenge, the insurer's burden is to show that there is "no set of circumstances" in which the RADV Rule's statutory interpretation could be lawfully applied. *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 now offers two responses. First, the insurer broadens its definition of "population-level" recoveries implicating actuarial equivalence to any audit that extrapolates its findings to a group of beneficiaries, no matter how small (either in absolute terms or as a fraction of the contract's population). Then Humana denies that it bears the burden described by *Salerno* and *Associated Builders*, and insists that it should prevail if any extrapolated audit would implicate the actuarial-equivalence provision, even if some (or all!) of the pending audits do not. Neither argument is persuasive.

i. At least some extrapolated RADV audits are indistinguishable from audits that do not use sampling and extrapolation.

In its most recent brief, Humana takes the position that whether an audit seeks "population-level" recoveries—and therefore, on its account, whether the statute requires a prior determination that the audit recovery would not upset the payment model—depends not on the *scope* of the audit, but rather on its *method of proof*. Opp. at 14–15. Humana does not dispute that "sampling of similar claims and extrapolation from the sample is a recognized method of proof" when the government seeks to recover overpayments, which it is free to use in Medicare Advantage audits. *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005); *see* Opp. at 36 n.10. But the insurer insists that using this method implicates the actuarial-equivalence provision,

regardless of the ultimate scope of the audit. Its argument fails, because Humana cannot explain why the statute should apply differently to otherwise identical audits.

As the government explained in its opening brief, some extrapolated RADV audits concern groups of interest no larger than those that have previously been audited without the use of extrapolation. To take one concrete example, the government has identified a group of 43 beneficiaries whose reported diagnoses it wishes to audit, on a Medicare Advantage contract that serves more than 16,000 individuals. Dupee Decl. ¶ 20 (Gov't App'x 655–56) ("GA"); GA 681; *see* Gov't MSJ at 29.[1] Humana's position (on this motion, at least) is that if the government reviews the medical records of all 43 beneficiaries in this group of interest, then it may recover overpayments without making a separate inquiry into actuarial equivalence. But if the government instead examines the medical records of 35 beneficiaries and extrapolates its findings to the group of 43—as it intends to do, *see* Dupee Decl. ¶¶ 14–15 (GA 653–54)—then Humana maintains that this use of sampling and extrapolation implicates the actuarial-equivalence provision, *even if the two methodologies would calculate identical audit recoveries*.[2]

The Medicare statute cannot bear that interpretation. The statute provides that "the Secretary shall adjust the payment" to each Medicare Advantage insurer "for such risk factors as

[1] Because the Dupee Declaration "contains no new rationalizations" and "is merely explanatory of the original record," it is "admissible" for this Court's "consideration." *Olivares v. Transp. Sec. Admin.*, 819 F.3d 454, 464 (D.C. Cir. 2016) (cleaned up); *see AT&T Info. Sys., Inc. v. Gen. Servs. Admin.*, 810 F.2d 1233. 1236 (D.C. 1987) (explaining that "the record may be supplemented to provide . . . background information"); *accord Roe v. Dep't of Defense*, 947 F.3d 207, 221 (4th Cir. 2020). The declaration explains how pending RADV audits are being conducted, and attaches a publicly-available document that describes the audit methodology.

[2] The force of the example extends beyond this audit. CMS has previously conducted RADV audits of as many as 201 beneficiaries on a Medicare Advantage contract. Dupee Decl. ¶ 6 (GA 651); *see* RADV Rule, 88 Fed. Reg. 6643, 6647 (Feb. 1, 2023). Nine of its pending audits will use samples of 35 beneficiaries to calculate extrapolated overpayments for a group no larger than 202 beneficiaries. GA 679–81. CMS could have audited at least these nine groups of interest with using extrapolation.

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." 42 U.S.C. § 1395w-23(a)(1)(C)(i). As the government explained in its opening brief, and 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)." Gov't MSJ at 12; *see Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437, 440 (D.C. Cir. 2011); *Berger v. Xerox Corp. Ret. Income Guar. Plan*, 338 F.3d 755, 759 (7th Cir. 2003). The future medical costs for any particular beneficiary are unknowable, but risk adjustment allows the government to calculate their expected value—that is, the average medical costs for someone with the salient characteristics of that particular beneficiary.

Humana contends that audits using sampling and extrapolation are "actuarial" in a way that other audits are not, and therefore implicate the actuarial-equivalence provision even if other audits do not. Opp. at 14 (arguing that extrapolated audits involve "precisely the sort of actuarial analysis that falls within the actuarial-equivalence requirement"). But it misunderstands the term. An actuary is "[a] statistician who determines the present effects of future contingent events," and especially "one who calculates insurance and pension rates on the basis of empirically based tables." Black's Law Dictionary 45 (12th ed. 2024); *accord* Black's Law Dictionary 37 (7th ed. 1999). "Actuarial" is the adjectival form, describing the sort of calculations that actuaries make. *Id.* In Medicare Advantage, the "future contingent events" are medical costs, the "present effects" of which can be represented in a capitated monthly payment. As the *United* court noted, "the qualifier 'actuarial' necessarily implies an assessment made at the group or population level, not the individual level, so as to support credible statistical inferences." 16 F.4th at 886. That is true because, at the individual level, "future contingent events" are unknowable. Actuarial techniques

allow them to be estimated at the group or population level. But this does not mean, as Humana would have it, that all statistical analyses made at the group or population level are therefore "actuarial." What makes an analysis "actuarial" is its concern with "future contingent events," especially deaths and other insurable eventualities.[3]

That is not the sort of calculation that extrapolated RADV audits perform. Extrapolated RADV audits use statistical techniques to prove to a reasonable certainty something that is fundamentally knowable: whether the reported diagnoses for a group of Medicare Advantage beneficiaries are documented in their medical records. The government uses sampling and extrapolation as a cost- and labor-saving technique, to allow it to calculate overpayments without the time and expense of auditing every diagnosis reported for the group of interest.[4] But in theory, and quite often in practice, *see supra* at 5 & n.2, the government could instead review the medical record documentation for each diagnosis in question, and calculate overpayments for the same group of interest without using any statistical techniques. By contrast, no amount of resources would allow the government to determine with certainty how many members of that group will die in the coming year, nor what medical expenses they will incur. Those are "future contingent events," which can only be estimated actuarially. The existence of medical record documentation is not.

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[3] *See* American Heritage Dictionary (3d ed. 1996) (defining "actuary" as "[a] statistician who computes insurance risks and premiums"); Black's Law Dictionary 36 (6th ed. 1990) (defining "actuary" as "[a] statistician who computes insurance and pension rates and premiums," and an "actuarial table" as something which "indicates the life expectancy of a person").

[4] RADV audits can be uneconomical if they do not use sampling and extrapolation. For example, the 2011 audits cost roughly $50 million and recovered less than $4 million in overpayments. *See* RADV NPRM, 83 Fed. Reg. 54,982, 55,028 (Nov. 1, 2018); CMS, Payment Year 2011Contract-Specific Risk Adjustment Data Validation Questions and Answers (Jan 16, 2025), https://www.cms.gov/files/document/py2011-ma-radv-q-01-16-2025pdf.pdf.

Humana also argues that extrapolated audits of groups of interest implicate the actuarial-equivalence provision because they calculate overpayments "for each and every enrollee within the contract who has the defining characteristic of the cohort." Opp. at 15. But that is equally true of audits that examine the reported diagnoses for a group of interest without using extrapolation, as at least six pending RADV audits will do. Dupee Decl. ¶ 19 (GA 655). Humana again fails to distinguish audits that (on the arguments it has presented here) clearly do not implicate the actuarial-equivalence provision.

Because Humana does not argue that beneficiary-by-beneficiary audits of a group of interest implicate the actuarial-equivalence provision, and (at a minimum) cannot distinguish extrapolated audits of equivalent size, it cannot show that the RADV Rule's statutory interpretation is invalid as applied to extrapolated audits that could practically have been conducted without the use of extrapolation.[5] And that failure is fatal to its statutory claim.

ii. Humana must—but cannot—show that there is "no set of circumstances" in which the challenged statutory interpretation is lawful.

As the government has explained, on this facial statutory challenge Humana must show that there is "no set of circumstances" in which the RADV Rule's statutory interpretation can be lawfully applied. *Salerno*, 481 U.S. at 745; *Associated Builders*, 826 F.3d at 220. That means it is Humana's burden to show that all extrapolated RADV audits implicate the actuarial-equivalence provision, rather than the government's burden to show that none of them do. If the Court concludes that there is some class of extrapolated RADV audits (such as those discussed above) that do not implicate the actuarial-equivalence provision on the arguments that Humana has

[5] Humana never attempts to explain how extrapolating overpayment recoveries for a small handful of beneficiaries could upset the actuarial equivalence of payments on a contract with thousands of other beneficiaries whose diagnoses are not being audited.

presented here, then it can resolve the insurer's statutory challenge in the government's favor without reaching the question reserved by the *United* court: whether the actuarial-equivalence provision applies differently to audits that "would effectively eliminate—and require repayment for—all unsupported codes in a Medicare Advantage insurer's data." 16 F.4th at 892.

Humana responds by attempting to invert the burden described in *Associated Builders*, arguing that unless the government's statutory interpretation is permissible in every possible application, then the rule which adopted it cannot stand. Opp. at 13–14. That is flatly contrary to binding precedent. *Associated Builders* was a facial challenge to a rule that "modifie[d] procedures relating to union representation elections." 826 F.3d at 218. A group argued that, under the governing statute, employers must "be allowed to contest all issues of . . . voter eligibility at pre-election hearings." *Id.* at 221–22. The challenged rule generally "defer[red] employer challenges to voter eligibility issues until after an election is held." *Id.* at 219. As relevant here, the Fifth Circuit noted that "because this is a facial challenge, the [challengers] must demonstrate that the [rule's] provisions would not be valid under any set of circumstances." *Id.* at 223. They could not do so, because the challenged rule provided the National Labor Relations Board with "discretion to determine voter eligibility issues in pre-election hearings" under certain circumstances. *Id.*

As relevant here, the plaintiffs argued that voter eligibility must *always* be determined before the election, and the government argued that pre-election determinations were *never* required by statute. *Id.* at 222. The challenged rule placed eligibility determinations after the election by default, but provided discretion for the Board to make a pre-election determination when it saw fit to do so. The Fifth Circuit concluded that, *even if the challengers' statutory argument was right and the government's was wrong*, the rule would be lawfully applied if and when the Board exercised its discretion to determine voter eligibility in a pre-election hearing.

The existence of such a lawful application—even one that might never arise—was enough for the rule to survive a facial challenge. Humana's argument cannot be squared with *Associated Builders*.[6]

Humana has chosen not to argue (as it apparently believes) that all overpayments identified through RADV audits implicate the actuarial-equivalence provision. It only contends that extrapolated audits do. But some extrapolated audits concern groups of interest no larger than those at issue in earlier RADV audits, and only slightly larger than pending audits that will not use extrapolation. The insurer cannot explain why the statute should be read to treat otherwise identical (or nearly identical) audits differently, just because one audit uses extrapolation and the other examines every medical record by hand. Because Humana cannot justify that distinction, the RADV Rule's statutory interpretation must be lawful at least as applied to those indistinguishable audits. And Humana's facial statutory challenge therefore fails.

C. The RADV Rule is not contrary to law, because extrapolated RADV audits do not implicate the actuarial-equivalence provision.

i. The statute requires an assessment of actuarial equivalence when the government establishes risk adjustment factors, not when it audits the diagnosis data reported by insurers.

The Medicare statute requires the government to "adjust" its payments to Medicare Advantage insurers "for such risk factors as age, disability status, gender, institutional status, and

[6] The Tenth Circuit's decision in *Scherer v. U.S. Forest Service* does not support Humana's position either. 653 F.3d 1241 (10th Cir. 2011). That case involved fees for the use of Forest Service land. The statute prohibited fees for visitors who only engaged in certain activities (parking, hiking, etc.) but allowed fees for the use of certain amenities (toilets, interpretive exhibits, etc.). *Id.* at 1242–43. In one location, the Forest Service charged everyone a fee. Hearing a facial challenge to this policy, the Tenth Circuit explained that the plaintiff "can't meet the burden of showing that there are *no set of circumstances* where the . . . fee is lawfully collected," because it was lawful to collect a fee from anyone who used covered amenities. *Id.* at 1244. And so even if the government's statutory position—that it could levy a blanket fee—was wrong, it still prevailed because the fee could sometimes be lawfully collected.

such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). It is an "elementary rule of statutory interpretation" that these "[w]ords receive their plain, obvious and common sense meaning, unless context furnishes some ground to control, qualify, or enlarge it." *United States v. Bronstein*, 849 F.3d 1101, 1108 (D.C. Cir. 2017) (cleaned up). In its opening brief, Humana suggested that the plain meaning of this provision makes extrapolated RADV audits subject to an analysis of their impact on "actuarial equivalence" before any overpayments calculated by those audits can be recovered. The insurer's argument was that extrapolated audit recoveries "'adjust the payment amount' to [a Medicare Advantage insurer] based on the 'health status'" of its insured beneficiaries, by recovering payments predicated on diagnoses that lack medical record support. Humana MSJ at 23 (quoting § 1395w-23(a)(1)(C)(i)).

In response, the government explained that this interpretation—which would seem to make "the recovery of individual overpayments, and indeed the making of individual payments to insurers on the basis of the diagnoses they report" subject to continual "reevaluation of actuarial equivalence," Gov't MSJ at 35—was foreclosed by the statute. Most importantly, the actuarial-equivalence provision "does not make a free-floating reference to all adjustments 'for health status,'" but "specifically" refers "to adjustments 'for health status under paragraph (3),'" *id.* at 34, which concerns the "Establishment of risk adjustment factors," 42 U.S.C. § 1395w-23(a)(3) ("Paragraph 3"). "[A]djustment[s] for health status . . . so as to ensure actuarial equivalence" are therefore achieved through the "[e]stablishment of risk adjustment factors" under "paragraph (3)" and not through audit recoveries. *Id.* § 1395w-23(a)(1)(C)(i), (3). To be sure, the statute requires the government to use the risk adjustment factors it has established, but it does not require a reassessment of actuarial equivalence each time the adjustment factors are applied. As we

explained, "the actuarial-equivalence provision governs the establishment of payment rates, not the recovery of overpayments." Gov't MSJ at 32.

Humana offers several objections. First, it maintains that the government does not "adjust *any* payments" when it establishes risk factors, and that adjustments within the meaning of § 1395w-23(a)(1)(C)(i) only occur when the risk factors are applied to particular payments. Opp. at 5. That argument strains the structure of Paragraph 3, which contains three subparagraphs that are relevant here. Subparagraph A required the agency to "submit to Congress . . . a report on the method of risk adjustment of payment rates under this section, to be implemented under subparagraph (C), that accounts for variations in per capita costs based on health status." 42 U.S.C. § 1395w-23(a)(3)(A). Subparagraph B, entitled "Data Collection," is the statutory provision under which Medicare Advantage insurers submit diagnosis data for purposes of risk adjustment. *Id.* § 1395w-23(a)(3)(B). Finally, Subparagraph C directs the "implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status." *Id.* § 1395w-23(a)(3)(C)(i). Under an adjacent provision, the government accomplishes that by annually announcing "[t]he risk . . . factors to be used in adjusting [payment] rates under subsection (a)(1)(C)." *Id.* § 1395w-23(b)(1)(B)(i)(II).

Once the government has published risk factors under Subparagraph C and its adjacent provisions, and collected diagnosis data under Subparagraph B, determining the payment owed to an insurer for covering a particular beneficiary is a matter of simple arithmetic. The government provides one term (the risk adjustment factors) and insurers provide the other (the diagnoses), much in the way that an interest payment is the mechanical result of an interest rate and a principal amount. *Cf.* Opp. at 5–6. The interpretive question is at what point in this process the government must "ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). Is it when the

government implements a system of risk adjustment by publishing the risk factors? Or must the government assess "actuarial equivalence" when it mechanically applies those adjustment factors to the diagnosis data submitted by insurers, and corrected through RADV audits?

Humana contends that when the government, in an extrapolated RADV audit, corrects the diagnosis data provided by the insurer, it cannot go on to rerun the arithmetic that calculates payments without first 1) reconsidering the accuracy of its own published risk factors, or 2) considering whether it should refrain from recovering some payments that were based on diagnoses lacking medical record support. *See infra* at 19–20. In short, Humana contends that the actuarial-equivalence provision bars a mechanical reapplication of the established risk factors to the corrected data.[7] But Paragraph 3 makes clear that it is the "risk adjustment methodology" which "makes adjustments to capitation rates for health status," *id.* § 1395w-23(a)(3)(C)(ii), within the meaning of the actuarial-equivalence provision, and it uses "makes adjustments" almost synonymously with "accounts for." *Id.* § 1395w-23(a)(3)(A) (discussing "the method of risk adjustment of payment rates under this section . . . that accounts for variations in per capita costs based on health status"); *id.* § 1395w-23(a)(3)(C)(i) (requiring the "implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status"). When the government implements its system of risk adjustment by publishing risk factors, it thereby accounts for variations in per capita costs based on health status. And that is all that the statute requires.

[7] Humana may object that this is not literally what extrapolated RADV audits do, but that is a distinction without a difference. Extrapolated audits are designed to calculate a statistically valid approximation of the results of a diagnosis-by-diagnosis audit, followed by a mechanical application of the risk factors to the corrected data. As discussed elsewhere, the government's decision to use this "recognized method of proof," *Lahey*, 399 F.3d at 18 n.19, in its audits does not affect the application of the actuarial-equivalence provision. *See supra* at 5–7 & *infra* at 15.

The government's obligation "to ensure actuarial equivalence" in Medicare Advantage payments requires it to establish risk adjustment factors that predict medical costs on the basis of certain factual predicates, including "health status." *Id.* § 1395w-23(a)(1)(C)(i). It cannot be reasonably interpreted to limit the government's ability to assess whether the diagnosis data reported by insurers is accurate, and apply its published risk factors to corrected data as necessary.

Humana goes on to suggest that the direction to "adjust" payments for "risk factors . . . including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence," 42 U.S.C. § 1395w-23(a)(1)(C)(i), is "illustrative, not exclusive." Opp. at 6. The government acknowledges that payment adjustments for "age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate" are equally subject to the actuarial-equivalence provision (though it has generally deemphasized those adjustments for the sake of clarity in its briefing here). 42 U.S.C. § 1395w-23(a)(1)(C)(i). But that is beside the point: RADV audits do not examine a beneficiary's reported age or "other [risk] factors." *Id.* They concern the accuracy of the diagnosis data on which the government relies in its risk "adjustment for health status under paragraph (3)." *Id.*

Next, Humana argues that the broader "statutory and regulatory structure" prohibits the government's interpretation, Opp. at 7, though it again "ignores th[e] web of cross-references" that connect the actuarial-equivalence provision to Paragraph 3 and the adjacent provisions regarding the annual publication of risk factors, Gov't MSJ at 34; *see id.* at 33. As the government previously explained, Humana's structural argument boils down to the observation 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."

Gov't MSJ at 36. The key question is *when* the government must assess actuarial equivalence: when it establishes the risk factors, or each time that it mechanically applies them?[8]

Humana goes on to deny that its argument would necessarily apply to "the recovery of individual overpayments," *id.* at 35—though the insurer believes that it should, *see* Opp. at 9—because it contends that extrapolated RADV audits are "actuarial" in a way that individual audits are not. But using statistical techniques to prove the existence (or absence) of medical record documentation is not "actuarial": whether such documentation exists is a present, knowable fact, and Humana's argument would have the statute apply differently to otherwise indistinguishable audits, based only on the method of proof chosen by the auditor. *See supra* at 5–7.

Finally, the Court should not credit Humana's suggestion that the government's statutory interpretation is a post-hoc rationalization "that deserves little weight." Opp. at 5. The RADV Rule sets out the government's view 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." 88 Fed. Reg. at 6656. The APA does not require the government to unpack its statutory interpretation in all of the detail appropriate for a legal brief, and the Court must uphold reasoned decision-making so long as "the agency's path may be reasonably discerned." *Handley v. Chapman*, 587 F.3d 273, 281 (5th Cir. 2009) (quoting *Bowman Transp., Inc. v. Arkansas–Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)). Nor would a more stringent

[8] In its opening brief, Humana misread the RADV Rule to suggest that the government believed "RADV audits are exempt from the actuarial-equivalence requirement because they occur after the fact of CMS's prospective payments" to Medicare Advantage insurers. Humana MSJ at 24 (quotation omitted). The government disclaimed this argument and explained that the actuarial-equivalence provision applies to the *establishment* of risk adjustment factors and not their *application*, regardless of whether the application occurs when the payment was initially made, or later when the validity of reported diagnoses is examined. *See* Gov't MSJ at 32–36 & n.16.

rule make sense after the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024). The government does not claim any deference for its statutory interpretation; it is rather this Court's responsibility "to say what the law is." *Marbury v. Madison*, 1 Cranch 137, 177 (1803). The question here is the statute's meaning, and not the government's rationale.

ii. *United* supports the government's position.

The D.C. Circuit's opinion in *United* supports the position that the government must assess actuarial equivalence when it establishes the risk adjustment factors, and not when it audits the diagnosis data reported by insurers. As the Court is aware, that case concerned Medicare Advantage payments to which insurers are "not entitled"—the statute calls them "overpayments"—which must be promptly returned when they are "identified." 42 U.S.C. § 1320a-7k(d)(2)(A), (d)(4)(B). The Overpayment Rule said that "a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment," 79 Fed. Reg. at 29,921, and the insurer argued that this result was barred by the actuarial-equivalence provision.

The D.C. Circuit responded with a close reading of that provision, explaining that "the text of section 1395w-23(a)(1)(C)(i) limits the scope of the actuarial-equivalence requirement." *United*, 16 F.4th at 884. It noted the cross-references to other provisions requiring "predetermined monthly payments . . . to insurers," and explained that they "indicate that the actuarial-equivalence requirement is not broadly applicable, but instead limited to the specified context of CMS's calculation and disbursement of monthly payments in the first instance." *Id.* at 885.[9] Then the

[9] In arriving at this conclusion, the *United* court emphasized the actuarial-equivalence provision's cross-references to "subparagraph (A)(i)" and "subparagraph (B)(i), (B)(ii), and (B)(iii)," *see* 16 F.4th at 884, while the government's argument has placed greater weight on its cross-reference to "paragraph (3)." The cross-references are mutually reinforcing, and lead to the same conclusion.

court discussed its opinion in *Stephens* and concluded that "actuarial equivalence is satisfied consistently with *Stephens* so long as CMS reasonably concluded" that its "relative-factor values" and the traditional Medicare data used to calculate them were "sufficiently accurate." *Id.* The court summarized these conclusions in the introduction, explaining that "[a]ctuarial equivalence is a directive to CMS" that "describes the goal of the risk-adjustment model Congress directed CMS to develop." *Id.* at 870–71. The court reached these holdings by interpreting the text of the actuarial-equivalence provision on its face.

Then the *United* court distinguished the overpayment and actuarial-equivalence provisions, in the language to which Humana directs our attention: "The actuarial-equivalence requirement and the overpayment-refund obligation apply to different actors, target distinct issues arising at different times, and work at different levels of generality." *Id.* at 886. Much of that also distinguishes RADV audits, which examine the accuracy of the diagnosis data submitted for payment by insurers, from the establishment of risk factors by the government. The submission of diagnosis data and the publication of risk factors are performed by "different actors"; the audits and initial payments occur at "different times"; and audits work at a "different level[] of generality" from the establishment of payment rates that govern the entire Medicare Advantage program. The D.C. Circuit went on to explain that "section 1395w-23(a)(1)(C)(i)'s use of the qualifier 'actuarial' necessarily implies an assessment made at the group or population level, not the individual level, so as to support credible statistical inferences," whereas "the overpayment-refund obligation . . . corrects particular mistaken payments to Medicare Advantage insurers that exceed what the relevant medical records support." *Id.* But to observe that correcting "particular mistaken payments" cannot be "actuarial" because it is not a statistical "assessment made at the group or population level" does not imply that all statistical assessments made at the group level are

therefore "actuarial." As discussed above, they are not. *See supra* at 5–7. Finally, the *United* court's rejection of the argument that "the actuarial-equivalence principle reaches beyond its statutory home to impose an implied—and functionally prohibitive—legal precondition on the requirement to return known overpayments," *id.* at 870, does not imply that the case would have been decided differently if the overpayment provision were located closer to section 1395w-23(a)(1)(C)(i). And in any event this case, like *United*, concerns the government's ability to recover payments to which insurers are "not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B).

Humana misreads the analytical structure of the *United* opinion, which begins by interpreting the text of the actuarial-equivalence provision, goes on to distinguish the overpayment provision, and concludes by explaining that the insurer's argument would produce absurd results. Nowhere does the *United* court say (or imply) that its reading of the actuarial-equivalence provision is limited or motivated by the distinctions with the overpayment provision that it then goes on to draw. Humana accuses the government of failing to "grapple with" the "actual reasoning" of the *United* opinion, but it has committed that error itself. Opp. at 9.

iii. Because the actuarial equivalence provision only applies to the establishment of risk adjustment factors, it can only support a challenge to those risk adjustment factors.

In its opening brief, the government explained that insurers who question the actuarial equivalence of Medicare Advantage payments have an available remedy: they may challenge the risk adjustment factors announced each year. *See* Gov't MSJ at 26–27, 35–36. Humana responds that its "challenge to the Final Rule's RADV audit methodology" is not "improper" just because it could have challenged the risk factors instead. Opp. at 19. But that is not the government's point. Humana cannot use the actuarial-equivalence provision to limit Medicare Advantage audit recoveries because that provision does not apply to audits: it "governs the establishment of

payment rates, not the recovery of overpayments." Gov't MSJ at 32; *supra* at 10–15. Humana's only remedy is a challenge to the risk factors because the actuarial-equivalence provision only applies to the "[e]stablishment of risk adjustment factors." 42 U.S.C. § 1395w-23(a)(3).

Humana insists that it aims to address an "actuarial defect" that "arises" from the government's "audit methodology" and not the risk factors themselves. Opp. at 18. As the Court is aware, and as relevant here, Medicare Advantage payments are a function of 1) the risk factors published by the government, and 2) the diagnoses reported by insurers. The risk factors are calculated by "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." Gov't MSJ at 10. Diagnoses may be reported for payment if—and only if—they are supported by medical record documentation, a consistent requirement for diagnosis reporting throughout the Medicare program. *Id.* at 5–8; *see* RADV Rule, 88 Fed. Reg. at 6644–45. Despite the many audit programs that "conduct medical record review of Part A and B claims," Gov't MSJ at 6, Humana (like other insurers before it) characterizes the diagnosis data from traditional Medicare as "unaudited," and posits that RADV audits apply "a different documentation standard" to the Medicare Advantage program, which the government must "account[] for" in its audit methodology. Opp. at 17.

There are two ways to understand Humana's argument. On the one hand, it is an argument that "errors in Part A and B [diagnosis] data cause the risk factors for diagnoses to be too low" in the Medicare Advantage program, given the requirement of medical record documentation for each diagnosis submitted for payment. Gov't MSJ at 35; *see* Humana MSJ at 12 (suggesting that erroneous diagnoses in traditional Medicare claims data "result[] in lower coefficients"—*i.e.*, risk adjustment factors—in the Medicare Advantage program). And on the other hand, it is an

argument that requiring medical record documentation for each Medicare Advantage diagnosis is too demanding, given the calibration of the risk factors on traditional Medicare data. *See* Opp. at 17–18. There are thus two ways that the supposed inconsistency between the calibration and application of the risk factors could be resolved: by increasing the risk factors (and thus insurers' payment rates) or by loosening the documentation standard, allowing insurers to claim or retain payment for some diagnoses that are not supported by medical records. When Humana denies that it is attacking the risk adjustment factors, *see* Opp. at 17, that is what it means: the risk factors are fine, *so long as the government allows Humana to retain some payments based on unsupported diagnoses*.

But because the actuarial-equivalence provision only applies to the establishment of risk adjustment factors, it only allows Humana to mount its argument in the other direction, by challenging the calibration of the risk factors. Humana would prefer to use the statute as a limit on the government's ability to make audit recoveries, just as the insurer in *United* tried to wield it as a defense against the obligation to return overpayments. *See* 16 F.4th at 886. But because "the actuarial-equivalence requirement is . . . limited to the specified context of CMS's calculation and disbursement of monthly payments in the first instance," *id.* at 885, it cannot support a challenge to RADV audit methodologies.[10] That is why Humana's failure to "challenge[] the values CMS assigned to the risk factors" is "fatal" to its actuarial-equivalence claim: that is the only place where the actuarial-equivalence provision applies. *Id.* at 871.

[10] As the government has made clear, RADV audits address payment inaccuracies resulting from diagnosis codes unsupported by medical records, they "do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation." 83 Fed. Reg. at 55,041 (emphasis added).

D. The coding pattern adjustment independently supports the RADV Rule.

Since 2014, Congress has required that Medicare Advantage payments be reduced by at least a fixed percentage, which is currently 5.9%. 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(III). Congress offered no explanation for its choice of that threshold, and the government has made the minimum allowable reduction each year. Although we do not know how the legislature arrived at a mandatory 5.9% reduction, it is clear from the face of the statute that "Congress . . . evaluated the accuracy of the payments made to Medicare Advantage insurers under the CMS-HCC model," concluded that the payments were "too high, and mandated their reduction." Gov't MSJ at 37. In its opening brief, the government described this as a "holistic congressional assessment of the accuracy of Medicare Advantage payments." *Id.* at 39–40.

Humana contends that, before the government can make recoveries from extrapolated RADV audits, it must assess the impact of those recoveries on the actuarial equivalence of the payment model, and consider whether it should raise Medicare Advantage payment rates or lower the program's documentation standards for audited insurers (allowing them to retain some payments based on unsupported diagnoses). *See supra* at 13. In the RADV Rule, the government concluded that even if the Medicare statute would otherwise require such an assessment, when "CMS has . . . implemented the minimum . . . reduction required by statute," "the only reasonable interpretation of the Act is that" Congress expected the government to "pay [insurers] at those reduced rates, under the existing payment model, and enforce the longstanding documentation requirements through . . . audits." 88 Fed. Reg. at 6657 (footnote omitted). Said differently, "it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision . . . while at the same time prohibiting CMS in an adjacent provision . . . from enforcing [its] longstanding documentation requirements," which is all that RADV audits do. *Id.*

Humana now offers three responses. First, it points to prior agency statements indicating that RADV audits correct inaccurate diagnosis codes, while this coding adjustment accounts for the incentive to report additional accurate diagnoses. Opp. at 21–22. But the RADV Rule and the government's argument here, which turn on the congressional decision to reduce Medicare Advantage payments by at least a fixed percentage, are not to the contrary. When Congress arrived at a mandatory reduction of 5.9%, it acted against a background that remains unchanged today: payments are calculated by a risk adjustment model calibrated on traditional Medicare data, and operated on a standard of medical record documentation for each diagnosis. Congress therefore must have expected that the payment reduction of 5.9% would be calculated against risk scores produced by this model and documentation standard. *See* RADV Rule, 88 Fed. Reg. at 6657. Because Humana's argument would disturb the expectation on which Congress relied in choosing a level for the mandatory payment reduction, it is not a reasonable interpretation of the statute.

Humana goes on to dispute the government's argument by mischaracterizing it. It is not the government's position that "Congress effectively barred [it] from any policies inuring to [insurers'] financial benefit," Opp. at 23, but rather that the statute, as a whole, cannot reasonably be read to predicate enforcement of the medical record documentation requirement through extrapolated RADV audits on the government's reassessment of actuarial equivalence.

Humana also takes issue with the government's observation that the text of the coding adjustment provision, which alters "the adjustment under clause (i) for health status to payment amounts," 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I), "reinforces the government's interpretation of . . . the actuarial-equivalence provision" contained in clause (i) "as applying only to the establishment of risk adjustment factors." Gov't MSJ at 38–39. As the government has explained, 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." *Id.* at 39. Humana responds that "this argument thoroughly misunderstands the order of operations" in risk adjustment, because the coding adjustment "is an across-the-board reduction to an enrollee's risk *score*," rather than the individual risk factors. Opp. at 24. But there is no difference between applying the coding adjustment to individual risk factors or cumulative risk scores—those are mathematically identical operations[11]—and the statute authorizes either approach. Moreover, the text of this provision suggests that the statute contemplates one single adjustment for health status (when the risk factors are established) rather than many separate adjustments (each time they are applied). 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I) (discussing "*the* adjustment under clause (i) for health status to payment amounts"); *see also id.* § 1395w-23(a)(1)(C)(iii)(I) (altering "*the* adjustment under clause (i)" for certain individuals); 1395w-23(a)(1)(I)(i) (telling the agency how "to determine *the* appropriate adjustment for health status under subparagraph (C)(i)") (all emphases added).

Finally, Humana again suggests that these purely statutory arguments should be dismissed as post-hoc rationalizations, Opp. at 23, or else because the RADV Rule set them out in an overly "conclusory" fashion, *id.* at 25. But it relies on cases in which an agency was either exercising delegated authority under the repudiated *Chevron* doctrine, *see Madison Gas & Elec. Co. v. EPA*, 25 F.3d 526, 529 (7th Cir. 1994), or relying on a statutory interpretation that the reviewing court rejected, *Am. Fed'n of Gov't Emps., AFL-CIO v. FLRA*, 24 F.4th 666, 674–75 (D.C. Cir. 2022). Humana cites no case for the proposition that this Court's responsibility to "determine the best

[11] For a simplified example, imagine two risk factors of 0.5 each and a mandatory reduction of 20%. If the risk factors are first added together to make a risk score of 1.0, and then the mandatory reduction is applied, the result is 0.8. But if the reduction is instead applied directly to the risk factors, reducing them to 0.4, then their sum will be also 0.8.

reading of the statute" is limited by the detail with which the government explained its own statutory interpretation in the Federal Register. *Loper Bright*, 144 S. Ct. at 2266. The government's position, here as above, *see supra* at 15–16, was adequately articulated in the RADV Rule, and should be evaluated on its merits.

In sum, Humana's statutory challenge fails because it cannot show that there is "no set of circumstances" in which the RADV Rule can be lawfully applied. And if the Court reaches the ultimate merits of Humana's statutory arguments, its challenge fails there as well.

II. The RADV Rule was not arbitrarily adopted.

In its opening brief, Humana suggested that the RADV Rule arbitrarily failed to "engage with the possibility that applying an FFS Adjuster" to reduce extrapolated RADV audit recoveries, "even if not required as a statutory matter," "would constitute sound policy promoting the continued health of the Medicare Advantage program." Humana MSJ at 37. The government replied, in part, that "[t]he actuarially sound administration of the program is served by the recovery of overpayments," and noted the RADV Rule's emphasis on the importance of medical record documentation of diagnoses submitted for payment. Gov't MSJ at 42; *see id.* at 41.

In its most recent brief, Humana refocuses its arbitrary-and-capricious argument on the government's decision to reverse its statement in a 2012 guidance document that CMS would "apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset" to the extrapolated recoveries calculated by that audit methodology. GA 97; *see* Opp. at 26–27. But as the government has explained, that guidance document "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 therein, which "aimed to estimate a much larger fraction of potential overpayments than the extrapolation methodologies that are currently in use." Gov't MSJ at 47 &

n.20 (quoting GA 94). The government "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." *Id.* at 47; *see id.* at 44. Because "CMS did not make a broad representation that 'any extrapolated RADV audit . . . would incorporate an FFS Adjuster,'" as Humana has suggested, *id.* at 47 (quoting Humana MSJ at 44), the RADV Rule did not reverse that position, which the government never took. *See infra* at 29–30. And so even if the government had failed to justify its reversal of the 2012 guidance document, that "would not support a facial challenge to the RADV Rule," Gov't MSJ at 40, which has many applications that do not rely on the reversal. *See Associated Builders*, 826 F.3d at 220.

In any event, the government's reversal of the 2012 guidance document was amply justified. In accordance with its view that "the actuarial-equivalence provision governs the establishment of payment rates," Gov't MSJ at 32, the government assesses actuarial equivalence when it establishes risk adjustment factors, with the intention that those risk factors be applied to diagnoses reported by Medicare Advantage insurers in accordance with the programmatic requirements—that is, diagnoses that are supported by medical record documentation. Stated plainly, the risk adjustment factors are designed to adequately compensate Medicare Advantage insurers *who only report documented diagnoses*. *See* RADV Rule, 88 Fed. Reg. at 6655.

If auditing diagnoses and recovering overpayments produces an "actuarial defect," Opp. at 27, then the government has calculated the risk factors incorrectly. That is why the FFS Adjuster was a "conceptual error": it contemplated that either different payment rates or a different documentation standard should apply to audited Medicare Advantage contracts, when the purpose of the audits is to enforce the existing requirement of medical record documentation, so that payments are made properly according to the published risk factors. Gov't MSJ at 42. And that

is why the RADV Rule concluded that "even if systematic payment error exists" in the Medicare Advantage program, it should be corrected when the government establishes payment rates, and not when it audits diagnoses. RADV Rule, 88 Fed. Reg at 6,660. To accept Humana's argument that auditing diagnoses and recovering overpayments produces "actuarial defects" would imply that the published risk factors are properly applied to a mix of diagnoses, only some of which are supported by medical records. That is in fact Humana's view. *See* Opp. at 28. But the government has never intended its risk factors to support payment for diagnoses that lack medical record documentation,[12] and it was not arbitrary for the RADV Rule to adhere to the government's view that any "actuarial defect" in the Medicare Advantage program should be corrected through changes to the risk factors rather than the longstanding documentation standard that applies throughout Medicare. *See* Gov't MSJ at 5–8.

Whether there is an "actuarial defect" in Medicare Advantage payments is a question for another day, as the parties agree. The government has explained its view that there is not, Gov't MSJ at 42–44, and Humana has explained its view that there is, Humana MSJ at 37–38; Opp. at 29–31, but the question would only arise in a challenge to the establishment of risk factors, which is the action to which the actuarial-equivalence provision applies. Humana agrees that "it is not necessary for this Court to reach that question to resolve this case." Humana MSJ at 3.

III. The RADV Rule s procedurally valid.

The government proposed "not to apply" an "FFS Adjuster" to its "audit findings," 83 Fed. Reg. at 55,048, and it finalized that proposal, *see* RADV Rule, 88 Fed. Reg. at 6658 ("[W]e have

[12] If Humana is arguing that, given the design of the risk adjustment system, the government should have allowed insurers to claim payment for diagnoses unsupported by medical record documentation, that is directly contrary to *United* and beyond the scope of the RADV Rule, which did not alter the program-wide requirement of medical record documentation.

decided not to apply an FFS Adjuster in RADV audits. . . ."). Humana says that the decision rested on "purely legal rationales," Opp. at 3; Humana MSJ at 19, yet insists that it was deprived of notice and an opportunity to comment. The insurer's position, here as in its earlier allusions to post-hoc rationalizations, is quite remarkable. Humana evidently believes that when the government proposes action on the basis of a statutory interpretation, finalizes its proposal, and convinces a Court that its interpretation is correct, the final action is nonetheless procedurally vulnerable unless the government laid out the full details of its statutory argument in its notice of proposed rulemaking. *See* Opp. at 32–33. But there is no case to stand for that proposition.

Humana invokes the Fifth Circuit's statement that an "agency's rationale" for its "rule must be made clear and subjected to public comment," in a case which upheld the proposition that an agency must notify the public of the factual basis on which it proposes to exercise its regulatory discretion.[13] But the government was not exercising discretion, much less on a factual basis, when it announced its statutory interpretations in the RADV Rule.

And even if the government had an obligation to seek comment on its statutory interpretations, it did so. The notice of proposed rulemaking articulated the rationale 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

[13] *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 382 (5th Cir. 2021). In that case, the Fifth Circuit was reviewing a regulator's decision to ban children's toys with a particular concentration of certain chemicals. *Id.* at 372. The regulator had justified its proposal with data showing hazards to pregnant women, ten percent of whom had a "hazard index" of more than one, "which exceeded the acceptable risk,"; and "the average [hazard index] was five at the 95th percentile." *Id.* at 382. But the regulator finalized the rule "with reference to individual spot samples rather than an estimable percentage of the population that had potentially harmful exposure." *Id.* at 383. The Fifth Circuit concluded that this "change in methodology—whether right or wrong—was not reasonably foreseeable based on the Proposed Rule." *Id.* at 383.

55,041. In this context, "systematic payment error" and "issues with the accuracy of payments" clearly refer to concerns with the "actuarial equivalence" of payments. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). To say that "RADV audits do not address issues with the accuracy of payments" is to suggest that their recoveries are not subject to an assessment of actuarial equivalence. And any remaining ambiguity was resolved by the supplemental request for comment in 2019, which discussed the statutory provisions on which the government would rely, and asked whether they should be read to "inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology." 84 Fed. Reg. 30,983 (June 28, 2019). Humana cannot credibly maintain that a proposal "not to apply" an "FFS Adjuster," 83 Fed. Reg. at 55,048, and a request for comment on whether certain statutory provisions should "inform" that proposal, 84 Fed. Reg. at 30,983, deprived it of notice that the government was considering the conclusion that they did not require such an adjustment.[14]

And even if the government was required to provide notice of its statutory interpretation and failed to do so, any error was harmless. Humana argues that it was deprived of an opportunity to object to "the agency's . . . interpretation of the actuarial-equivalence provision." Opp. at 34. But if the Court concludes that this interpretation is "the best reading of the statute," *Loper Bright*, 144 S. Ct. at 2266, then objections would have been fruitless, and any failure to allow for them was harmless. *Shinseki v. Sanders*, 556 U.S. 396, 411 (2009); *see* Gov't MSJ at 46.

[14] Humana also suggests that the government was obligated to seek comment "on its interpretation of or reliance on the *UnitedHealthcare* decision." Opp. at 33. But that decision was not an independent basis for the RADV Rule; the government merely observed that its statutory interpretation was "consistent with the D.C. Circuit's decision." 88 Fed. Reg. at 6658.

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

In its opening brief, Humana argued that the RADV Rule was retroactive. Humana MSJ at 42–45. The government explained that it was not: extrapolated RADV audits are just a mechanism to enforce the pre-existing legal requirement of medical record documentation. Gov't MSJ at 46–47. Rather than disputing this directly, Humana points to passages from the Court's motion to dismiss opinion that do not prove its point. *See* Opp. at 38. The Court's conclusion that because of the RADV Rule "Plaintiffs will incur costs to change their actuarial calculations," ECF No. 36 at 9, recognized the cost of modeling recoveries from the new auditing regime as an injury-in-fact. But it did not suggest that the RADV Rule imposed new legal consequences for the submission of diagnoses unsupported by medical record documentation. It plainly did not.

The government also explained that it never had a policy "that any extrapolated RADV audit affecting Humana's existing Medicare Advantage contracts would incorporate an FFS Adjuster," as the insurer claimed, Humana MSJ at 44, but only that audits conducted according to the broad methodology set out in a 2012 guidance document would do so, *see* Gov't MSJ at 47.[15] In that document, CMS said that if its audit estimated a positive recovery, then "a preliminary payment recovery amount will be set at the lower bound" of a certain statistical confidence interval, and "CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount." GA 97. Quoting the same passage, Humana suggests that the government "promised to apply an FFS Adjuster to 'offset' <u>any</u> 'preliminary recovery amount.'" Opp. at 38. But the document said that an FFS Adjuster would "offset . . . <u>the</u> preliminary recovery

[15] "Audits for payment years 2011, 2012, and 2013" were "conducted according to th[e] methodology" set out in the 2012 guidance document, 83 Fed. Reg. at 55,038, though the government decided in the RADV Rule not to collect extrapolated recoveries. *See* 88 Fed. Reg. at 6654. Humana misunderstands the government to be arguing, contrary to this record, that the 2012 document was only intended to apply to a single year of audits. Opp. at 37–38.

amount" calculated at the previous step of its methodology and not, as Humana would have it, any preliminary recovery that it might calculate under any future methodology. GA 97 (emphasis added). For both of those reasons, the RADV Rule is not retroactive.

And even if the RADV Rule were retroactive, retroactive application is statutorily authorized if "the Secretary determines that . . . failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A), (ii). The Secretary has made that determination here, and Humana does not offer any basis for this Court to second guess it, nor any standard of review that would guide its inquiry. Certainly it was not arbitrary for the Secretary to determine that retroactive application of the RADV Rule "advances the public interest by protecting the overall integrity of the MA program." 88 Fed. Reg. at 6653.

Nor was it fundamentally unfair. *Cf.* Opp. at 40. "The core component of a RADV audit is ensuring that all diagnoses are properly supported by medical records." RADV Rule, 88 Fed. Reg. at 6653. Because insurers "have never been entitled to receive or retain payments associated with [diagnoses] that cannot be validated by medical records," retroactive application of the RADV Rule "would not upset any settled or reasonable reliance interests." *Id.*

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

Humana does not deny that the Court could afford it complete relief through an injunction prohibiting the enforcement of the RADV Rule against it. *See* Opp. at 41. Because such an injunction would afford complete relief, equitable principles favor its entry over a universal vacatur, if the Court finds that the RADV Rule was unlawfully adopted. *See* Gov't MSJ at 48–50.

CONCLUSION

For the reasons set forth above and in the government's cross-motion, summary judgment should be entered in its favor on all of the claims against it.

Respectfully submitted,

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