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

HUMANA INC., and HUMANA BENEFIT PLAN OF TEXAS, INC., Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	No. 4:23-cv-00909-O

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Civil Rule 56.3 of the United States District Court for the Northern District of Texas, Plaintiffs Humana Inc. and Humana Benefit Plan of Texas, Inc. (collectively, "Plaintiffs") respectfully move for summary judgment on all claims for relief in Plaintiffs' Complaint (ECF No. 1). Pursuant to Local Civil Rule 56.3(b), each of the matters required by Local Civil Rule 56.3(a) is set forth in the accompanying Brief in Support of Plaintiffs' Motion for Summary Judgment.

Plaintiffs respectfully request that the Court grant this motion and enter judgment in their favor.

Dated: October 7, 2024

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CERTIFICATE OF SERVICE

On October 7, 2024, a true and correct copy of the foregoing document was served upon all persons who have requested notice and service of pleadings in this case via the Court's CM/ECF system.

/s/ Timothy S. Durst
Timothy S. Durst

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BRIEF IN SUPPORT OF
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I. INTRODUCTION

The final agency action at issue in this case ("the Final Rule") threatens the future of a health benefits program that provides healthcare to more than 30 million seniors across the country. The Medicare Advantage program depends on private health insurers, known as Medicare Advantage Organizations or "MAOs," to offer Medicare benefits to seniors as an alternative to traditional Medicare. The program has been enormously popular and highly successful, producing better health outcomes and a broader array of benefits for seniors than they would receive under traditional Medicare.

When it created Medicare Advantage, Congress instructed the Centers for Medicare and Medicaid Services ("CMS") to fairly compensate MAOs like Plaintiffs Humana Inc. and Humana Benefit Plan of Texas, Inc., (collectively, "Humana") for the risks they assume in providing these Medicare benefits. Specifically, Congress required CMS "to ensure" that payments to MAOs are "actuarial[ly] equivalen[t]" to the payments the agency would expect to make to provide traditional Medicare benefits to the MAOs' enrollees. 42 U.S.C. § 1395w-23(a)(1)(C)(i).

The Final Rule departs from that command and undermines the actuarial foundation upon which Congress constructed the Medicare Advantage program. The Final Rule contends that although Congress required CMS to achieve actuarial equivalence between fee-for-service Medicare costs and MAO payments when it sets prospective payment rates for MAOs, the agency can lawfully disrupt that equivalence "after the fact" through its Risk Adjustment Data Validation ("RADV") audit program. CMS says these RADV audits—which, under the Final Rule, will statistically extrapolate the results of audit samples across an entire Medicare Advantage contract and thereby reduce contract-wide payments to MAOs—are exempt from the congressional command of actuarial equivalence. That purely legal conclusion is wrong, and CMS's rule

adopting it violates the Administrative Procedure Act's ("APA's") requirement that the agency comply with applicable law and provide a reasoned explanation for its policy choices.

The Final Rule represents a significant policy change. When CMS originally proposed to extrapolate RADV audit recoveries more than a decade ago, commenters pointed out that the inconsistency between the *unaudited* claims data used to set Medicare Advantage payment rates and the *audited* medical records used to calculate RADV audit recoveries would cause systematic underpayments to MAOs and thus disrupt actuarial equivalence. CMS publicly *endorsed that conclusion*, assuring MAOs that it would remedy the problem by applying a so-called "Fee-for-Service Adjuster" ("FFS Adjuster") to extrapolated RADV audits. In the 2018 Proposed Rule that preceded the Final Rule, CMS retracted that commitment based on an internal study purporting to show that the inconsistent documentation standards *would not* undermine actuarial equivalence. But that proposition crumbled during the APA's subsequent notice-and-comment period when actuarial and statistical experts demonstrated that the study actually proved systemic payment error *would* occur. In response, the Final Rule abandoned the study and adopted an entirely new position: that CMS could simply ignore its policy's actuarial defects because the actuarial-equivalence requirement does not even apply to these extrapolated RADV audits.

The Final Rule does not comply with the APA for two independent reasons. First, CMS's new, purely legal rationale for ignoring actuarial equivalence misreads the Medicare statute, and so is arbitrary and capricious and contrary to law. The statute's text, structure, and implementing regulations draw no distinction between actuarially unsound payment reductions that occur retrospectively and actuarially unsound payment reductions that occur prospectively. The statute requires CMS to honor actuarial equivalence *whenever* it adjusts population-level payments to MAOs based on health status—which extrapolated RADV audits indisputably do. While Humana

submits that the administrative record demonstrates conclusively that the Final Rule violates actuarial equivalence, it is not necessary for this Court to reach that question to resolve this case, and Humana does not ask the Court to do so. This APA action presents an antecedent question—whether CMS is correct that Congress exempted extrapolated RADV audit recoveries from the Medicare statute's actuarial-equivalence requirement. The agency's conclusion that the statute's actuarial-equivalence requirement does not apply to extrapolated RADV audits is both legally erroneous and arbitrary and capricious in violation of the APA. The Court should therefore vacate the Final Rule.

Second, putting aside the actuarial-equivalence mandate, the Final Rule offers no reasoned explanation for a policy change that threatens the actuarial soundness of a hugely important health benefits program. As public comments on the Proposed Rule explained, CMS's reversal of its position on the FFS Adjuster threatens harm to the Medicare Advantage program—not just underpayments to MAOs, but also higher premiums and reduced supplemental benefits for seniors. Even if the agency's assertion that the Medicare statute does not bar those harmful outcomes were correct, it would not furnish a rational reason to disregard them. The agency's failure to justify its new policy's consequences independently renders the Final Rule arbitrary and capricious.

Humana also contends that the Final Rule is procedurally defective under the APA because CMS failed to seek public comment on its newly offered rationale. This violation presents an alternative ground to vacate the Final Rule, regardless of the Court's ruling on the first two issues.

Only if the Court disagrees with Humana on these three claims for relief would it reach Humana's argument that the Final Rule's retroactive application of the new policy violates the APA. If the Court reaches this question and finds retroactive application improper, it should vacate

the Final Rule to the extent it applies retroactively or remand it to CMS with an order to eliminate the retroactive application.

Because the administrative record supporting the Final Rule does not justify CMS's unlawful agency action, Humana moves for summary judgment under Federal Rule of Civil Procedure 56. Humana respectfully asks the Court to grant this motion and set aside the Final Rule.[1]

II. LEGAL AND FACTUAL BACKGROUND

A. Medicare Advantage Program

For over five decades, the Medicare program has provided health insurance to Americans aged 65 or older, individuals suffering from serious long-term disabilities, and patients with end-stage renal disease. App. 008078. Parts A and B of the Medicare statute establish what is known as "traditional Medicare," often called "fee-for-service Medicare," under which CMS directly pays healthcare providers to treat Medicare beneficiaries. *See* 42 U.S.C. § 1395c *et seq.*; *id.* § 1395j *et seq.* Under Part C, also known as Medicare Advantage or MA, Medicare beneficiaries can instead choose to enroll in health plans offered by MAOs like Humana. *See id.* § 1395w-21 *et seq.* MAOs must provide Medicare Advantage enrollees at least the same benefits they would receive in fee-for-service Medicare. *See UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 886 (D.C. Cir. 2021). MAOs may also offer supplemental benefits, such as vision and dental benefits and prescription drugs. App. 008078.

This case concerns the methodology by which CMS compensates MAOs for the risks they assume to offer Medicare benefits to their enrollees. In establishing the Medicare Advantage program, Congress hoped to bring to Medicare "the health benefit design, delivery, and cost

[1] Throughout this brief, all emphasis is added and all internal quotation marks, alterations, and citations are omitted unless otherwise noted.

containment innovations that have occurred in the private sector."[2] Congress expected those efficiencies to be passed on to Medicare beneficiaries as MAOs competed to attract enrollees through superior benefits and lower costs. *See* 70 Fed. Reg. 4,588, 4,589 (Jan. 28, 2005). It designed the Medicare Advantage payment system to further these goals. App. 008459, 008469.

Under fee-for-service Medicare, CMS directly pays healthcare providers to treat Medicare beneficiaries. App. 008462. This fee-for-service model mostly reimburses providers retrospectively for each specific service rendered. *See* 42 U.S.C. § 1395ww(d)(1)-(4) (Part A); *id.* § 1395*l*(a)(1) (Part B). Under Medicare Advantage, by contrast, CMS prospectively pays MAOs a fixed monthly amount based on the cost that the agency estimates it would incur to provide fee-for-service Medicare benefits to the MAO's enrollee population. *See* 42 U.S.C. § 1395w-23. Medicare Advantage payments are not tethered to the volume of medical care enrollees ultimately consume, removing fee-for-service Medicare's incentive to provide unnecessary services. App. 008649. The program's fixed-payment structure also shifts financial risk to MAOs, which foot the bill when an enrollee consumes more medical services than anticipated but retain the savings when an enrollee consumes fewer services than expected. *See* 42 U.S.C. § 1395w-23.

The Medicare Advantage program has been a tremendous success: Just as Congress anticipated, Medicare Advantage plans today offer more comprehensive benefits and better clinical outcomes than fee-for-service Medicare, and 90 percent of MA beneficiaries express satisfaction with their health coverage. *See* App. 000963-64, 003866-67.

B. The Medicare Statute's Actuarial-Equivalence Requirement

In return for MAOs' commitment to provide at least the same benefits that enrollees would receive in fee-for-service Medicare, the Medicare statute requires CMS to "pay the same amount

[2] H.R. Rep. No. 105-217, at 585 (1997), https://www.congress.gov/105/crpt/hrpt217/CRPT-105hrpt217.pdf.

to Medicare Advantage insurers for their beneficiaries' care as CMS would spend on those same beneficiaries if they were instead enrolled in traditional Medicare." *UnitedHealthcare*, 16 F.4th at 883. The Medicare statute codifies this foundational bargain by ordering the agency to pay MAOs an amount "actuarial[ly] equivalen[t]" to the cost that CMS would expect to incur to provide fee-for-service Medicare benefits to those same enrollees. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

To "ensure actuarial equivalence," *id.*, Congress required CMS to develop and apply an actuarially sound method of "risk adjustment," *id.* § 1395w-23(a)(3). Risk adjustment maintains actuarial parity with costs in fee-for-service Medicare by adjusting payments to MAOs to account for differences in "enrollee health status and demographic factors," App. 008211-12, so that CMS pays MAOs "more to care for ill beneficiaries and less to care for healthy ones," App. 008483. The Medicare statute's actuarial-equivalence requirement applies whenever CMS "adjust[s] the payment amount . . . for such risk factors as age, disability status, gender, institutional status, and . . . health status." 42 U.S.C. § 1395w-23(a)(1)(C)(i).

C. Risk Adjustment, Medicare Advantage Bids, and the CMS-HCC Model

CMS implements this statutory command by measuring the costs associated with various risk factors in fee-for-service Medicare, *see* App. 008831, and then compensating MAOs based on the prevalence of those risk factors in their enrollee populations, App. 007836-37, 008008-09. CMS calculates its risk-adjusted payments to MAOs for each enrollee by multiplying two components: (1) a "base rate" representing the agency's estimate of the expected cost to provide fee-for-service Medicare benefits to an enrollee of average risk in a given locale, and (2) a "risk score" unique to each Medicare Advantage enrollee that accounts for that enrollee's actual demographic and health characteristics. App. 008009.

CMS sets base rates each year for Medicare Advantage payments through an annual

bidding process. *Id.* Every June, MAOs submit bids to the agency estimating the revenue needed to provide fee-for-service Medicare benefits to an enrollee of average risk in a given locale. *See* 42 U.S.C. § 1395w-24(a); 42 C.F.R. § 422.254(a)(1), (b). Each bid must be certified by a member of the American Academy of Actuaries, *see* 42 U.S.C. § 1395w-24(a)(6)(A)(iii); 42 C.F.R. § 422.254(b)(5), and CMS must confirm that the bid is based on sound actuarial estimates, *see* 42 U.S.C. § 1395w-24(a)(6)(B)(ii); 42 C.F.R. § 422.256(b). CMS compares each MAO's bid to an agency-created benchmark for the relevant geographic area to determine the base rate. 42 U.S.C. § 1395w-23(a)(1)(B)(i), (ii) .

The agency then calculates risk scores for each Medicare Advantage enrollee using a risk-adjustment methodology called the "CMS-HCC Model." App. 008009-10, 008030-31. To measure and classify enrollees' health risks, CMS uses standardized "diagnosis codes" associated with different health conditions. App. 008831. The agency groups these codes into "Hierarchical Condition Categories," or "HCCs," each of which represents a set of related health conditions. App. 008030. To quantify the "expected medical expenditures"—the risk—associated with each HCC, CMS analyzes claims for payment ("claims data") that healthcare providers submitted to fee-for-service Medicare for medical care rendered to beneficiaries. App. 008831. Based on that calculation, the agency assigns a coefficient to every HCC. *Id.* The coefficients for a Medicare Advantage enrollee's reported health conditions can be added together, along with demographic and other risk coefficients, to calculate the enrollee's risk score. App. 007782-83. CMS normalizes the coefficients so that the average fee-for-service Medicare beneficiary will have a risk score of 1.0. App. 007782.

In a simplified example, a 74-year-old man whose healthcare providers submit diagnosis codes to his MAO for diabetes with chronic complications, congestive heart failure, and acute

myocardial infarction would have a risk score of 1.920. App. 008230. That risk score reflects CMS's estimate that his healthcare expenses will be 92 percent (0.920) higher than the average fee-for-service Medicare beneficiary. *Id.*[3]

Risk Score	Risk Coefficient
Male, age 70-74	0.597
Diabetes with chronic complications (HCC 18)	0.344
Congestive heart failure (HCC 85)	0.355
Acute myocardial infarction (HCC 86)	0.410
Interaction between diabetes and congestive heart failure	0.214
Total Risk Score	**1.920**

If the Medicare Advantage plan's base rate in this example were $1,000 per month, CMS would pay the MAO that administers the plan a monthly amount of $1,920 for this enrollee—the $1,000 base rate multiplied by the enrollee's risk score of 1.920. *See* App. 008010.

Each year, CMS publishes the HCC coefficients it will use to risk adjust payments. *See* 42 U.S.C. § 1395w-23(b)(1)(B)(i). MAOs rely on these published coefficients to calculate the centerpiece of their bids: the revenue required to provide fee-for-service Medicare benefits to an enrollee with an average risk score. App. 003711; 42 U.S.C. § 1395w-24(a)(6)(A)(i). In so doing, the MAOs' actuaries must account for the documentation standard used to create those coefficients. *See* App. 003711. In particular, CMS has chosen to measure the costs associated with each HCC based entirely on the diagnosis codes that fee-for-service Medicare providers report to the agency in claims for payment—CMS does not uniformly or even routinely audit the reported diagnosis codes to confirm that they are documented in beneficiaries' medical records.

[3] CMS included this hypothetical example in a December 2018 report to Congress based on then-applicable risk factors. App. 008200, 008230. For simplicity, this reproduction omits three HCCs that do not contribute to this hypothetical enrollee's risk score. *See* App. 008230.

App. 003700. The agency's calculation thus measures the expected cost associated with a fee-for-service Medicare provider's *reporting* of the diagnosis code, rather than the cost associated with medical conditions *documented* in the beneficiary's medical record. *Id.* That distinction has substantial actuarial implications, *see infra* at 12-15, which MAOs must consider when estimating the revenue needed to offer fee-for-service Medicare benefits to a prospective enrollee with an average risk score. App. 003711-12.

D. The Coding-Intensity Adjustment

Because fee-for-service Medicare providers are paid based on services they render to beneficiaries rather than diagnosis codes they report to CMS, they have "no incentive to report more than one" diagnosis code. App. 008872; *see also* App. 008759; App. 000771 (noting that MAOs "may be coding more completely" than fee-for-service Medicare providers).[4] MAOs, on the other hand, are incentivized to "find and report as many diagnoses as can be supported by the medical record" and thereby "legitimately increase [their enrollees'] risk scores" to reflect the full risk they bear. App. 008872-73. Shortly after CMS implemented its risk-adjustment model, Congress grew concerned that this asymmetrical incentive structure could result in "risk scores that are [not] consistent across both fee-for-service and Medicare Advantage settings," disrupting actuarial equivalence between the two programs. 152 Cong. Rec. H54 (daily ed. Feb. 1, 2006)

[4] The Court may take judicial notice of the 2009 Advance Notice and the other official, publicly available government documents cited herein (*see* App. 000009-000725) under Federal Rule of Evidence 201(b)(2) as not "subject to reasonable dispute because [they] . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *See, e.g.*, *Texas v. Cardona*, 2024 WL 3658767, at *41 n.135 (N.D. Tex. Aug. 5, 2024) (taking judicial notice of "the Department's April 29, 2024 Final Rule"); *NAACP v. Trump*, 298 F. Supp. 3d 209, 248 & n.32 (D.D.C. 2018) (taking judicial notice of an agency's FAQ website that did not appear in the administrative record); *Grant v. Dep't of Treasury*, 194 F. Supp. 3d 25, 28 n.2 (D.D.C. 2016) (finding that "the Administrative Judge's Initial Decision, Treasury's Final Agency Decision, and MSPB's Final Order are official, public documents subject to judicial notice").

(statement of Rep. Thomas); *see* 152 Cong. Rec. S438 (daily ed. Feb. 1, 2006) (statement of Sen. Grassley) (same); *see also* App. 007752 (CMS rate notice quoting Senator Grassley's statement); App. 008415.

Thus, in 2006, Congress instructed CMS to "conduct an analysis" of the "differences in coding patterns between Medicare Advantage plans and [fee-for-service Medicare] providers." Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5301(b), 120 Stat. 4, 51 (2006). CMS determined in 2009 that such differences existed, and that those differences warranted an across-the-board downward adjustment of Medicare Advantage enrollee risk scores to "better assure financial neutrality" between the two programs. App. 007750-52, 007759. Congress responded in 2010 by amending the Medicare statute to require a downward adjustment to Medicare Advantage risk scores, commonly called the Coding-Intensity Adjustment. *See* Health Care & Education Reconciliation Act, Pub. L. No. 111-152, § 1102(e), 124 Stat. 1029, 1046 (2010).

The Coding-Intensity Adjustment "does not . . . address unsupported . . . [diagnosis] codes reported by Medicare Advantage insurers, but only the practice, relative to traditional Medicare, of overreporting [diagnosis] codes that are nonetheless accurate." *UnitedHealthcare*, 16 F.4th at 877. CMS has consistently and repeatedly maintained that the Coding-Intensity Adjustment and RADV audits address distinct issues. App. 003708. For example, in 2010, CMS denied that the Coding-Intensity Adjustment was "duplicative of any RADV audit-related adjustments" or that the agency was "double counting the impact of inaccurate [diagnosis] coding," and publicly stated that—unlike RADV audits—the Coding-Intensity Adjustment was "not intended to adjust for inaccurate coding." App. 007776-77; *accord, e.g.,* App. 000648 ("[S]ection 1853(a)(1)(C)(ii) addresses the incentive for all [MAOs] to identify more valid, supported codes on all HCCs, and therefore report more diagnoses . . . .").

E. Extrapolated RADV Audits and the FFS Adjuster

The Medicare statute does not prescribe a specific documentation standard for the Medicare Advantage risk-adjustment system. CMS specified a documentation standard through sub-regulatory guidance, asserting that MAOs are not entitled to payment for diagnosis codes that are not documented in enrollees' medical records. App. 007780-81. But MAOs "must obtain the risk adjustment data" they submit to CMS "from the provider . . . that furnished the item or service," 42 C.F.R. § 422.310(d)(1), and do not typically receive the underlying medical records from healthcare providers, *see* App. 007784. Accordingly, the agency has always recognized that MAOs "cannot reasonably be expected to know that every piece of data is correct." 65 Fed. Reg. 40,170, 40,268 (June 29, 2000). It requires MAOs only to "mak[e] good faith efforts to certify" that the diagnosis codes they submit to the agency are "accura[te], complete[], and truthful[]" based on their "best knowledge, information, and belief." *Id.*; *see also* 42 C.F.R. § 422.504(*l*).

CMS periodically conducts RADV audits to "validat[e]" the diagnosis codes MAOs submit to the agency. 42 C.F.R. § 422.310(e). According to CMS, RADV audits "ensure[] the integrity and accuracy of risk adjustment payment data," 42 C.F.R. § 422.2, thereby "further[ing] actuarial equivalence," App. 007380. Each year, the agency audits a subset of Medicare Advantage contracts and requires the MAOs that administer those contracts to submit medical records for a sample of their enrollees. *See* App. 007344; 42 C.F.R. § 422.310(e). CMS then evaluates whether the medical records document the diagnosis codes reported for those enrollees. App. 007344.

For many years after launching RADV audits in 1999, CMS recouped only the payments corresponding to specific diagnosis codes within the audited sample that it concluded were inadequately documented by medical records. App. 007344-45. For example, if a RADV audit found that the medical records of the 74-year-old man described *supra* at 8 did not adequately support the diagnosis code for congestive heart failure (HCC 85), CMS would recoup from the

MAO only a payment equal to $355 per month—the base rate of $1,000 multiplied by 0.355, the risk coefficient of the undocumented congestive heart failure.

In 2010, CMS announced that it would start using RADV audits to calculate "payment error estimate[s]" for the entire enrollee population of the audited Medicare Advantage contract—and to recover extrapolated contract-wide repayments based on those estimates. App. 007409-11. Under this new proposal, CMS would still audit diagnosis codes for only a sample of a contract's enrollees, but would use the results to recoup an extrapolated payment associated with the statistically estimated rate of undocumented diagnosis codes for the entire contract. App. 007411.

Commenters identified a critical flaw in this approach. Humana and others explained that the agency's proposal was "actuarially unsound . . . because it would simultaneously use two very different sets of data to measure diagnoses—non-validated [fee-for-service Medicare] Claims Data" for "the development of payment rates," and "validated [Medicare Advantage] Claims Data"—documented in medical records—"on the back end of [the RADV] audit[]." App. 007493. In other words, CMS's proposal would estimate the agency's costs associated with a given diagnosis code based on *claims forms* submitted by fee-for-service Medicare providers, but would pay audited MAOs based only on diagnosis codes *documented in the enrollees' medical records*. *See* App. 001702; App. 001686-87. Humana and others explained that these inconsistent documentation standards would systematically underpay audited MAOs by dividing the fee-for-service Medicare expenses associated with a given HCC across a larger pool of Medicare beneficiaries (*i.e.*, those for whom a diagnosis code had been reported in a claim form), resulting in lower coefficients—but then applying those lower payment rates to fewer Medicare Advantage enrollees (*i.e.*, only those for whom a diagnosis code was documented in the medical record). *See, e.g.*, App. 003726; App. 007493.

The American Academy of Actuaries agreed, warning CMS that this "type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities." App. 007625. The next year, the Actuarial Standards Board adopted an authoritative Actuarial Standard of Practice requiring that the "type of input data that is used in the application of [a] risk adjustment [model] . . . be reasonably consistent with the type of data used to develop the model." App. 008898.

The actuarial problem inherent in this inconsistent documentation standard would also mean that MAOs' previous bids no longer reflected the true risk they accepted. App. 007529. If those earlier bids had accounted for the revenue reduction resulting from such RADV audits, they "would have been substantially higher, resulting in higher member premiums and/or fewer supplemental benefits offered to members." *Id*. Again, the American Academy of Actuaries agreed, noting that "the uncertainty related to a plan's ultimate post-audit risk score could make it difficult for actuaries to . . . certify the plan bid" as the Medicare statute requires. App. 007625.

CMS acknowledged this problem internally. CMS documents show the agency *knew* that setting risk coefficients using unaudited fee-for-service Medicare claims data—which include diagnosis codes "for beneficiaries who don't actually have the disease, or for whom the medical record documentation is not clear"—"*tends to reduce the estimated average costs of various conditions* and therefore our [Medicare Advantage] risk adjustment factors." App. 001703. One internal agency document illustrated the problem using four hypothetical fee-for-service Medicare beneficiaries whose healthcare providers reported a diagnosis code for diabetes to CMS, but only three of whose medical records documented such a code, App. 001688:

Why does FFS Diagnosis Error Matter?

	Diabetes on Claim?	Diabetes in medical record?	FFS Cost
Beneficiary A	Yes	Yes	$4000
Beneficiary B	Yes	Yes	$4000
Beneficiary C	Yes	Yes	$4000
Beneficiary D	Yes	No	$0
		Total	$12,000
		Diabetes Value for MA payment	$3,000

This illustration shows that by using diagnosis codes reported in claims forms to estimate how much fee-for-service Medicare would pay for these beneficiaries—the "Diabetes on Claim?" column—but medical records to make payments to MAOs—the "Diabetes in medical record?" column—CMS would depress the average expected cost associated with a diabetes diagnosis code by 25 percent, from $4,000 to $3,000. *Id*. If the agency had instead chosen to use diagnosis codes *documented in medical records* to calculate the risk coefficient for diabetes and also paid the MAO only for enrollees with diagnosis codes documented in the medical records, it would calculate a $4,000 average cost per enrollee and pay the MAO that amount for three enrollees—a total of $12,000. Similarly, if CMS used only the diagnosis codes *reported* in fee-for-service Medicare claims data to calculate the risk coefficient and paid the MAO for all enrollees *reported* to have diabetes diagnosis codes without regard to the enrollees' medical records, it would calculate a $3,000 average cost and pay the MAO that amount for four enrollees—also a total of $12,000. Under either scenario, the agency's payments to MAOs and anticipated fee-for-service Medicare costs for the same population would be equivalent.

But as CMS acknowledged internally, its 2010 proposal—to use diagnosis codes *reported* in claim forms by fee-for-service Medicare providers to calculate risk coefficients while paying

audited MAOs only for diagnosis codes *documented* in enrollees' medical records—would have calculated a $3,000 average cost for diabetes diagnosis codes and paid that amount for only three enrollees, for a total of just $9,000. App. 001689. This scenario would have resulted in the agency paying the MAO $3,000 *less* than CMS would pay for the same four beneficiaries' fee-for-service Medicare benefits, as reflected in the right-most column in the CMS chart below:

Why does FFS Diagnosis Error Matter?

	Diabetes reported by MA plan?	Diabetes in medical record?	CMS Payment to Plan	Plan Cost	RADV	CMS Payment to Plan
Beneficiary A	Yes	Yes	$3000	$4000		$3000
Beneficiary B	Yes	Yes	$3000	$4000		$3000
Beneficiary C	Yes	Yes	$3000	$4000		$3000
Beneficiary D	Yes	No	$3000	$0	($3000)	$0
Beneficiary E	Yes	No	$3000	$0	($3000)	$0
		Total	$15,000	**$12,000**	($6,000)	**$9,000**

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CMS thus concluded internally that it could not use "one documentation standard for RADV, which is perfection," and "another documentation standard for risk adjustment, which reflects a certain level of [fee-for-service Medicare] codes that aren't documented in a medical record." App. 001702. The agency reasoned that "[f]or our payments to be as accurate as possible, we should be using the same standard for both." *Id.*

To remedy this actuarial defect, CMS considered an FFS Adjuster that would "offset . . . recovery amounts under RADV" audits to account for diagnosis codes in fee-for-service Medicare claims data not documented in beneficiaries' medical records. App. 001690. By "tak[ing] into account how CMS payments would change if [the] perfection standard that is applied under RADV was also used when calculating risk adjustment model values," this FFS Adjuster would "[e]nsure[] that RADV and [Medicare Advantage prospective] payments are on the same

documentation standard." *Id.* Given the underpayments threatened by this inconsistent documentation standard, the agency concluded that the FFS Adjuster "makes sense and from a technical point of view is the right thing to do." App. 001703.

In February 2012, CMS issued a notice that publicly adopted the FFS Adjuster in a revised RADV audit methodology, which recognized "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)," and promised to "account[] for" that difference using the FFS Adjuster. App. 007703-04. CMS stated that it would calculate the FFS Adjuster "based on a RADV-like review of records submitted to support [fee-for-service Medicare] claims data," and would apply it "as an offset" to any payments that it recovered in extrapolated RADV audits. *Id.*

In the years that followed the 2012 notice, Humana expressly premised its Medicare Advantage bids on CMS's representation that it would apply an FFS Adjuster in extrapolated RADV audits and structured its business in reliance on the agency's commitment. App. 003711.

III. PROCEDURAL HISTORY

A. The Proposed Rule Reverses Policy on the FFS Adjuster Based on a New Study.

For more than six years after announcing the FFS Adjuster, CMS said nothing else publicly or to Humana about how the FFS Adjuster would function. *See* App. 003696, 000726-007341. Then in 2018, the agency unexpectedly backtracked, issuing a Proposed Rule retracting the FFS Adjuster. *See* App. 000726-32. This reversal occurred during APA litigation over a different Medicare Advantage regulation (the "Overpayment Rule"), which required MAOs to return any funds received for individual diagnosis codes that the MAO *knew* were not documented in the enrollees' medical records. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018). The U.S. District Court for the District of Columbia vacated the Overpayment

Rule on September 7, 2018, on the ground that it violated the Medicare statute's mandate of actuarial equivalence. *Id.* at 186-87. In support of its holding, the court pointed to the same inconsistent documentation standard at the heart of the RADV dispute and concluded that the double standard would "inevitabl[y]" undercompensate MAOs. *Id.* at 184-87.

The November 2018 Proposed Rule announced that CMS would not apply an FFS Adjuster to extrapolated RADV audit recoveries, relying on a new CMS study purportedly showing that undocumented diagnosis codes in fee-for-service Medicare claims data do not "bias" payments to MAOs. App. 000731, 007388. The agency further stated that even if such a bias existed, the FFS Adjuster would inappropriately "introduce inequities between audited and unaudited" MAOs "by only correcting the payments made to audited" MAOs. App. 000731. CMS did not initially release the study or its underlying data, nor did the agency's Chief Actuary certify the study, as required by agency guidelines. App. 003748-49, 003774. But the agency immediately invoked the study's conclusions to seek reconsideration of the order invalidating the Overpayment Rule, which the district court denied. *UnitedHealthcare Ins. Co. v. Azar*, 2020 WL 417867, at *4 (D.D.C. Jan. 27, 2020). The D.C. Circuit later reversed, holding that actuarial equivalence does not apply to the Overpayment Rule, but the court also observed—as discussed *infra*—that RADV audits are "plainly distinguishable" from recoupments for individual diagnosis codes that MAOs learn are not documented in their enrollees' medical records. *UnitedHealthcare*, 16 F.4th at 871, 893 n.1.

In response to the Proposed Rule, a host of commenters noted that CMS had not provided adequate information about the study to permit meaningful review. *See, e.g.*, App. 000746, 000793-94, 001004, 001061, 001214. The agency then released some data, but eventually admitted that it had lost key outputs of the study and would need to replicate its analysis. *See* App. 000740. In June 2019, CMS released the new study, reasserting that "diagnosis error in . . . FFS

[claims] data does not" lead to systematic "payment bias" in the Medicare Advantage program. App. 007408.

Commenters, including Humana, explained how a series of methodological errors by the agency *guaranteed* that its study would produce the finding of no payment bias that the agency needed in the Overpayment Rule litigation, regardless of what the underlying data actually showed. *See* App. 001561-62, 003716-28, 004219-20, 005207-34. Among other methodological flaws, CMS had drastically underestimated the rates of diagnosis codes in fee-for-service Medicare claims data not documented in medical records and had introduced a statistically inexplicable "adjustment" that was apparently designed to erase any payment bias the study would have otherwise detected. *See* App. 003722-24. When expert actuaries retained by Humana replicated CMS's analysis and corrected these errors, they found that diagnosis codes lacking medical-record documentation in fee-for-service Medicare claims data would systemically deflate Medicare Advantage payment rates by at least 9.9 percent. *See* App. 003750, 003761; *see also* App. 003663-66.

B. The Final Rule Abandons the Study and Relies on an Entirely Different, Purely Legal Rationale to Support CMS's New Policy Rejecting the FFS Adjuster.

CMS published its Final Rule on February 1, 2023, "finalizing that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings," beginning retroactively with payment year 2018. App. 007342-43; *see* App. 007342-64. The agency further confirmed that it was "finalizing a policy whereby CMS will not apply an FFS Adjuster in RADV audits." App. 007343.

The Final Rule abandoned both of the Proposed Rule's rationales for eliminating the FFS Adjuster. CMS disavowed the study that had been the Proposed Rule's chief justification, acknowledging its "inherent limitations." App. 007358. The agency likewise declined to rely on

the Proposed Rule's only other rationale for discarding the FFS Adjuster—the contention that applying an FFS Adjuster would somehow "introduce inequities between audited and unaudited plans." App. 000731. Rather than defend the actuarial soundness of its new policy, the agency declared that "[e]ven if systematic payment error exists"—that is, even if the inconsistent documentation standard does in fact undercompensate MAOs—an FFS Adjuster was not required because that systematic under-compensation "does not impact the requirement that submitted [diagnosis codes] must be adequately supported by medical records." App. 007358. The agency offered two new, purely legal rationales for that conclusion.

First, the Final Rule relied on the D.C. Circuit's decision in the Overpayment Rule litigation, *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), to conclude that extrapolated RADV audits need not comply with the Medicare statute's actuarial-equivalence requirement. App. 007343. Although *UnitedHealthcare* did not involve RADV audits, CMS asserted that the decision was "consistent with" the proposition "that the actuarial equivalence provision of the [Medicare] statute applies only to how CMS risk adjusts the payments it makes to MAOs and not to the obligation of MAOs to return improper payments (for example, payments for unsupported diagnosis codes)." *Id.* CMS did not address or even mention the D.C. Circuit's observation that the RADV audit context is "materially distinct" from payment recoveries under the Overpayment Rule. *UnitedHealthcare*, 16 F.4th at 892. The agency never sought public comment on *UnitedHealthcare*'s significance to the Proposed Rule. App. 007338-41.

Second, CMS cited the Coding-Intensity Adjustment to support its new position. The agency concluded that "it would be unreasonable to interpret the [Medicare] Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial-equivalence provision) from

enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits)." App. 007355. While the Final Rule repeated this assertion several times, App. 007343, 007355-57, 007359, it never once explained *why* such a reading would be unreasonable, or the relevance of the Coding-Intensity Adjustment to RADV audits or actuarial equivalence. Nor did the Final Rule acknowledge CMS's previous statements that the Coding-Intensity Adjustment was not "duplicative of any RADV audit-related adjustments" and that the Coding-Intensity Adjustment and RADV audit recoveries would not "double count[] the impact" of diagnosis codes not documented in the medical record because the Coding-Intensity Adjustment is "not intended to adjust for inaccurate coding." App. 007776-77.

While CMS stated that it "do[es] not agree" with commenters' concerns that the Final Rule would create an actuarially unsound discrepancy between fee-for-service Medicare and Medicare Advantage payments, it made no serious attempt to respond to those comments; it merely asserted, without explanation, that the comments were "not adequate[]" to overcome its disagreement. App. 007358. The agency did not address comments stating that the Final Rule would require MAOs to increase enrollee premiums and reduce supplemental benefits, and that the retroactive application of the new audit policy would expose MAOs to unanticipated liabilities at odds with the agency's past promises. *See* App. 001223, 002392-429 (Winkelman Actuarial Report), 003717-19, 004218, 005202-05.

C. Humana's Claims for Relief Under the APA

Humana filed suit on September 1, 2023, challenging the Final Rule under the APA. Humana's three claims for relief assert that: (1) the Final Rule is arbitrary and capricious and contrary to law because it reverses CMS's prior policy on the FFS Adjuster without an adequate explanation, relying solely on legal justifications that misinterpret the Medicare statute, ECF No. 1, ¶¶ 72-77; (2) CMS promulgated the Final Rule without observance of procedure required by

law, *id.* ¶¶ 88-91; and (3) CMS acted contrary to law and abused its discretion in deciding to apply the new policy retroactively beginning in payment year 2018, *id.* ¶¶ 71, 78-87.

IV. LEGAL STANDARD

A. Administrative Procedure Act

This Court must "hold unlawful and set aside" agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction [or] authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D). An agency's statutory interpretations deserve no deference; the "[C]ourt shall decide all relevant questions of law" and "interpret . . . statutory provisions" by "applying [the Court's] own judgment." *Rest. L. Ctr. v. U.S. Dep't of Labor*, 115 F.4th 396, 403 (5th Cir. 2024) (quoting 5 U.S.C. § 706 and *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261 (2024)).

B. Summary Judgment

"Summary judgment is appropriate when 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Rest. L. Ctr.*, 115 F.4th at 403 (quoting Fed. R. Civ. P. 56(a)). In APA cases, summary judgment is the "mechanism for deciding . . . whether, as a matter of law, the evidence in the administrative record permitted the agency to make the decision it did." *Mock v. Garland*, 2024 WL 2982056, at *2 (N.D. Tex. June 13, 2024) (O'Connor, J.).

V. ARGUMENT

A. The Final Rule Is Contrary to Law and Arbitrary and Capricious Under the APA Because CMS Has Provided No Legally Sound Rationale for the Agency's Reversal of Its Prior Policy Requiring an FFS Adjuster for Extrapolated RADV Audits.

The Final Rule is contrary to law and arbitrary and capricious because CMS relied solely on incorrect legal conclusions—that the Medicare statute's actuarial-equivalence requirement does

not apply to extrapolated RADV audits and that the Coding-Intensity Adjustment somehow excuses CMS from applying an FFS Adjuster. *See* 5 U.S.C. § 706(2)(A), (C). The Final Rule is also arbitrary and capricious because, even if the agency's legal conclusions were correct, CMS did not explain why it was reasonable to abandon the FFS Adjuster. *See id.* § 706(2)(A).

1. The Medicare Statute's Actuarial-Equivalence Requirement Applies to Extrapolated RADV Audits.

CMS's primary justification for the Final Rule is that extrapolated RADV audits are not governed by the Medicare statute's "actuarial equivalence" requirement—and need not satisfy actuarial principles—because they occur "after the fact" of the agency's initial payments to MAOs. App. 007343, 007355. This legal conclusion clashes with the Medicare statute's plain text, which subjects *any* population-level payment "adjustment" based on "health status" to the actuarial-equivalence mandate. 42 U.S.C. § 1395w-23(a)(1)(C)(i). It conflicts with the statute's structure, which establishes a comprehensive system to achieve actuarially sound Medicare Advantage payments. And it ignores CMS's own regulations, which treat RADV audits as just one component of the broader risk-adjustment system governed by the actuarial-equivalence requirement.

CMS rests its novel statutory reading on the D.C. Circuit's *UnitedHealthcare* decision, which held that actuarial equivalence does not apply to the Overpayment Rule. App. 007342-43. The agency theorizes that actuarial equivalence does not apply to extrapolated RADV audits because, like the Overpayment Rule, such audits implicate "the obligation of MAOs to return improper payments." *Id.* That self-serving reading ignores the reasoning of *UnitedHealthcare*, which confirmed that actuarial equivalence applies to population-level payment adjustments and expressly distinguished RADV audits from the Overpayment Rule.

i. The Medicare statute's plain text, statutory structure, and regulatory context all demonstrate that the statute's actuarial-equivalence requirement applies to extrapolated RADV audits.

The actuarial-equivalence requirement applies to extrapolated RADV audits, which result in population-level payment "adjustments" based on enrollees' "health status" and fundamentally impact the actuarial soundness of risk adjustment in Medicare Advantage. 42 U.S.C. § 1395w-23(a)(1)(C)(i). The statutory text, structure, and regulatory context all confirm that conclusion.

a. Statutory Text. This Court's starting point, "[a]s always," is the statutory text. *Campos-Chaves v. Garland*, 144 S. Ct. 1637, 1647 (2024). The Medicare statute requires CMS to "adjust the payment amount" under 42 U.S.C. § 1395w-23(a)(1)(A)(i) and (B)(i)-(iii)—the monthly payments CMS makes to MAOs—"for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . *so as to ensure actuarial equivalence*." *Id.* § 1395w-23(a)(1)(C)(i).

As a textual matter, the analysis is straightforward: Like risk scores, extrapolated RADV audits "adjust the payment amount" to an MAO based on the "health status" of a Medicare Advantage plan's enrollee population, and so are subject to actuarial equivalence. *Id.* Extrapolated RADV audits purport to more accurately measure the "health status" of a Medicare Advantage plan's enrollee population by statistically estimating the likelihood that diagnosis codes submitted to CMS are documented in enrollees' medical records. The Final Rule proposes to "adjust . . . payment[s]" to the MAO by recouping payments corresponding to the diagnosis codes that CMS expects to be—in its estimate—inadequately documented in the enrollees' medical records across the *entire contract population*. App. 007345. Such an audit would thus "make" the agency's

payments to the MAO for an audited contract "correspondent or conformable"[5] to what CMS determines, through the audit, to be the "health status" of the enrollee population. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Or, as CMS has previously put it, RADV audits "further[] actuarial equivalence" by ensuring the "accuracy" of the data that determines payments to MAOs and permitting corresponding "adjustments" to those payments. App. 007380.

The Final Rule asserts that extrapolated RADV audits are exempt from the actuarial-equivalence requirement because they occur "after the fact" of CMS's prospective payments to MAOs. App. 007355. But the statutory language does not differentiate based on timing. RADV audits occur "retrospectively" only because, as a practical matter, "CMS cannot confirm in real time the data insurers submit for their millions of beneficiaries." *UnitedHealthcare*, 16 F.4th at 877. That practical constraint does not meaningfully distinguish extrapolated RADV audits from other adjustments the agency could perform *before* payment, such as using the results of previous audits to impose across-the-board payment adjustments or performing audits before finalizing payments to MAOs. Nothing in the statutory text suggests that Congress intended to allow CMS to dodge its obligation to ensure actuarial equivalence simply by structuring a payment adjustment to occur "after the fact." The statute specifies function, not timing—*all* population-level "adjust[ments]" to MAOs' "payment amount[s]," retrospective or otherwise, are subject to the actuarial-equivalence mandate. 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Courts interpreting statutory requirements regularly decline to judicially affix the sort of unwritten temporal limitation for which CMS argues. *See, e.g.*, *Gallardo By & Through Vassallo v. Marstiller,* 596 U.S. 420, 429 (2022) (interpreting statutory provision granting "any rights . . .

[5] *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("to make correspondent or conformable"; "to bring the parts of to a true or more effective relative position").

to payment for medical care" to cover "not only rights to payment for past medical expenses, but also rights to payment for future medical expenses"); *United States v. Cortez-Gonzalez*, 929 F.3d 200, 203 (5th Cir. 2019) (declining to impute temporal limitation concerning *when* a conviction occurred, where "plain text" of sentencing guideline imposed no such limit); *Rest. L. Ctr.*, 115 F.4th at 409 (rejecting regulation containing "temporality requirement . . . found nowhere in the statute"). The Court should do the same here and reject CMS's attempt to impose an atextual temporal limitation on the statute's actuarial-equivalence requirement.

b. Statutory Structure. CMS's attempt to exempt RADV audits from the actuarial-equivalence requirement also conflicts with other provisions in the Medicare statute. The statute works as a whole to accomplish Congress's objective of creating an actuarially sound system of risk adjustment. The Final Rule would permit CMS to nullify that actuarial soundness, and so cannot be reconciled with the broader system Congress devised.

The actuarial-equivalence requirement has been a part of the Medicare statute since Congress created Medicare Part C, and it serves as the cornerstone of the program's risk-adjusted payment system. Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 299 (1997). The "'goal of risk adjustment' is 'to pay [Medicare Advantage] plans accurately.'" *UnitedHealthcare*, 16 F.4th at 873-74 (citing 152 Cong. Rec. S438-02 (daily ed. Feb. 1, 2006) (statement of Sen. Grassley)) (alteration in original). By mandating payments equivalent to the costs that CMS would expect to incur for an MAO's enrollees in fee-for-service Medicare, the statute ensures that the two programs' costs are aligned and that MAOs are not just adequately compensated, but "reward[ed] . . . to the extent that they achieve genuine efficiencies over traditional Medicare in addressing the same health conditions." *Id.* at 874.

The actuarial-equivalence requirement's foundational command anchors a host of

mechanisms Congress adopted to ensure the actuarial soundness of the Medicare Advantage program relative to fee-for-service Medicare. To start, Congress required that "an outside, independent actuary" evaluate "the actuarial soundness" of the risk-adjustment system CMS established to satisfy actuarial equivalence. 42 U.S.C. § 1395w-23(a)(3)(A). The agency must continually fine-tune that system based on data from fee-for-service Medicare, preserving the actuarial equivalence between the programs by "using the same methodology as is expected to be applied in making payments" to MAOs. *Id.* § 1395w-23(b)(4)(D).

In turn, Congress requires MAOs to base their bids on fee-for-service Medicare data and risk coefficients provided by CMS, directly linking estimated fee-for-service Medicare expenditures to bids and resulting risk-adjusted payments. The agency—acting through its Chief Actuary—must publish key information such as total per-capita fee-for-service expenditures and average risk factors based on reported fee-for-service diagnoses, *see id.* § 1395w-23(b)(4)(A), (B), which permits MAOs to construct actuarially sound bids that include the estimated costs of providing fee-for-service Medicare benefits to an average-risk beneficiary. Consistent with that data, MAOs' annual bid submissions must describe the "actuarial basis" for their bids, *id.* § 1395w-24(a)(6)(A)(iii), and the agency's Chief Actuary then reviews the actuarial assumptions and data in those bids to determine their "appropriateness," *id.* § 1395w-24(a)(5)(A). Finally, before making payments to MAOs, Congress requires CMS to apply the Coding-Intensity Adjustment, reducing enrollee risk scores by a predetermined percentage, *id.* § 1395-w23(a)(1)(C)(ii), to further improve "financial neutrality" between payments to healthcare providers in fee-for-service Medicare and payments to MAOs, *see* App. 007750-51, 007759. In short, the Medicare statute contemplates that, at every step, payments in the Medicare Advantage program reflect, in an actuarially sound manner, the expenditures CMS would expect to make to provide fee-for-service

Medicare benefits to an MAO's enrollees.

CMS argues that the statute requires actuarial soundness at the outset of the payment process, but allows the agency to later change those payments in a manner that introduces "systematic payment error," negating the important work done by these interlocking actuarial requirements. App. 007355, 007358. Nothing in the structure or design of the Medicare statute supports that conclusion and the Court should not lightly assume that Congress drafted this statute "to be so at war with itself." *Santos-Zacaria v. Garland*, 598 U.S. 411, 429 (2023). RADV audits are simply one component of a multi-step, congressionally mandated process that seeks to align Medicare Advantage payments with fee-for-service Medicare costs for similarly situated populations. Allowing such audits to negate the same actuarial equivalence that Congress undisputedly required at every preceding step would undermine the statute's clear objectives, infecting MAO compensation with the kind of "systemic payment error" that a host of adjacent statutory provisions seek to prevent. App. 007355, 007358. That interpretation is illogical. *See Clark v. Uebersee Finanz-Korporation, A.G.*, 332 U.S. 480, 489 (1947) (declining to "impute to Congress a purpose to paralyze with one hand what it sought to promote with the other"); *United States v. Braxtonbrown-Smith*, 278 F.3d 1348, 1352 (D.C. Cir. 2002) ("[T]he court must avoid an interpretation that undermines congressional purpose considered as a whole when alternative interpretations consistent with [it] are available.").

c. Regulatory Structure. The context of the regulation authorizing RADV audits, 42 C.F.R. § 422.310(e), also confirms that extrapolated RADV audits are simply part of the broader risk-adjustment process governed by the Medicare statute's actuarial-equivalence requirement. The RADV regulation is located in a section of the Code of Federal Regulations titled "Risk adjustment data," 42 C.F.R. § 422.310. Section 422.310 provides detailed requirements for the

risk-adjustment data that MAOs must submit to CMS, *id.* § 422.310(a)-(e), the deadlines for submission of that data, *id.* § 422.310(g), and the uses to which the agency may put the data, *id.* § 422.310(f). Within that broader scheme, section 422.310(e) provides that MAOs must "submit a sample of medical records for the validation of risk adjustment data, as required by CMS" and "remit improper payments based on RADV audits, in a manner specified by CMS." When the agency first proposed section 422.310 in 2004, it explained that the regulation "reflect[ed] changes [CMS] made *in the methodology for risk adjusting MA payments*." 69 Fed. Reg. 46,866, 46,903 (Aug. 3, 2004). As the source of its authority to collect risk-adjustment data under section 422.310, the agency cited the statutory paragraph setting forth the actuarial equivalence mandate—42 U.S.C. § 1395w-23(a)(1)(C). *See* 69 Fed. Reg. at 46,903.

CMS contends that although it located its authority to conduct RADV audits in section 1395w-23(A)(1)(C), extrapolated RADV audits are somehow exempt from that paragraph's governing standard. That reading makes no sense. When Congress authorizes agency action within the scope of and consistent with a particular "statutory boundary," *Loper Bright*, 144 S. Ct. at 2268, the agency must act consistently with that mandate, *see Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 110 F.4th 762, 775-76 (5th Cir. 2024) (affirming vacatur of rule, reasoning that an agency's "general authorization for creating the mechanics of" a program cannot override statutory provisions dictating the program's operation). The actuarial-equivalence requirement's applicability to RADV audits is further confirmed by the RADV provision's placement in a regulation that, in CMS's own words, sets out the "methodology for risk adjusting MA payments," 69 Fed. Reg. at 46,903, alongside regulations governing MAOs' submission of risk-adjustment data and the agency's use of that data. As that regulatory placement further confirms, RADV audits are simply one component of the agency's broader risk-adjustment

payment system—a system governed by actuarial equivalence.

ii. The D.C. Circuit's reasoning in *UnitedHealthcare* confirms that extrapolated RADV audits are not exempt from the Medicare statute's actuarial-equivalence requirement.

The Final Rule relies heavily on *UnitedHealthcare* to support CMS's conclusion that actuarial equivalence does not apply to extrapolated RADV audits. *See* App. 007343. Humana maintains that *UnitedHealthcare*'s holding, which does not bind this Court, is incorrect. But this Court need not reach that question because the case plainly does not support the Final Rule; if anything, the D.C. Circuit's reasoning supports Humana's position here.

In *UnitedHealthcare*, the D.C. Circuit held that actuarial equivalence did not apply to the Overpayment Rule, which requires MAOs to return individual risk-adjusted payments when MAOs learn that a diagnosis code previously submitted to CMS is not documented in the enrollee's medical records. *UnitedHealthcare*, 16 F.4th at 870-71. Holding that actuarial equivalence applies "at the group or population level, not the individual level," the D.C. Circuit reasoned that the Overpayment Rule corrects only "particular mistaken payments to Medicare Advantage insurers." *Id.* at 886. Actuarial equivalence was inapplicable, the D.C. Circuit concluded, because the Overpayment Rule did not "obligate[] insurers to audit their reported data," but only "to refund amounts they *know* were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary's medical records." *Id.* at 884. The court further observed that the "actuarial-equivalence requirement and the overpayment-refund obligation" (1) "apply to different actors"; (2) "target distinct issues arising at different times"; and (3) have different "statutory home[s]." *Id.* at 870, 886.

In so holding, the court specifically explained that the Overpayment Rule was "plainly distinguishable" from the "contract-level RADV audits" at issue in the Final Rule:

Contract-level RADV audits, which would effectively eliminate—and require

> repayment for—all unsupported codes in a Medicare Advantage insurer's data, are an error-correction mechanism that is materially distinct from the Overpayment Rule challenged here, which requires only that an insurer report and return to CMS *known errors* in its beneficiaries' diagnoses that it submitted as grounds for upward adjustment of its monthly capitation payments.

Id. at 892; *see id.* at 871, 893 n.1. Eliding the crux of this reasoning and its express distinction of extrapolated RADV audits, the Final Rule plucks one line from the decision and asserts that actuarial equivalence does not apply because "the RADV program, like the Overpayment Rule, applies *after the fact* to require MAOs to refund any payment to which they are not entitled." App. 007355. The agency's flawed legal conclusion ignores virtually all of the reasoning supporting *UnitedHealthcare*'s holding.

First, CMS ignores *UnitedHealthcare*'s emphasis that the Overpayment Rule required only discrete and individualized, rather than population-level, repayments from MAOs. The D.C. Circuit reasoned that individualized repayments did not implicate the actuarial-equivalence requirement because the word "actuarial . . . implies an assessment made at the group or population level." 16 F.4th at 886. That holding has no application to extrapolated RADV audits, which "effectively . . . require repayment for[] all unsupported codes in a Medicare Advantage insurer's data." *Id.* at 892. The government made the same point in its *UnitedHealthcare* briefing, distinguishing extrapolated RADV audits, "which approximate[] comprehensive auditing of diagnoses for audited contracts and years," from the Overpayment Rule, which "entails only correction of specific, identified errors." Gov't Br. at 19, *UnitedHealthcare v. Becerra*, No. 18-5326 (D.C. Cir. Apr. 23, 2020).

Second, the D.C. Circuit explained that the Overpayment Rule and the actuarial-equivalence mandate apply to "different actors." 16 F.4th at 886. Whereas the Overpayment Rule imposes a requirement on *MAOs* to refund known and identified overpayments, the actuarial-

equivalence mandate "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.* The D.C. Circuit reasoned that because the Overpayment Rule specifies *MAOs'* obligations, it was not subject to the actuarial-equivalence requirement's command *to CMS*. Setting aside that conclusion's validity, it does not support CMS's contention that *the agency itself* is exempt from the actuarial-equivalence requirement so long as it conducts a payment adjustment retroactively.

Third, the D.C. Circuit stressed that the overpayment-refund obligation has a different "statutory home" than the actuarial-equivalence mandate. *Id.* at 870. The court found it implausible that the "actuarial-equivalence principle reaches beyond its statutory home" in section 1395w-23 "to impose an implied—and functionally prohibitive—legal precondition on the requirement to return known overpayments" arising from a totally separate statutory provision, 42 U.S.C. § 1320a-7k(d), which Congress adopted in 2010 to govern overpayments in *any* Medicare or Medicaid program. *Id.* But Humana argues the inverse here, urging only that the actuarial-equivalence mandate applies within its "statutory home," which includes extrapolated RADV audits authorized by that same statutory provision. *See supra* at 27-28.

UnitedHealthcare separately noted that the statutory command to ensure actuarial equivalence for payments to MAOs "under this section"—section 1395w-23—indicates that actuarial equivalence is "limited to the specified context of CMS's calculation and disbursement of monthly payments in the first instance," which section 1395w-23 regulates. 16 F.4th at 885. Although CMS seizes on this one aspect of the court's reasoning to assert that actuarial equivalence does not apply to *any* recoupment of payments that occurs "after the fact" of its initial risk-adjusted payment, s*ee* App. 007355, the D.C. Circuit said no such thing and the court's rationale simply does not hold for extrapolated RADV audits. As explained *supra* at 27-28, the agency's RADV

regulations are set forth as part of CMS's broader risk-adjustment regulatory framework, were promulgated as an exercise of the Secretary's authority under § 1395w-23(a)(1)(C), and aim to refine the Secretary's assessment of population-level health status for purposes of risk-adjusted payment. *See also supra* at 23. Those regulations can only be understood as part of the agency's broader payment framework "under this section," notwithstanding the fact that "CMS cannot confirm in real time the data insurers submit for their millions of beneficiaries" and must therefore conduct RADV audits retrospectively. *UnitedHealthcare*, 16 F.4th at 877.

UnitedHealthcare is distinguishable on multiple bases and does not support CMS's conclusion that extrapolated RADV audits are exempt from the statutory actuarial-equivalence requirement. To the contrary, the thrust of its reasoning supports Humana's position here. The statutory interpretation in the Final Rule is simply incorrect and the Court should reject it.

2. The Coding-Intensity Adjustment Does Not Support the Final Rule.

As an alternative rationale for abandoning the FFS Adjuster, CMS posits that a different statutory provision, 42 U.S.C. § 1395w-23(a)(1)(C)(ii)—the Coding-Intensity Adjustment—gives it free rein to recoup payments from MAOs even if the recoupments disrupt actuarial equivalence. As explained *supra* at 10, the Coding-Intensity Adjustment accounts for "differences in coding patterns between Medicare Advantage plans," on the one hand, "and providers under [fee-for-service Medicare]," on the other, *id.* § 1395w-23(a)(1)(C)(ii)(I). The Final Rule contends that "it would not be reasonable to read the Social Security Act . . . as requiring a reduction in payments to MAOs by a statutorily-set minimum adjustment in the coding[-intensity] adjustment, while at the same time . . . requiring an offset to the recovery amounts calculated for CMS audits." App. 007343; *see* App. 007356 (similar). That conclusion, for which the Final Rule offered no explanation, is inconsistent with the agency's prior statements acknowledging that the Coding-

Intensity Adjustment and RADV audits address different issues and cannot be squared with basic principles of statutory construction.

a. To begin, the Final Rule is inconsistent with CMS's own past statements, yet fails to recognize, much less address, that inconsistency. The agency has always acknowledged that the Coding-Intensity Adjustment and RADV audits address two distinct issues. The Coding-Intensity Adjustment addresses MAOs' incentive—which is not present in fee-for-service Medicare—to fully report all applicable diagnoses such that "similarly situated beneficiaries appear sicker." App. 000017 (outlining coding-pattern study); App. 007711-15 (coding-pattern study results); App. 007750, 007759, 008872-73, 008415; *see* Health Care & Education Reconciliation Act, Pub. L. 111-152, § 1102(e), 124 Stat. 1029 (2010). Just a year after adopting the Coding-Intensity Adjustment, the agency rejected the contention that it was "duplicative of any RADV audit-related adjustments," explaining that—unlike RADV audits—the Coding-Intensity Adjustment was "not intended to adjust for inaccurate coding." App. 007776-77. In other words, the Coding-Intensity Adjustment "does not . . . address unsupported . . . [diagnosis] codes reported by Medicare Advantage insurers"—the subject of RADV audits—"but only the practice, relative to traditional Medicare, of overreporting codes that are nonetheless accurate." *UnitedHealthcare*, 16 F.4th at 877. Even the Final Rule recognizes that the Coding-Intensity Adjustment "accounts for differences in coding patterns between MA and Medicare FFS, given that MAOs have a greater incentive than FFS providers to report diagnoses." App. 007355.

Neither the RADV audit program nor the FFS Adjuster concerns the *completeness* of the diagnosis codes reported by MAOs. Rather, RADV audits aim to recoup payments for diagnosis codes that CMS deems to be *undocumented* in the medical record. *See supra* at 11. The purpose of the FFS Adjuster was to account for the presence of undocumented codes in the fee-for-service

Medicare claims data used to calibrate the HCC risk-adjustment payment rates. *See supra* at 15-16. That is why CMS has previously rejected the contention that the Coding-Intensity Adjustment was "artificially punitive" when applied on top of RADV audits: RADV audits "do not measure the overall increase in risk scores that is the result of coding pattern differences." App. 000112; *see also* App. 000294-95 ("RADV Audits . . . do not address coding pattern differences between MA and FFS."); App. 000047.

The Final Rule acknowledges that "the [Coding-Intensity Adjustment], unlike RADV, is not intended to address unsupported or inaccurate codes reported by MAOs in particular instances." App. 007356. Yet CMS never explains how a statutory mechanism targeting a wholly distinct issue excuses the agency from its obligation to ensure that RADV audits do not disrupt actuarial equivalence. Nor does CMS acknowledge its apparent abandonment of its longstanding view that the Coding-Intensity Adjustment and RADV audits are distinct. That failure alone renders the agency's reasoning arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 56 (1983) ("While the agency is entitled to change its view . . . , it is obligated to explain its reasons for doing so."); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009) (agencies must provide a "reasoned explanation . . . for disregarding facts and circumstances that underlay . . . [a] prior policy," which at the very least requires that the agency "display awareness that it *is* changing position") (emphasis in original).

b. CMS's rationale also fails as a matter of administrative law because it is entirely "conclusory." *Am. Fed'n of Gov't Emps., AFL-CIO v. Fed. Labor Rels. Auth.*, 24 F.4th 666, 674-76 (D.C. Cir. 2022) (statutory interpretation supported only by "conclusory reasoning" is arbitrary and capricious); *see Madison Gas & Elec. Co. v. EPA*, 25 F.3d 526, 529 (7th Cir. 1994) (vacating agency action premised on cursory statutory interpretation). Although the Final Rule repeatedly

states that the Coding-Intensity Adjustment somehow demonstrates that Congress did not require extrapolated RADV audits to honor actuarial equivalence, CMS never explains why. *See* App. 007343, 007356-57, 007359. The agency does not even identify how the Coding-Intensity Adjustment relates to extrapolated RADV audits, much less explain how it entitles CMS to pursue extrapolated RADV audit recoveries that disrupt actuarial equivalence.[6]

c. CMS's new view of the Coding-Intensity Adjustment is also wrong as a matter of statutory construction. Where a statute's plain text is "harmonious with the statutory framework" and creates "nothing textually inconsistent" with other provisions, courts decline to infer that another statutory provision restricts that plain language absent some "indication . . . in the text of the statute" that Congress so intended. *Quarles v. St. Clair*, 711 F.2d 691, 700-01 (5th Cir. 1983). The Final Rule identifies nothing "[in]harmonious" or "textually inconsistent" about reading the actuarial-equivalence requirement to extend to RADV audits, *id.*, and there is no textual indication that Congress intended the Coding-Intensity Adjustment to limit the actuarial-equivalence requirement in that way. Because the Coding-Intensity Adjustment and the FFS Adjuster address distinct actuarial issues, there is nothing unreasonable about the former decreasing payments to MAOs while the latter may sustain payments by reducing RADV audit recoveries. The Final Rule offers no reason to conclude that all actuarial issues must skew payments in the same direction, and the fact that Congress mandated a downward adjustment to address one actuarial problem (*i.e.*, the differing coding patterns between fee-for-service Medicare and Medicare Advantage) says nothing about what is required to address a different one (*i.e.*, the recoupment of funds from MAOs

[6] Defendants cannot remedy this deficiency through legal briefing. It is a "foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action," *Michigan v. EPA*, 576 U.S. 743, 758 (2015), not "counsel's *post hoc* rationalizations," *State Farm*, 463 U.S. at 50.

based on a documentation standard inconsistent with the standard used to develop the risk-adjustment payment model). The actuarially sound solutions to those two problems might have opposing effects on net payments to MAOs, but that does not license CMS to ignore one of them.

To the extent the Coding-Intensity Adjustment is relevant at all, it reaffirms the critical importance of actuarial parity between Medicare Advantage and fee-for-service Medicare. The purpose of the Coding-Intensity Adjustment is to "establish[] risk scores that are *consistent* across both fee-for-service and Medicare Advantage settings." App. 007752 (citing 152 Cong. Rec. S438-02 (daily ed. Feb. 1, 2006) (statement of Sen. Grassley)). Thus, the "coding-intensity adjustment [is] designed to achieve" "actuarial equivalence in payment amount," and cannot reasonably be read to authorize actuarially unsound RADV audit recoveries. App. 007380.

3. CMS's New Rationale Does Not Adequately Explain Why Abandoning the FFS Adjuster Is Warranted.

Even if CMS were correct that the Medicare statute's actuarial-equivalence requirement does not apply to RADV audits, the Final Rule still offers no reasoned justification for the agency's decision to abandon the FFS Adjuster. The APA requires policy decisions to be "reasonable and reasonably explained." *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009). Agency actions grounded in correct statutory interpretations can nonetheless be arbitrary and capricious—the Court must ensure that the "agency has engaged in reasoned decisionmaking within th[e] boundaries" of its statutory authority. *Rest. L. Ctr.*, 115 F.4th at 408. In making that assessment, the Court must determine whether the agency "examined 'the relevant data' and articulated 'a satisfactory explanation' for its decision, 'including a rational connection between the facts found and the choice made.'" *Dep't of Com. v. New York*, 588 U.S. 752, 773 (2019) (quoting *State Farm*, 463 U.S. at 43). And when, as here, the agency "chang[es] course" by reversing a prior policy, it must "supply a reasoned analysis for the change beyond that which may

be required when an agency does not act in the first instance." *State Farm*, 463 U.S. at 42. Under these settled principles, the Final Rule is doubly defective because CMS failed to adequately justify its decision to renounce actuarial integrity in extrapolated RADV audits, *id*. at 43, and the Final Rule "runs counter to the record evidence," *MCR Oil Tools, LLC v. U.S. Dep't of Transp.*, 110 F.4th 677, 697-98 (5th Cir. 2024).

CMS's core substantive justification for abandoning the FFS Adjuster is a legal conclusion, not a reasoned policy justification. *See* App. 007343. Despite recognizing its responsibility as a steward of the "overall long-term success of the RADV program and ultimately the Part C program," App. 007354, CMS did not meaningfully engage with the possibility that applying an FFS Adjuster—even if not required as a statutory matter—would constitute sound policy promoting the continued health of the Medicare Advantage program. Instead, the agency affirmatively disclaimed any reliance on its original basis for eliminating the FFS Adjuster: a study that purportedly "found that errors in Medicare FFS claims data do not lead to systematic payment error in the MA program," but that actuarial and statistical experts thoroughly discredited. App. 007355, 007358 ("[T]he finalization of our proposal not to apply an FFS Adjuster does not depend on the results of our study."); *see* App. 000726-37.

Having abandoned that justification, CMS failed to adequately explain how it could be "rational" to nonetheless proceed with the Final Rule fully cognizant of the acknowledged risk of "systematic payment error." *Dep't of Com.*, 588 U.S. at 773; App. 007358. That failure is particularly stark because CMS has been well aware, for many years, of the empirical and actuarial problems presented by the inconsistency between audited Medicare Advantage data and unaudited fee-for-service Medicare claims data. It recognized in 2012 that the FFS Adjuster was needed to address the inconsistent documentation standards implicated by extrapolated RADV audits. App.

007703-04. And commenters highlighted this issue in response to the Proposed Rule, explaining that mathematical biases caused by the presence of undocumented diagnosis codes in the fee-for-service Medicare claims data used to build the CMS-HCC model would necessarily underpay MAOs without an FFS Adjuster. *See supra* at 15-16; App. 003696 (Humana Comment), 001396, 004237-38, 005193-94, 006344, 002401-02.

CMS's primary response to all of these critiques—that even if such "systematic payment error exists, it does not impact the requirement that submitted diagnoses must be adequately supported by medical records," App. 007358—is a non sequitur. That response simply fails to grapple with these actuarial risks. The agency appears to have implicitly concluded that its interest in enforcing its medical-record requirement outweighs the interests of MAOs and the public in actuarially sound administration of the Medicare Advantage program. But CMS offered no justification at all for that remarkable conclusion. The Final Rule thus failed to offer a "satisfactory explanation" for the agency's decision to reject the commenters' arguments without addressing their underlying policy concerns. *Calumet Shreveport Refin., L.L.C. v. EPA*, 86 F.4th 1121, 1133 (5th Cir. 2023).

And the aside in the Final Rule that CMS "d[id] not agree with those commenters who claim that our study or their counter-studies provide evidence that [Medicare] FFS errors systematically reduce payments to MAOs" is no answer because that cursory statement of disagreement likewise offers no rational explanation for eliminating the FFS Adjuster. App. 007358.

First, the agency's observation that its study found low beneficiary-level "error rates" in fee-for-service Medicare claims data cannot explain the Final Rule because CMS expressly disclaimed "the results of our study" as a justification. *Id.* And rightly so: commenters

demonstrated empirically the flawed methodology underlying this finding. *See* App. 003720-21 (Humana comment); *see also* App. 001414, 001457, 001570 (noting the beneficiary error rates had "no empirical basis" and "conflicts with available evidence"), 004230, 004233. CMS did not even attempt to respond to those comments.

Second, CMS speculated that two data trends—under-coding in fee-for-service Medicare and expenditures associated with over-coding—*might* "offset" the payment error resulting from its new policy. App. 007358. The agency never pointed to those contentions in the Proposed Rule, App. 000726-32, and in any event commenters explained why they were incorrect. *See* App. 003728 (explaining that the Kronick and Welch study cited in the Final Rule in fact contradicts CMS's position), 001192, 007678-79. But rather than substantively respond to those comments, the Final Rule merely asserts that they did not "adequately address these effects." App. 007358. That conclusory assertion does not satisfy the APA's reasonable-explanation requirement. *See Sierra Club v. EPA*, 884 F.3d 1185, 1198 (D.C. Cir. 2018) (agency's "hunch" insufficient to support policy); *see AFGE v. Fed. Labor Rels. Auth.*, 24 F.4th 666, 676 (D.C. Cir. 2022) (faulting agency's "drive-by procedure and conclusory reasoning").

Third, CMS asserted that because commenters identified payment error ranging from 9% to 33%, developing an FFS Adjuster may not be "reasonable or practical." App. 007358. But that is no answer. An agency cannot just throw up its hands when confronted by empirical evidence that presents a difficult policy choice. To the contrary, multiple expert analyses demonstrating a payment bias of *at least* 9% calls for CMS to address the problem, not ignore it; the agency cannot "bury its head in the sand and ignore 'data it did not want to consider.'" *MCR*, 110 F.4th at 698 (quoting *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 776 (5th Cir. 2023)). The agency's failure

to provide a reasoned policy justification for the abandonment of the FFS Adjuster independently renders the Final Rule arbitrary and capricious under the APA.

B. The Final Rule Is Procedurally Invalid Under the APA.

1. The Proposed Rule Did Not Provide Adequate Notice of CMS's Final Rationale.

The APA requires that "[t]he agency's rationale for [a] rule must be made clear and subjected to public comment," *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 381-82 (5th Cir. 2021); *see* 5 U.S.C. § 553(c) (agency must give "interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments"). The Final Rule violates that foundational APA requirement.

CMS originally committed to adopt the FFS Adjuster to "calculate a permissible level of payment error . . . and limit RADV audit recovery to payment errors above that level." App. 000728. The Proposed Rule subsequently retracted that commitment based on the agency's "study regarding the presence and impact of diagnosis error in FFS claims data," contending that "diagnosis error in FFS claims data does not lead to systematic payment error in the MA program." App. 000730-31; *see also* App. 000741. Thus, for more than a decade, CMS's statements focused on the FFS Adjuster's effectiveness for eliminating payment error resulting from the inconsistent documentation standards implicated by the proposal for extrapolated RADV audits. After releasing the study data, and more than two years before the D.C. Circuit decided *UnitedHealthcare*, CMS requested additional comment on whether 42 U.S.C. § 1395w-23(a)(1)(C) "mandate[d]," "prohibit[ed]," or "should otherwise be read to inform" whether to apply an FFS Adjuster—but never articulated any reason why actuarial equivalence would not apply, never explained it had so concluded, and never sought comment on the effect *UnitedHealthcare* would have on that analysis. App. 000741.

The Final Rule abandoned the Proposed Rule's analysis. Rather than the factual merits or design of the FFS Adjuster, CMS instead rejected the foundational premise that it was even required to maintain actuarial equivalence in extrapolated RADV audits. At no point before issuing the Final Rule did CMS ever seek comment on that analysis or conclusion, including after the D.C. Circuit decided *UnitedHealthcare*. App. 000726-42, 007338-41. Thus, its rationale was neither "clear" nor "subjected to public comment." *Tex. Ass'n of Mfrs.*, 989 F.3d at 381-82; *see Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212 (5th Cir. 1991) (agency improperly failed to "give notice as to its intended methodology").

2. The Lack of Notice Prevented Humana from Submitting Objections Disputing CMS's Final Reasoning.

The notice-and-comment requirement is designed to provide the public with "an accurate picture" of the agency's reasoning so commenters can "communicate information, concerns, and criticisms." *Conn. Light & Power Co. v. Nuclear Regul. Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir. 1982). Here, CMS's procedural error denied Humana and other commenters that fair opportunity to dispute the agency's final reasoning. *See Tex. Ass'n of Mfrs.*, 989 F.3d at 382 ("change in the justification for the Proposed Rule and the justification for the Final Rule" denied commenters fair notice). Given the agency's prior focus on the operation of and actuarial basis for the FFS Adjuster, Humana and other industry participants focused their comments on the validity and efficacy of its study. *See, e.g.*, App. 003695-742. Although some commenters noted that actuarial equivalence applied, *see, e.g.*, App. 000895, 001396, they lacked notice of CMS's ultimate position or rationale and could not comment on it..

Had Humana known that CMS would offer an entirely new legal rationale, it would have been able to submit "specific and credible objections." *Chamber of Com. of U.S. v. SEC*, 443 F.3d 890, 905 (D.C. Cir. 2006), including explaining why the D.C. Circuit's reasoning in

UnitedHealthcare does not support the agency's conclusions in the Final Rule. *See supra* at 28-32. By denying Humana the opportunity to articulate that analysis for CMS, the agency eliminated any chance that it would reconsider its faulty legal position. *See U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979) (refusing to "assume that there was no prejudice to petitioners" from agency's procedural error because the "[a]bsence of . . . prejudice must be clear for harmless error to be applicable"). CMS thus promulgated the Final Rule "without observance of procedure required by law," 5 U.S.C. § 706(2)(D), and the Final Rule should be vacated.

C. The Final Rule Is Contrary to Law and Arbitrary and Capricious Under the APA Because It Improperly Applies Retroactively to RADV Audits Conducted for Payment Years Before the Rule's Effective Date.

The Final Rule is also contrary to law and arbitrary and capricious because it applies retroactively without congressional authorization and without sufficient justification. The Final Rule expressly applies retroactively to payment years 2018 to 2023, attaching new legal consequences to actions long since completed and upsetting the actuarial assumptions underlying Medicare Advantage bids long since submitted. App. 007343. The Medicare statute does not authorize that retroactive rulemaking, *see* 42 U.S.C. § 1395hh(e)(1)(A), and the Final Rule's harsh consequences render retroactive application "so unfair as to be arbitrary and capricious" even if it were statutorily permissible, *Microcomputer Tech. Inst. v. Riley*, 139 F.3d 1044, 1051 (5th Cir. 1998). The Court should, at minimum, vacate the Final Rule to the extent it permits CMS to retroactively apply its new methodology to Medicare Advantage contracts formed under a different legal regime, or remand with an order to eliminate this retroactive application.

1. The Final Rule Applies Retroactively to Payment Years Preceding Its Promulgation.

To determine if a regulation is retroactive, the Court first "examines whether the regulation clearly expresses whether it is to be applied retroactively." *Germain v. U.S. Bank Nat'l Ass'n*, 920

F.3d 269, 274 (5th Cir. 2019). "[I]f there is no clear expression as to retroactivity, the [C]ourt then considers whether the regulation would have a retroactive effect." *Id.* at 274-75. The Final Rule is retroactive under both tests.

First, the Final Rule expressly applies to RADV audits dating back to payment year 2018, App. 007343, and so "clearly expresses . . . it is to be applied retroactively," *Germain*, 920 F.3d at 274; *cf. Kuhl v. U.S.*, 467 F.3d 145, 149 (2d Cir. 2006) (regulation "expressly retroactive" where it applied to proceedings commenced before the regulation). The Final Rule expressly applies CMS's new policy to extrapolated RADV audits of Medicare Advantage contracts executed before its effective date. *See* App. 007342-43 (CMS "*will* begin collection of extrapolated overpayment findings" without applying an FFS Adjuster "for any CMS and OIG audits conducted in [payment year] 2018 and any subsequent payment year"). The agency itself estimates that this retroactive change will significantly alter payments to audited Medicare Advantage plans for those payment years. *See* App. 007361-63. The Final Rule is expressly retroactive.

Second, the Final Rule's effects on completed transactions confirm its retroactivity. Determining if a regulation has retroactive effect "demands a commonsense, functional judgment about whether the new provision attaches new legal consequences to events completed before its enactment." *Germain*, 920 F.3d at 275 (quoting *INS v. St. Cyr*, 533 U.S. 289, 321 (2001), *superseded on other grounds by* 8 U.S.C. § 1252(a)(5)). "There is a retroactive effect when the new regulation takes away or impairs vested rights . . . , *creates a new obligation, imposes a new duty*, or attaches a new disability, in respect to transactions or considerations already past." *Id.* (emphasis in original); *see Handley v. Chapman*, 587 F.3d 273, 283 (5th Cir. 2009) (similar). Under this test, a rule is retroactive where it "alters the method for calculating" Medicare payments owed for services provided in previous fiscal years since "[a]ny rule that alters the method for

calculating [payments] changes the legal consequences of treating . . . patients." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 17 (D.C. Cir. 2011).

The Final Rule is similarly retroactive. As an initial matter, it applies to previous years for which MAOs have already submitted their bids to CMS estimating the revenue needed to provide fee-for-service Medicare benefits to an enrollee with an average risk score of 1.0 in a given geographic area. *See, e.g.*, App. 003712; *see also* 42 U.S.C. § 1395w-24(a)(6)(A)(iii); 42 C.F.R. § 422.254(b). Those bids were required to presume certain revenues based on actuarial assumptions, and Humana expressly—and reasonably—relied on CMS's commitments to apply an FFS Adjuster when calculating anticipated revenues in the bids. *See supra* at 16; *see also* ECF No. 30 at 15-16. The agency then executed contracts with Humana and other MAOs based on those approved bids. *See* 42 U.S.C. §§ 1395w-21 through 1395w-28. Both Humana's bids and the resulting contracts are "events completed before" the Final Rule's enactment. *Germain*, 920 F.3d at 275.

The Final Rule also alters the legal regime upon which those events were based. Before 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. App. 007703-04. The Final Rule reversed that policy, promising lower payments and jeopardizing these contracts' underlying actuarial assumptions. *See* App. 007361-63 (estimating that the agency will collect hundreds of millions of dollars in additional audit recoveries from MAOs). Numerous cases have recognized that changing payments or payment methodologies under the Medicare program constitutes retroactive rulemaking. *See Ne. Hosp. Corp.*, 657 F.3d at 17; *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 207 (1988) (rule used to "recoup sums previously paid" to fee-for-service Medicare providers was impermissibly retroactive); *Regents of the Univ. of Cal. v. Burwell*,

155 F. Supp. 3d 31, 47 (D.D.C. 2016) ("regulation alter[s] the past legal consequences of past actions" when it "change[s] the amount of reimbursement for already-provided Medicare services" (emphasis omitted)).

CMS asserts that the Final Rule changes nothing because it is simply a "codifi[cation]" of MAOs' preexisting obligation to return payments for diagnosis codes not documented by medical records. *See* App. 007342. Not so. The agency considered this medical-record requirement when it publicly pledged to apply the FFS Adjuster in 2012. It concluded that "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)," App. 007703-04, necessarily means that there is "a permissible level of payment error" in RADV audits, App. 000728. "[T]o account for" that fact, CMS pledged that, notwithstanding its sub-regulatory medical-record requirement, the agency would "apply a Fee-for-Service Adjuster . . . amount as an offset" to any extrapolated audit recovery. App. 007703-04. By eliminating the FFS Adjuster and effectively insisting on perfect medical-record documentation in audited contracts, the Final Rule drastically changes that policy. *See* 65 Fed. Reg. at 40,268 (acknowledging that MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [federal regulators] believe is reasonable to enforce").

2. CMS Lacks Statutory Authority to Apply the Final Rule Retroactively.

CMS cannot apply the Final Rule retroactively without "an express statutory grant" of authority. *Bowen*, 488 U.S. at 208-09. The Medicare statute grants such authority but only where retroactive application "(i) is necessary to comply with statutory requirements," or where "(ii) failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A). The Final Rule invokes both exceptions, but neither applies.

i. No statute requires retroactive application of the Final Rule.

CMS cannot establish the Final Rule is "necessary to comply with statutory requirements," 42 U.S.C. § 1395hh(e)(1)(A)—a question that is solely for this Court. *See, e.g.*, *Calumet*, 86 F.4th at 1134 ("no deference" to agency's retroactivity determinations).

The Final Rule states that retroactive application is required to comply with the Payment Integrity Information Act of 2019 or "PIIA," *see* 31 U.S.C. § 3352 *et seq*. But the PIIA nowhere authorizes—much less requires—CMS to retroactively impose its extrapolated RADV audit methodology. The PIIA is a generic payment-integrity statute that requires federal agencies to assess the potential for improper payments and report on strategies for recovering them. *See* 31 U.S.C. § 3352(a)-(h). While the PIIA contains a broad instruction for agencies to "conduct recovery audits . . . in a manner designed to ensure the greatest financial benefit to the Federal Government," *id.* § 3352(i)(1)(A)-(B), it nowhere mandates that those audits take any particular form—retroactive or otherwise. CMS's attempt to read such a requirement into the PIIA is unpersuasive.

First, the RADV audits at issue here do not resemble typical "recovery audits" rooted in settled obligations; the Final Rule *changes* MAOs' settled expectations by altering the actuarial foundations underpinning bids submitted to CMS long before the Final Rule's effective date. *See supra* at 16, 43-44. The PIIA's general audit mandate does not require the agency to adopt any specific position on the core substantive actuarial dispute at the heart of this case, much less require that the agency's resolution apply retroactively.

Second, the Final Rule itself contradicts CMS's position on the PIIA's "requirements." The agency decided "*not* to extrapolate for [payment year] 2011 through 2017 audits," App. 007349, thereby conceding that the PIIA imposes on the agency no statutory obligation to maximize the government's "financial benefit" for *those* payment years. *See* App. 007353. If

retroactive application going back to payment year 2018 were truly "*necessary* to comply with [the PIAA]," 42 U.S.C. § 1395hh(e)(1)(A), there is no logical reason why retroactive application would be *unnecessary* as to prior payment years.

ii. Applying the Final Rule only prospectively would not be contrary to the public interest.

In the Final Rule, CMS contends that retroactive application serves the public interest by saving the federal government money. App. 007352 (Final Rule "reduc[es] the improper allocation of taxpayer dollars that can otherwise be used for other purposes"). The agency then concludes that the Final Rule "would not upset any settled or reasonable reliance interests" because "MAOs have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records." *Id.* Neither justification satisfies the statutory "public interest" exception or passes muster under arbitrary and capricious review.

First, CMS overreads the Medicare statute's public-interest exception. The agency essentially asserts that *any* policy change that leads to lower payments or larger audit recoupments is *necessarily* in the public interest. But that unbounded reading of the public-interest exception would likely swallow the general prohibition against retroactive application of regulations under the Medicare statute. The public's interest in larger audit recoveries is a consideration that may be insufficient when weighed against other harms, *see League of Wilderness Defs./Blue Mountains Biodiversity Project v. Connaughton*, 752 F.3d 755, 765 (9th Cir. 2014), and courts should not assume that the government's self-interest in maximizing revenue is "the same" as the public interest, *La. Env't Servs., LLC v. City of Shreveport*, 2007 WL 9812956, at *8 (W.D. La. May 30, 2007); *see Clarke v. CFTC*, 74 F.4th 627, 643-44 (5th Cir. 2023) ("[T]he public interest is served when administrative agencies comply with their obligations under the APA."). CMS's all-or-nothing view would "eviscerate the rule" established by the Medicare statute, which generally

forbids retroactive rulemaking. *Mitchell v. Fed. Bureau of Prisons*, 587 F.3d 415, 421 (D.C. Cir. 2009).

Second, CMS's dismissal of Humana's reliance interests cannot survive arbitrary and capricious review. "When an agency changes course . . . it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020); *see Clarke*, 74 F.4th at 644 (agency must take "reliance interests . . . into account before abruptly changing course"). Courts have recognized "significant reliance interests" where, for instance, a regulated party incorporated CMS policy into budget forecasts critical to "planning for future years and structuring its business." *Scott & White Health Plan v. Becerra*, 693 F. Supp. 3d 1, 16-17 (D.D.C. 2023). Here, CMS's commitment to apply an FFS Adjuster engendered reliance interests similar to those in *Scott & White Health Plan*, where the agency's abandonment of an apportionment ratio affected the "significant reliance interests" of a health plan that "had planned and budgeted around revenue figures that were calculated using [the prior] apportionment ratio." *Id.* at 19-20 (finding reliance arguments "particularly persuasive" given CMS's prior inconsistent statements and the Medicare statute's "strong rule against retroactivity").

Indeed, Humana's reliance interests are even stronger than those at issue in *Scott & White*. This case concerns the actuarial foundations of Humana's contracts and the viability of the Medicare Advantage risk-adjustment model as a whole. Humana reasonably relied on the agency's 2012 promise of an FFS Adjuster and factored this representation into the actuarial projections for its bids to CMS. *See* App. 003710-12. And even in the 2018 Proposed Rule, CMS never suggested that it would make the brand-new argument that actuarial equivalence does not apply *at all* to extrapolated RADV audits. *See supra* at 40-41. That shift is meaningfully different;

MAOs could be confident—even after the 2018 Proposed Rule—that CMS would comply with the APA, account for commenters' views concerning the agency's study, and honor the statutory mandate of actuarial equivalence. Indeed, that assumption was plainly reasonable—CMS declined to even attempt to justify the new policy empirically in response to those comments. Yet the agency failed to even "assess whether there were reliance interests" affected by its policy reversal, much less "determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents of the Univ. of Cal.*, 591 U.S. at 33; *see Scott & White Health Plan*, 693 F. Supp. 3d at 18 (invalidating CMS's changed approach to compensating health plans because "the Administrator failed even to acknowledge that the agency was diverging from any past policy or practice . . . let alone explain the reasons for the switch"). Therefore, CMS lacks authority under the Medicare statute to apply the Final Rule to Medicare Advantage bids and contracts predating its effective date.

3. Retroactive Application of the Final Rule Is Arbitrary and Capricious Given Humana's Significant Reliance Interests.

The Final Rule's retroactive features are invalid for an additional reason, even if statutorily authorized: retroactive application would be "so unfair as to be arbitrary and capricious." *Microcomputer Tech. Inst.*, 139 F.3d at 1050. In conducting this analysis, courts must consider factors such as "fair notice, reasonable reliance, and settled expectations." *Treasure State Res. Indus. Ass'n v. EPA*, 805 F.3d 300, 305 (D.C. Cir. 2015). "The typical form of unfairness that retroactivity may wreak is by radically undermining the value of costs that parties incurred in reasonable reliance on continuation of the status quo. . . ." *Id.*

Weighing "the ills of retroactivity against the disadvantages of prospectivity," *Microcomputer Tech. Inst.*, 139 F.3d at 1050, retroactive application of the Final Rule would be improper. The statutory regime governing Medicare Advantage depends on actuarial estimates

that are inherently forward-looking: the Medicare Advantage program requires MAOs to make actuarially sound predictions, based on CMS-provided data, of the cost of medical care for an average beneficiary over the course of a year. 42 U.S.C. § 1395w-24(a)(6)(A)(iii). But the Final Rule disrupts the actuarial assumptions underlying bids submitted before its publication, and in doing so "undermin[es] the value" of Humana's prior efforts to submit actuarially sound bids that would adequately compensate it for the risks it assumed to provide fee-for-service Medicare benefits for its enrollees. *Treasure State*, 805 F.3d at 305. CMS provides no explanation for that decision other than asserting that the Final Rule is consistent with its view of MAOs' preexisting obligations. App. 007352. The agency's justification is incorrect, *see supra* at 44-45, and therefore arbitrary. *See Scott & White*, 693 F. Supp. 3d at 18-19 (vacating agency action as arbitrary and capricious where CMS failed to acknowledge reversal of "past policy or practice" or provide adequate justification).

VI. CONCLUSION

For the foregoing reasons, the Court should grant Humana's motion for summary judgment and vacate the Final Rule.

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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2024, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all participating counsel of record.

/s/ Timothy S. Durst