

**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' RESPONSE TO DEFENDANTS' CROSS-MOTION FOR SUMMARY  
JUDGMENT**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Civil Rule 56.4 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 file this Response to Defendants' Cross-Motion for Summary Judgment. Pursuant to Local Civil Rule 56.4(b), each of the matters required by Local Civil Rule 56.4(a) is set forth in the accompanying Plaintiffs' Consolidated Reply in Support of Motion for Summary Judgment and Opposition to Defendants' Cross-Motion for Summary Judgment.

Plaintiffs respectfully request that the Court grant Plaintiffs' Motion for Summary Judgment and deny Defendants' Cross-Motion for Summary Judgment.

Dated: February 3, 2025

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**CERTIFICATE OF SERVICE**

On February 3, 2025, 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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**PLAINTIFFS' CONSOLIDATED REPLY IN SUPPORT OF  
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CROSS-MOTION FOR SUMMARY JUDGMENT**

	<b>Page</b>
I. INTRODUCTION .....	1
II. ARGUMENT .....	3
A. The Government Offers No Persuasive Defense of the Final Rule’s Purely Legal Rationales.....	3
1. The Government fails to defend persuasively the Final Rule’s conclusion that the Medicare statute’s actuarial-equivalence requirement does not apply to extrapolated RADV audits. ....	4
a. The Government’s reading of the actuarial-equivalence requirement cannot be squared with the statute’s plain text or structure. ....	4
b. The D.C. Circuit’s decision in <i>UnitedHealthcare</i> does not support the Government’s argument that extrapolated RADV audits are exempt from actuarial equivalence. ....	9
c. The Government’s attack on Humana’s “facial challenge” lacks merit because statistically extrapolated RADV audits based on cohorts and sub-cohorts of an entire MAO’s contract membership result in population-level payment adjustments and, thus, must comply with the statute’s actuarial-equivalence requirement. ....	11
d. Humana has no reason to challenge the CMS-HCC risk coefficients because they do not necessarily violate the Medicare statute’s actuarial-equivalence requirement.....	16
2. The Coding-Intensity Adjustment does not support CMS’s rationale for the Final Rule because it addresses fundamentally different actuarial issues than extrapolated RADV audits.....	20
B. The Government Offers No Credible Justification for CMS’s Decision to Abandon the FFS Adjuster, Confirming That the Final Rule Is Arbitrary and Capricious. ....	25
1. The FFS Adjuster addressed a fundamental actuarial problem with extrapolated RADV audits that CMS acknowledged for years. ....	26
2. The Final Rule offers no empirical basis to abandon the prior CMS policy adopting a FFS Adjuster. ....	29
C. The Government’s Procedural Defense of the Final Rule Is Unpersuasive. ....	32
1. The Final Rule is not a “logical outgrowth” of the Proposed Rule because it relies on entirely different justifications. ....	32
2. CMS’s failure to provide proper notice unfairly prejudiced Humana and thus was not harmless. ....	34
D. The Final Rule Is Retroactive and Congress Granted CMS No Authority to Engage in Retroactive Rulemaking. ....	35

**TABLE OF CONTENTS**

**(continued)**

	<b>Page</b>
1. The Government fails to refute the Final Rule’s retroactive effects or Humana’s reasonable reliance on CMS’s 2012 RADV Notice.....	35
2. Congress has not authorized retroactive application of the Final Rule, and retroactive application would be arbitrary and capricious in any event. ....	38
E. Vacatur Is the Appropriate Remedy. ....	41
III. CONCLUSION.....	41

## TABLE OF AUTHORITIES

	Page(s)
<b>Cases</b>	
<i>Associated Builders &amp; Contractors of Tex., Inc. v. Nat'l Labor Relations Bd.</i> , 826 F.3d 215 (5th Cir. 2016).....	12, 13
<i>Black Rock City LLC v. Haaland</i> , 2022 WL 834070 (D.D.C. Mar. 21, 2022).....	19
<i>Bowen v. Georgetown Univ. Hosp.</i> , 488 U.S. 204 (1988).....	5, 35, 38
<i>Bridas S.A.P.I.C. v. Gov't of Turkmenistan</i> , 345 F.3d 347 (5th Cir. 2003).....	4
<i>Chamber of Commerce of the U.S. v. U.S. Dep't of Labor</i> , 885 F.3d 360 (5th Cir. 2018).....	41
<i>Clark v. Uebersee Finanz-Korporation, A.G.</i> , 332 U.S. 480 (1947).....	8
<i>Decker v. Nw. Env't Def. Ctr.</i> , 568 U.S. 597 (2013).....	5
<i>Dep't of Commerce v. New York</i> , 588 U.S. 752 (2019).....	25, 26, 29
<i>Dep't of Homeland Sec. v. Regents of the Univ. of Cal.</i> , 591 U.S. 1 (2020).....	39
<i>Env't Integrity Project v. E.P.A.</i> , 425 F.3d 992 (D.C. Cir. 2005).....	33
<i>Exxon Mobil Corp. v. Allapattah Servs., Inc.</i> , 545 U.S. 546 (2005).....	33
<i>Franciscan All., Inc. v. Becerra</i> , 47 F.4th 368 (5th Cir. 2022).....	40
<i>Germain v. U.S. Bank Nat'l Ass'n</i> , 920 F.3d 269 (5th Cir. 2019).....	35
<i>Heniff Transp. Sys., L.L.C. v. Trimac Transp. Servs.</i> , 847 F.3d 187 (5th Cir. 2017).....	7
<i>Hometown 2006-1 1925 Valley View, L.L.C. v. Prime Income Asset Mgmt., L.L.C.</i> , 595 Fed. App'x 306 (5th Cir. 2014).....	6
<i>Hull v. Kapstone Container Corp.</i> , 2018 WL 4409798 (N.D. Tex. Sept. 17, 2018).....	27, 29

**TABLE OF AUTHORITIES**

(continued)

	<b>Page(s)</b>
<i>In re Bell Petroleum Servs.</i> , 3 F.3d 889 (5th Cir. 1993).....	14
<i>Loper Bright Enters. v. Raimondo</i> , 144 S. Ct. 2244 (2024).....	26
<i>Louisiana v. U.S. Dep’t of Energy</i> , 90 F.4th 461 (5th Cir. 2024).....	5
<i>Medina Cnty. Env’t Action Ass’n v. Surface Transp. Bd.</i> , 602 F.3d 687 (5th Cir. 2010).....	15
<i>Mexican Gulf Fishing Co. v. U.S. Dep’t of Commerce</i> , 60 F.4th 956 (5th Cir. 2023).....	34
<i>Microcomputer Tech. Inst. v. Riley</i> , 139 F.3d 1044 (5th Cir. 1998).....	34, 38, 40
<i>Mock v. Garland</i> , 75 F.4th 563 (5th Cir. 2023).....	33
<i>Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.</i> , 463 U.S. 29 (1983).....	passim
<i>Nat’l Tel. Coop. Ass’n v. FCC</i> , 563 F.3d 536 (D.C. Cir. 2009).....	26
<i>Ne. Hosp. Corp. v. Sebelius</i> , 657 F.3d 1 (D.C. Cir. 2011).....	35
<i>Quarles v. St. Clair</i> , 711 F.2d 691 (5th Cir. 1983).....	22, 23
<i>Ratanasen v. Cal. Dep’t of Health Servs.</i> , 11 F.3d 1467 (9th Cir. 1993).....	36
<i>Regents of the Univ. of Cal. v. Burwell</i> , 155 F. Supp. 3d 31 (D.D.C. 2016).....	35
<i>Rest. L. Ctr. v. U.S. Dep’t of Labor</i> , 120 F.4th 163 (5th Cir. 2024).....	26
<i>Sabal v. Anti-Defamation League</i> , 2024 WL 5113497 (N.D. Tex. Dec. 13, 2024).....	27
<i>Santos-Zacaria v. Garland</i> , 598 U.S. 411 (2023).....	8



**TABLE OF AUTHORITIES**

(continued)

	<b>Page(s)</b>
<i>Scherer v. U.S. Forest Serv.</i> , 653 F.3d 1241 (10th Cir. 2011).....	13
<i>SEC v. Chenery Corp.</i> , 318 U.S. 80 (1943).....	30
<i>Tex. Ass’n of Mfrs. v. U.S. Consumer Prod. Safety Comm’n</i> , 989 F.3d 368 (5th Cir. 2021).....	32, 34
<i>Tex. Med. Ass’n v. U.S. Dep’t of Health &amp; Human Servs.</i> , 110 F.4th 762 (5th Cir. 2024).....	40
<i>Texas v. Biden</i> , 20 F.4th 928 (5th Cir. 2021).....	41
<i>Treasure State Res. Indus. Ass’n v. EPA</i> , 805 F.3d 300 (D.C. Cir. 2015).....	40
<i>United States v. Lahey Clinic Hosp., Inc.</i> , 399 F.3d 1 (1st Cir. 2005).....	36
<i>United States v. Rahimi</i> , 144 S. Ct. 1889 (2024).....	12
<i>United States v. Salerno</i> , 481 U.S. 739 (1987).....	12, 14
<i>UnitedHealthcare Ins. Co. v. Becerra</i> , 16 F.4th 867 (D.C. Cir. 2021).....	passim
<i>Wages &amp; White Lion Invs., L.L.C. v. FDA</i> , 90 F.4th 357 (5th Cir. 2024).....	30
<b>Statutes</b>	
31 U.S.C. § 3352(i)(1)(A).....	43
31 U.S.C. § 3352(i)(1)(B).....	43
42 U.S.C. § 1320a-7k(d).....	11
42 U.S.C. § 1395hh(e)(1)(A).....	43, 44
42 U.S.C. § 1395w-23(a)(1)(A).....	5
42 U.S.C. § 1395w-23(a)(1)(C).....	9
42 U.S.C. § 1395w-23(a)(1)(C)(i).....	passim

**TABLE OF AUTHORITIES**

(continued)

	<b>Page(s)</b>
42 U.S.C. § 1395w-23(a)(1)(C)(ii) .....	25
42 U.S.C. § 1395w-23(a)(3) .....	6
42 U.S.C. § 1395w-27(e)(4) .....	33
5 U.S.C. § 706(2)(A).....	13
5 U.S.C. § 706(2)(C).....	13
<b>Regulations</b>	
42 C.F.R. § 422.310 .....	8
69 Fed. Reg. 46,903 .....	8
<b>Other Authorities</b>	
CMS, <i>Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2025</i> , <a href="https://www.cms.gov/files/document/cy2025-ma-bpt-instructions20240405.pdf">https://www.cms.gov/files/document/cy2025-ma-bpt-instructions20240405.pdf</a> .....	30

## I. INTRODUCTION

The Government’s response to Humana’s motion for summary judgment is largely an exercise in misdirection.<sup>1</sup> In its opposition and cross-motion, the Government mostly ignores Humana’s arguments and instead offers a series of strawmen, at times based on extra-record evidence not considered by the agency and so not properly before the Court. For instance, the Government contends that Humana must empirically prove that extrapolated RADV audits will necessarily underpay MAOs; that Humana is seeking a “defense” to a separate obligation to return known overpayments; that Humana must file a separate lawsuit to address payment errors it identifies; and that Humana is raising a flawed “facial challenge” because CMS is extrapolating audit results only to certain “cohorts” of enrollees within audited contracts. None of these arguments answer Humana’s core contentions in the motion, and they are wrong in any event. The Court should grant Humana’s motion because the purely legal conclusions on which the agency based the Final Rule—that the Medicare statute’s actuarial-equivalence requirement *never* applies to extrapolated RADV audits and that the Coding-Intensity Adjustment forecloses an FFS Adjuster—conflict with the statute’s text and purpose. Thus, under the APA, the Final Rule is both arbitrary and capricious and contrary to law.

Nor does the Government meaningfully rebut Humana’s alternative argument that the Final Rule is arbitrary and capricious because it provides no reasoned justification for abandoning the FFS Adjuster as a matter of policy. CMS previously recognized that it could not soundly apply “one documentation standard for RADV, which is perfection,” while at the same time applying

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<sup>1</sup> Unless otherwise noted, all defined terms and acronyms in this Consolidated Reply and Opposition have the same meaning as in Humana’s Brief in Support of Plaintiffs’ Motion for Summary Judgment (“Humana MSJ”), ECF No. 44, and all emphasis is added and quotation marks, alterations, and citations omitted. The Government’s opposition, ECF No. 63, is cited as “Gov’t Br.”

“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. In the Final Rule, the agency did not empirically disprove this conclusion; to the contrary, it abandoned the study that attempted to do so. The Government’s primary response is not a rebuttal of the arguments Humana actually presented to this Court, but the non sequitur that Humana should be required to file a separate lawsuit challenging the agency’s risk coefficients. But that makes no sense. The actuarial defect at issue here arises from the inconsistency between the unaudited fee-for-service Medicare claims data used to develop the coefficients and the documentation standard the agency now seeks to apply in extrapolated RADV audits. There is nothing inherently unlawful or actuarially unsound about CMS relying on unaudited fee-for-service Medicare claims data to construct Medicare Advantage payment rates, and if the agency’s payments to MAOs relied solely on unaudited claims data for Medicare Advantage enrollees, the actuarial-equivalence requirement would likely not be implicated. The Final Rule is the agency policy that introduces the inconsistent documentation standards and the resulting actuarial defect, and CMS provided no sensible analysis that could support the agency’s decision to simply ignore the issue.

The Government’s response to Humana’s procedural claims is equally unavailing. CMS never disclosed the legal analysis underlying the Final Rule as the APA requires, so its adoption was procedurally defective. Because Humana was denied the opportunity to make specific arguments in response to that analysis, the agency’s failure cannot be deemed harmless. The Final Rule is also impermissibly retroactive because it applies new legal consequences to conduct completed years ago without the requisite statutory authority. Moreover, the Government has no answer to Humana’s argument that the severe consequences of applying the Final Rule retroactively supply an independent basis to preclude it from doing so.

The standard remedy for such deficiencies is vacatur. The Government’s request that the Court adopt some other form of relief ignores binding precedent and provides no supporting analysis. Humana’s motion should be granted and the Government’s cross-motion denied.

## II. ARGUMENT

### A. The Government Offers No Persuasive Defense of the Final Rule’s Purely Legal Rationales.

In its motion, Humana’s primary submission is that the Final Rule violates the APA because the rule’s purely legal rationales are incorrect as a matter of law. Humana MSJ at 21-36. In opposition, the Government variously attempts to recast Humana’s lawsuit as a challenge to the CMS-HCC risk coefficients that the agency uses to set Medicare Advantage payment rates, Gov’t Br. at 26-27, 36, an attack on CMS’s sub-regulatory medical-record requirement, *id.* at 25-26, or a contention that “population-level audit recoveries would necessarily produce inaccurate payments,” *id.* at 36. None of this responds to Humana’s actual argument against the Final Rule.

This APA action is limited to the two legal rationales on which CMS rested the Final Rule: (1) that the actuarial-equivalence requirement never applies to extrapolated RADV audits and (2) that the Coding-Intensity Adjustment somehow precludes an FFS Adjuster.<sup>2</sup> Both rationales are incorrect as a matter of law, and the APA therefore requires that the Final Rule be vacated as arbitrary and capricious and not in accordance with law. The Government cannot shield CMS’s flawed legal reasoning by pointing to other challenges that it believes Humana could have or should have brought.

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<sup>2</sup> As explained in the motion, 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. Humana MSJ at 2-3. 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.

**1. The Government fails to defend persuasively the Final Rule’s conclusion that the Medicare statute’s actuarial-equivalence requirement does not apply to extrapolated RADV audits.**

The Government fails to effectively defend the Final Rule’s conclusion that actuarial equivalence never applies to extrapolated RADV audits. The Government’s position rests on (1) a flawed textual argument proffered nowhere in the Final Rule, and (2) selective quotations from the D.C. Circuit’s opinion in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), that continue to ignore the court’s actual reasoning. In short, the opposition presents no reason to conclude the Final Rule was correct in carving extrapolated RADV audits out of the Medicare statute’s actuarial-equivalence requirement.

**a. The Government’s reading of the actuarial-equivalence requirement cannot be squared with the statute’s plain text or structure.**

In the Final Rule, CMS asserted that because RADV audits occur “after the fact” of the agency’s initial payments to MAOs, they need not satisfy the statute’s actuarial-equivalence requirement. App. 007343, 007355. The Government declines to defend that temporal limitation, admitting that its statutory “argument does not depend on the ‘timing’ of a payment adjustment[.]” Gov’t Br. at 34 n.16.<sup>3</sup>

The opposition instead adverts to the language of 42 U.S.C. § 1395w-23(a)(1)(C)(i), but misreads the statute. That provision states that the agency shall “adjust” payments to MAOs for “such risk factors as age, disability status, gender, institutional status, and such other factors as the

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<sup>3</sup> In a footnote, the Government nonetheless posits that a temporal limitation would not be “entirely atextual,” *id.*, pointing to the statute’s command that CMS “shall make monthly payments under this section *in advance*,” *id.* (quoting 42 U.S.C. § 1395w-23(a)(1)(A) (emphasis in Government’s brief)). That footnote cannot resuscitate an argument that the Government abandons in the body of its brief, *see Bidas S.A.P.I.C. v. Gov’t of Turkmenistan*, 345 F.3d 347, 356 n.7 (5th Cir. 2003), and is meritless in any event. The requirement that CMS pay MAOs “in advance” of the month in which the MAO provides benefits does not exempt the amount ultimately paid from the actuarial-equivalence requirement, which applies to all “adjust[ments]” to “payment amounts.” 42 U.S.C. § 1395w-23(a)(1)(A), (C); *see Humana MSJ* at 24-25.

Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). The Government contends that because the referenced “paragraph (3)” commands CMS to develop health-related risk factors for use in risk-adjusting payments to MAOs, the actuarial-equivalence mandate applies only to “payment adjustments made through the ‘Establishment of risk adjustment factors.’” Gov’t Br. at 34. This novel statutory argument, proffered for the first time in this litigation, is the sort of “post hoc rationalization[.]” for agency actions that deserves little weight. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988); *see also Decker v. Nw. Env’t Def. Ctr.*, 568 U.S. 597, 614 (2013); *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co. (State Farm)*, 463 U.S. 29, 50 (1983) (“[C]ourts may not accept appellate counsel’s post hoc rationalizations for agency action.”); *accord Louisiana v. U.S. Dep’t of Energy*, 90 F.4th 461, 469 (5th Cir. 2024). In any event, the Government’s statutory interpretation is wrong for multiple reasons.

*First*, it is not clear what the Government means by “payment adjustments made through the ‘Establishment of risk adjustment factors.’” Gov’t Br. at 34. The phrase has no obvious meaning, and the opposition provides little clarity. But none of the possible meanings support the Final Rule. To the extent the Government is arguing that the actuarial-equivalence requirement applies only to the process of establishing the risk factors themselves through the CMS-HCC model, that interpretation cannot be correct. The actuarial-equivalence requirement applies to “adjust[ments]” to “payment amounts.” 42 U.S.C. § 1395w-23(a)(1)(C)(i). CMS did not adjust *any* payments to MAOs when it established the risk factors used in the CMS-HCC model; it only calculated the coefficients that it would later use to do so. *See id.* § 1395w-23(a)(3). Just as the process of calculating interest rates does not automatically produce an interest payment on a bank

deposit, the development of risk-coefficients does not automatically result in a risk-adjusted payment to an MAO.

To the extent the Government is suggesting that actuarial equivalence governs only payment adjustments executed using CMS's risk-adjustment methodology, the argument fails because extrapolated RADV audit recoveries would be calculated using that very same methodology: in such audits, CMS would estimate the diagnosis codes in the relevant enrollee population that are not documented in medical records and then calculate recoupments using the same risk factors it used to remit payments to the MAO for those same enrollees in the first place. *See Gov't App. 000671*. If CMS's use of risk coefficients to adjust initial payments to an MAO based on a population's health status qualifies as a "payment adjustment[]" made through the "Establishment of risk adjustment factors," there is no logical reason why the agency's subsequent application of those same coefficients to re-adjust payment based on its post-audit assessment of the population's health status would not. *Gov't Br. at 34*. Indeed, the Final Rule itself confirms that extrapolated RADV audits "would enable [CMS] to make contract-level payment adjustments" to MAOs based on the agency's revised assessment of the health status of an MAO's enrollee population. *App. 007345*.

And as Humana's motion noted, CMS could theoretically adjust payment based on extrapolated RADV audits *before* disbursing initial monthly payments to MAOs. *See Humana MSJ at 24-25*. The Government attempts no response to that observation, and offers no logical explanation for why the statutory treatment of such payment adjustments should differ simply because practical necessity requires CMS to perform the adjustments later.

*Second*, the Government's argument ignores the "hornbook" rule of statutory interpretation that the word "including" is "illustrative, not exclusive." *Hometown 2006-1 1925 Valley View*,



*L.L.C. v. Prime Income Asset Mgmt., L.L.C.*, 595 Fed. App'x 306, 311 (5th Cir. 2014); *see Heniff Transp. Sys., L.L.C. v. Trimac Transp. Servs.*, 847 F.3d 187, 191 (5th Cir. 2017) (“the phrase ‘including’ in the statute indicates that the examples . . . listed in the statute are . . . illustrative and non-exhaustive”). Under that principle, the phrase “including adjustment for health status under paragraph (3)” *illustrates*—but does not *limit*—the payment adjustments subject to the actuarial-equivalence mandate. 42 U.S.C. § 1395w-23(a)(1)(C)(i). So even if the Government were correct that payment adjustments based on extrapolated RADV audits are not adjustments “under paragraph (3),” the statutory question would remain whether such recoveries are payment adjustments for “such risk factors as age, disability status, gender, institutional status,” or any “such other factors as the Secretary determines to be appropriate.” *Id.*; *see also id.* (“The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.”). The statutory text confirms that health status is the sort of risk factor Congress anticipated would be subject to actuarial equivalence, and Congress’s use of the illustrative word “including” refutes the Government’s contrary position.

*Third*, the Government’s parsimonious reading of the actuarial-equivalence provision clashes with the relevant statutory and regulatory structure. As Humana explained—and as the Government does not dispute—the actuarial-equivalence requirement anchors a host of statutory mechanisms ensuring that the final payments to MAOs are equivalent to the costs of providing fee-for-service Medicare benefits to the MAOs’ enrollees. *See Humana MSJ* at 25-27. Nor does the Government dispute that CMS has always treated the RADV audit program as part of the broader, integrated system of risk adjustment subject to the actuarial-equivalence mandate. *See id.* at 27-29. CMS located its authority for the RADV program in the statutory paragraph requiring actuarial equivalence, *see* 69 Fed. Reg. 46,866, 46,903 (Aug. 3, 2004) (citing 42 U.S.C. § 1395w-

23(a)(1)(C)), then promulgated the RADV regulations in the section of the Code of Federal Regulations that governs the agency’s entire process of “adjusting” payments—from the initial establishment of coefficients, to the submission of risk adjustment data, through the RADV audit process, *see* 42 C.F.R. § 422.310. The Government responds to none of these points—and nowhere explains how RADV regulations can now be divorced from the other processes CMS undertakes to develop an actuarially sound system of risk adjustment.

The Government also ventures no explanation for why Congress would have gone to such great lengths to ensure the actuarial soundness of the Medicare Advantage program relative to fee-for-service Medicare, only to allow CMS to undermine that carefully constructed statutory scheme through actuarially unsound audits.<sup>4</sup> Indeed, the Final Rule expressly acknowledges that it would tolerate extrapolated RADV audits that would produce “systemic payment error” to MAOs—despite all of the statutory and regulatory tools designed to ensure that MAOs receive actuarially equivalent payments. App. 007355, 007358. The Government’s interpretation would put the statute “at war with itself,” with no statutory language or other evidence to suggest Congress intended such a counterintuitive result. *Santos-Zacaria v. Garland*, 598 U.S. 411, 429 (2023); *see Clark v. Uebersee Finanz-Korporation, A.G.*, 332 U.S. 480, 489 (1947).

*Finally*, the Government asserts that if extrapolated RADV audits are an “adjustment for health status” subject to actuarial equivalence, “then so too is the recovery of individual overpayments,” implying that Humana’s interpretation of the statute conflicts with the D.C. Circuit’s opinion in *UnitedHealthcare*. Gov’t Br. at 35. But that argument ignores

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<sup>4</sup> Given the congressional emphasis on actuarial equivalence, it is damning to this rulemaking process that the administrative record contains no evidence that the agency’s Office of the Actuary reviewed or approved the Final Rule. *See* App. 007358 (reciting and not refuting comment that “CMS did not identify a qualified actuary involved in the study” relied upon in the Proposed Rule).

*UnitedHealthcare*'s explanation that the actuarial-equivalence requirement does not apply to the individual payments at issue in the Overpayment Rule because the "use of the qualifier 'actuarial' necessarily implies an assessment made at the group or population level, not the individual level, so as to support credible statistical inferences." *UnitedHealthcare*, 16 F.4th at 886. The D.C. Circuit thus concluded that it was implausible that Congress intended to apply the term "actuarial" to "particular mistaken payments." *Id.* Although Humana believes *UnitedHealthcare* incorrectly concluded that actuarial-equivalence does not apply to recoupments of individual payments, that question is not at issue in this case because—even under *UnitedHealthcare*—the phrase "adjust payment . . . so as to ensure actuarial equivalence" applies to group or population-level risk assessments such as extrapolated RADV audits. *See infra* Section II.A.1.b.

**b. The D.C. Circuit's decision in *UnitedHealthcare* does not support the Government's argument that extrapolated RADV audits are exempt from actuarial equivalence.**

As Humana explained in its motion, the Final Rule's reliance on the *UnitedHealthcare* decision is misguided because that opinion expressly distinguished extrapolated RADV audits from the Overpayment Rule that the D.C. Circuit was reviewing, and because the court's logic supports Humana's position here. *See* Humana MSJ at 29-32. The Government's argument in this Court fails to grapple with either Humana's analysis or the D.C. Circuit's actual reasoning.

While acknowledging that *UnitedHealthcare* is not binding on this Court, the opposition leans on the opinion like a crutch. The Government's refrain is that the D.C. Circuit "held" that the actuarial-equivalence requirement is not "'broadly applicable' throughout the Medicare Advantage program," but applies only to "'CMS's calculation and disbursement of monthly payments in the first instance.'" Gov't Br. at 26 (quoting *UnitedHealthcare*, 16 F.4th at 885); *see also id.* at 26, 35 (same). Absent from the Government's argument is any analysis of the context in which that quotation appears—because the court's actual reasoning does not support the

Government's position. The D.C. Circuit pointed to § 1395w-23(a)(1)(A)'s focus on "disbursement of monthly payments" to explain why the actuarial-equivalence provision would not apply to an entirely *different* statutory provision, 42 U.S.C. § 1320a-7k(d), which establishes an MAO's obligation to return known and individual overpayments. 16 F.4th at 884-86; *see id.* at 870 (concluding that the actuarial-equivalence requirement did not apply "beyond its statutory home"). Here, Humana posits only that the actuarial-equivalence provision applies to extrapolated audits conducted under the authority of § 1395w-23(a)(1)(C) itself, as part of the risk-adjustment system that provision establishes and regulates. *See* Humana MSJ at 31. In context, then, the Government's favored quotation from *UnitedHealthcare* supports Humana's position because it demonstrates why—as a matter of statutory construction—§ 1395w-23(a)(1)(C) applies to RADV audits authorized under that very "statutory home."

The Government weakens its position even further by completely ignoring two other grounds for distinguishing *UnitedHealthcare*, both of which establish that it does not provide a coherent rationale for the Final Rule. *First*, as noted, *UnitedHealthcare* concluded that actuarial equivalence applies "at the group or population level," and so determined that it did not reach the Overpayment Rule, which addresses only "particular mistaken payments to Medicare Advantage insurers." 16 F.4th at 886. The Government's failure to recognize this crucial distinction is all the more egregious in light of its feigned ignorance about Humana's argument that actuarial equivalence governs "population-level" adjustments like extrapolated RADV audits, *e.g.*, Gov't Br. at 28—a phrase the Government puts in scare quotes throughout its opposition, *see id.* at 35 (asserting without basis that *UnitedHealthcare*'s interpretation of § 1395w-23(a)(1)(C) "did not rest on any distinction between known and extrapolated overpayments, or individual and 'population-level' recoveries"). But the distinction between known, individual overpayments on

the one hand—which are not at issue in this case—and population-level adjustments that implicate actuarial principles on the other comes straight from the *UnitedHealthcare* opinion itself, the very authority that supposedly supports the Final Rule.

*Second*, the D.C. Circuit reasoned that the Overpayment Rule and the actuarial-equivalence mandate apply to “different actors.” 16 F.4th at 886. Again, Humana does not agree that the D.C. Circuit’s reasoning on this point is correct, but it undermines the Government’s reliance on *UnitedHealthcare* because both the actuarial-equivalence provision and the Final Rule are directed at CMS’s authority under the Medicare Advantage risk-adjustment system. *See id.*

Rather than address these arguments, the Government instead invokes *UnitedHealthcare* to argue that Humana’s real dispute is with CMS’s medical-record requirement. *See Gov’t Br.* at 25-27, 42 (citing *UnitedHealthcare* for the proposition that “[n]either Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer”). Not so. Humana does not question CMS’s authority to require medical-record documentation for submitted diagnosis codes. It simply maintains that if the agency seeks to enforce that requirement through population-level, statistically extrapolated RADV audits, CMS must do so in a manner that complies with the statutory command of actuarial equivalence. The D.C. Circuit “express[ed] no opinion” on that question, 16 F.4th at 893 n.1, and nowhere suggested that CMS’s interest in unfettered enforcement of a sub-regulatory documentation standard could trump Congress’s express statutory command.

- c. The Government’s attack on Humana’s “facial challenge” lacks merit because statistically extrapolated RADV audits based on cohorts and sub-cohorts of an entire MAO’s contract membership result in population-level payment adjustments and, thus, must comply with the statute’s actuarial-equivalence requirement.**

The Government next contends that, even if Humana were correct that “contract-level” extrapolation is subject to the statute’s actuarial-equivalence requirement, CMS can still ignore

actuarial equivalence when extrapolating audit results to specific groups of enrollees who share a particular health characteristic. *See* Gov't Br. at 31-32. The Government argues that Humana's "facial challenge" must therefore fail, since the Final Rule could be lawful "in some of its applications"—namely, those in which CMS exercises its discretion to extrapolate RADV audit results to some cohort of enrollees smaller than the population of an entire Medicare Advantage contract. *Id.* (citing *United States v. Rahimi*, 144 S. Ct. 1889, 1898 (2024)). This argument fails because, among other reasons, it rests on the demonstrably false premise that RADV audits of a cohort or sub-cohort of enrollees are not population-level payment adjustments.

*I.* To start, Humana contests the foundational reasoning CMS offers to justify the Final Rule, both because the agency unlawfully dispensed with a statutory mandate and because it failed to engage in reasoned decision making in adopting the Rule. Neither of those challenges turns on how CMS chooses to apply the Final Rule, so the Government's reliance on the "all applications" test articulated in *United States v. Salerno*, 481 U.S. 739 (1987), is misplaced.

The Government's two principal cases do not support its argument because both involved circumstances where the "facial" nature of the challenge depended on factual distinctions among potential applications. In *Associated Builders & Contractors of Texas, Inc. v. National Labor Relations Board*, 826 F.3d 215 (5th Cir. 2016), for instance, the plaintiff argued that a statutory requirement that the "Board hold an 'appropriate hearing' on questions of representation" before union representation elections necessarily required that questions of voter eligibility be subject to "pre-election hearings." *Id.* at 221. The Board's challenged rule granted the Board "discretion to defer consideration of individual voter eligibility" until after elections had taken place. *Id.* at 222. The court rejected the plaintiff's facial challenge because it could not show that the statute required *all* eligibility determinations to be made before the elections, or that it was arbitrary and

capricious to allow for discretion as to the timing of *some* eligibility determinations. *Id.* at 222-23.

Similarly, *Scherer v. U.S. Forest Service*, 653 F.3d 1241 (10th Cir. 2011), involved a facial challenge to the Forest Service’s imposition of certain “amenity fees” on visitors to a national park. *Id.* at 1242. The plaintiffs argued that the policy exceeded the agency’s statutory jurisdiction because the statute barred the agency from charging fees to one subset of visitors: those who used no facilities. *Id.* at 1243. Then-Judge Gorsuch, writing for a unanimous panel, concluded that because the agency could lawfully charge fees to those visitors using the amenities, a facial challenge could not succeed. *Id.* at 1243-44. Instead, the rule could only be challenged as applied to the visitors who did not use the facilities.

The Final Rule is meaningfully different from these other challenges, which involved the application of rules that may have been statutorily permissible as to some, and unlawful as to others. There is no such differentiation here: the Government contends that the actuarial-equivalence mandate never applies to any extrapolated RADV audits, and Humana contends that it applies to all of them. In other words, the Government’s misinterpretation of the statute is arbitrary and capricious and contrary to law in every possible application of the Final Rule, so *Salerno*’s reasoning poses no obstacle to Humana’s facial challenge.

Moreover, every application of the Final Rule depends on flawed legal reasoning that violates the APA’s foundational command that rules be set aside if they are “arbitrary and capricious,” “contrary to law,” or “in excess of statutory . . . authority, or limitations[.]” 5 U.S.C. § 706(2)(A), (C); *see Scherer*, 653 F.3d at 1245 (recognizing that an arbitrary and capricious challenge to the agency’s reasoning raises facial invalidity). CMS could have promulgated a rule specific to cohort audits, based on the rationale the Government now asserts in this litigation; but

it instead rested the Final Rule on the premise that the actuarial-equivalence requirement is categorically inapplicable to extrapolated RADV audits. The Final Rule's validity under the APA must rise or fall on the reasoning that CMS actually offered. *See In re Bell Petroleum Servs.*, 3 F.3d 889, 905 (5th Cir. 1993) (declining to "accept the [agency's] post-hoc rationalizations" because the court's decision on APA challenge "must be made on the basis of the rationale relied on by the [agency] as contained in the administrative record"). And that reasoning is limited to an erroneous statutory interpretation of the actuarial-equivalence requirement's scope. That incorrect legal rationale renders the Final Rule arbitrary and capricious and not in accordance with law, so there is "no set of circumstances" under which it may be lawfully applied. *Salerno*, 481 U.S. at 745.

2. In any event, regardless of whether CMS extrapolates its audit findings to *all* enrollees under a contract or a preselected "cohort," extrapolated RADV audits of a subset of enrollees with common characteristics unquestionably effectuate population-level payment adjustments. Because the agency's proffered "sub-cohort" methodology still "adjusts the payment amount" owed to MAOs under the audited contract through a fundamentally actuarial process, it must be subject to the statute's actuarial-equivalence mandate. 42 U.S.C. § 1395w-23(a)(1)(C)(i). As the D.C. Circuit observed in *UnitedHealthcare*, "'actuarial' necessarily implies an assessment made at the group or population level . . . so as to support credible statistical inferences." *UnitedHealthcare*, 16 F.4th at 866. A statistical analysis, made "at the group level," is precisely the sort of actuarial analysis that falls within the actuarial-equivalence requirement. *See supra* at 8-9, 10-11. And that is the sort of actuarial analysis that extrapolated cohort audits perform. *See Gov't App.* 000671.



Moreover, those extrapolated audits are, in effect, contract-wide because they call for CMS to adjust payments for each and every enrollee within the contract who has the defining characteristic of the cohort based on the audited sample. *See* Gov't Br. at 29 (explaining that for each audit involving extrapolation, "CMS will select a sample of 35 beneficiaries from the group of interest, review their medical records, and then extrapolate the results of that review to estimate overpayments for the entire group"). For instance, CMS's decision to construct an audit cohort of all enrollees within a particular contract with diagnosis codes "derived only from linked or unlinked chart review records," Gov't App. 000654, is in effect an audit of the entire contract population because the cohort captures all enrollees under the contract who have the defining characteristic. Thus, a cohort or subcohort extrapolated RADV audit is also subject to the actuarial-equivalence mandate, and the Government's proffered distinction is immaterial.

3. The Government submits the Declaration of Jennifer Dupee to support the assertion that the Final Rule is being applied in a legal fashion, but that declaration does not demonstrate the Rule's legality. *See* Gov't App. 000650-57. Of course, none of the Dupee testimony is in the administrative record on which CMS relied in promulgating the Final Rule.<sup>5</sup> Yet, the Government apparently feels compelled to leave the Court with the misimpression that many of the extrapolated RADV audits now underway are limited in scope. But whether an audited cohort is large or small has no bearing on whether CMS is conducting "an assessment made at the group or population level . . . so as to support credible statistical inferences." *UnitedHealthcare*, 16 F.4th at 866. And in fact, the declaration demonstrates beyond genuine dispute that CMS is pursuing many

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<sup>5</sup> Judicial review in APA cases is generally "limited to the record compiled by the agency," and the Government points to no "unusual circumstances justifying a departure from [that] general presumption." *Medina Cnty. Env't Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 706 (5th Cir. 2010).

significant extrapolated audits under the Final Rule, including audits of Humana’s contracts. *See, e.g.*, Gov’t App. 000655 ¶ 17 (describing “nine Humana contracts selected for audit in [payment year] 2018” alone), 000679-80 (listing thousands of Medicare Advantage enrollees in relevant “groups of interest” for selected audits).

The Dupee declaration explains that there are some pending RADV audits that will not involve extrapolation at all and, thus, will only seek to recover overpayments for those diagnosis codes that are found to be undocumented in individual enrollees’ medical records. Gov’t App. 000655 ¶ 19. To the extent the Government relies on audits that do not involve extrapolation, those audits are not being conducted pursuant to the authority announced in the Final Rule—which expressly adopts a new extrapolation policy—and so are irrelevant. *See* App. 007342 (Final Rule “codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018”). By definition, the new policy that Humana challenges here applies only when CMS or HHS-OIG is extrapolating an audit sample to a larger population of enrollees in the audited Medicare Advantage contract.

**d. Humana has no reason to challenge the CMS-HCC risk coefficients because they do not necessarily violate the Medicare statute’s actuarial-equivalence requirement.**

The Government repeatedly contends that rather than challenging the Final Rule, Humana must challenge the CMS-HCC risk coefficients CMS publishes annually. *See* Gov’t Br. at 26-27, 35-36. That argument fails because even if Humana could challenge the risk coefficients, as the Government argues, it would not necessarily follow that a challenge to the Final Rule is improper. In any event, the Government’s argument fundamentally misunderstands Humana’s objections, which center on an actuarial defect created by the Final Rule’s elimination of the FFS Adjuster—not the risk coefficients.

Humana is *not* alleging any injury caused solely by the risk coefficients. To the contrary, Humana agrees with the Government that CMS can choose to use unaudited *or* audited fee-for-service Medicare claims data—or, for that matter, Medicare Advantage encounter data—to generate risk coefficients for the Medicare Advantage program. *See, e.g.*, Compl. ¶¶ 43-44. Coefficients derived from unaudited fee-for-service Medicare claims data can satisfy actuarial equivalence if: (i) the coefficients are applied to *unaudited* Medicare Advantage encounter data; or (ii) CMS “accounts for” any differences between the documentation standard used to calculate the risk coefficients and the documentation standard used to adjust payments via RADV audits, App. 007703-04—which is precisely what the FFS Adjuster was designed to do. Unsurprisingly, then, Humana has never argued that the RADV audit program must “include a reevaluation of the published risk factors,” Gov’t Br. at 28, or assumed that “errors in Part A and Part B data cause the risk factors for diagnoses to be too low,” *id.* at 35.

The motion instead contends that Humana is injured by CMS risk-adjusting payments to the Company based on RADV audits that apply a different documentation standard than the standard used to develop the risk coefficients. *See, e.g.*, Humana MSJ at 2. Despite the Government’s misdirection, Humana’s position is nothing new. *See* App. 003706 (Humana comment explaining that “[t]he Data Inconsistency Issue only arises when CMS makes payment recoupments to account for unsubstantiated MA diagnosis codes (*i.e.*, *audited* MA data) without accounting for the fact that . . . risk coefficients [are] generated from *unaudited* Medicare FFS diagnosis codes”). The American Academy of Actuaries highlighted the actuarial problems with CMS’s approach as early as 2011, when it advised CMS that this “type of data inconsistency not only creates uncertainty, it may also create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities.” Humana MSJ at 13

(quoting App. 007625). Indeed, Actuarial Standard of Practice 45, issued by the Actuarial Standards Board, makes clear that the “type of input data that is used in the application of [a] risk adjustment [model] . . . [must] be reasonably consistent with the type of data used to develop the model.” *Id.* (quoting App. 008898).

Prior to the Proposed Rule in 2018, CMS freely acknowledged—both internally and to the public—this bedrock actuarial principle, explaining that the agency “should be using the same [documentation] standard for both” RADV audits and the development of risk coefficients, *id.* at 15 (quoting App. 001702), or applying an FFS Adjuster to “account[] for” the inconsistent documentation standards, *id.* at 16 (quoting App. 007703-04). Because the actuarial defect arises not from the coefficients but from a RADV audit methodology that fails to account for how the coefficients are developed, the Final Rule is the proper target of Humana’s APA challenge—as this Court implicitly recognized when it rejected the Government’s motion to dismiss. *See* Order Denying Defs.’ Mot. to Transfer Venue or Dismiss at 8-12, ECF No. 36 (holding that Humana sufficiently pleaded concrete injury traceable to Final Rule).

Given that there is nothing inherently wrong with risk coefficients developed using unaudited fee-for-service Medicare claims data and that CMS announced in 2012 that it would apply an FFS Adjuster to extrapolated RADV audits, Humana had no reason to bring an APA challenge until the publication of the Final Rule in 2023. Nor could a challenge to the coefficients for payment year 2024, for example, remedy the actuarial problem created by applying the Final Rule to prior payment years; only a challenge to the Final Rule could redress those injuries.

The Government has—at most—established that Humana *could* raise some of the arguments it levels against the Final Rule in a challenge to risk coefficients for payment years that post-date the Final Rule. But the Government cites no authority for the proposition that Humana

is *required* to do so, or that Humana’s challenge to the Final Rule’s RADV audit methodology is improper on that basis. *Cf. Black Rock City LLC v. Haaland*, 2022 WL 834070, at \*5 (D.D.C. Mar. 21, 2022) (rejecting argument that plaintiffs should have challenged earlier “estimate decisions” rather than later decisions calculating actual fees due).

Finally, the Government points to language in *UnitedHealthcare* to suggest that Humana’s objections must be raised in a challenge to the risk coefficients, Gov’t Br. at 26-27, but *UnitedHealthcare* does not support that proposition. The opposition suggests that the D.C. Circuit rejected UnitedHealthcare’s challenge to the Overpayment Rule by ruling that it “could not ‘use actuarial equivalence to litigate belated objections to the risk-adjustment model or the level of its monthly payments,’” and that the failure to challenge the risk coefficients is similarly “fatal” to Humana’s challenge here. *Id.* (quoting *UnitedHealthcare*, 16 F.4th at 887). That contention far overreads the cited language. In fact, the D.C. Circuit began its analysis of UnitedHealthcare’s *empirical* argument—that the Overpayment Rule actually caused a violation of actuarial equivalence—by noting that because UnitedHealthcare had not challenged the coefficients or base payment rates, the court would “accept the unchallenged validity of the overall design of the model, the risk factors considered by CMS . . . and the accuracy of the resultant values of relative factors.” 16 F.4th at 887. In that context, the court noted that UnitedHealthcare could not “litigate . . . objections” to those premises. *Id.* The court then proceeded to find that, on the merits, UnitedHealthcare had not proven that various inaccuracies in fee-for-service Medicare data “necessarily lead[] to any inflated or deflated relative factors,” or at what point “the removal of some, even if not all, unsupported codes from an insurer’s data would violate actuarial equivalence.” *Id.* at 887-91.

Although the D.C. Circuit’s analysis of those subsidiary points is incorrect, all the court did in the language cited by the Government was accept the coefficients as a baseline historical fact. And here, there is no dispute over that point. Humana takes no issue in this action with the coefficients. *See supra* at 2, 16-17. Also unlike UnitedHealthcare, Humana makes no *empirical* argument here that any particular audit approach in fact violates actuarial equivalence—indeed, the agency abandoned any empirical analysis of factors like those the D.C. Circuit discussed.<sup>6</sup> Rather, Humana disputes the sufficiency of the agency’s *legal justification* for the Final Rule. *UnitedHealthcare* cannot plausibly be read as holding that Humana’s legal challenge can only be understood as a “belated objection[]” to the risk coefficients. The Government’s reliance on *UnitedHealthcare* is therefore misplaced.

**2. The Coding-Intensity Adjustment does not support CMS’s rationale for the Final Rule because it addresses fundamentally different actuarial issues than extrapolated RADV audits.**

CMS’s alternative rationale for abandoning the FFS Adjuster—that the Coding-Intensity Adjustment allows the agency to pursue extrapolated RADV audit recoveries without regard to actuarial equivalence, *see* App. 007343, 007356—fares no better than its primary justification. As Humana demonstrated in its motion, the Final Rule’s reliance on the Coding-Intensity Adjustment: (a) is an unexplained departure from prior CMS statements recognizing that, unlike RADV audits, the Coding-Intensity Adjustment does not concern the recoupment of payments to MAOs based on diagnosis codes that lack medical record documentation; (b) does not comport with basic

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<sup>6</sup> *See supra* n.2 (explaining that, while Humana submits that the administrative record demonstrates that the Final Rule violates actuarial equivalence and would result in systematic underpayments to MAOs for the risks they accept to provide benefits to Medicare beneficiaries, the Court need not resolve those questions to decide this case). This APA action presents a different and preliminary question—whether CMS is correct that Congress exempted extrapolated RADV audit recoveries from the Medicare statute’s actuarial-equivalence requirement.

canons of statutory construction; and (c) otherwise fails as a matter of administrative law. Humana MSJ at 32-36. The Government offers no meaningful response to any of these arguments.

*a.* In the Final Rule, CMS concludes that Congress's command to impose a downward Coding-Intensity Adjustment to risk scores for Medicare Advantage enrollees grants the agency carte blanche to disregard actuarial equivalence when conducting RADV audits. *See* App. 007343, 007356. That argument, however, ignores that, for more than a decade, CMS has taken the position that the Coding-Intensity Adjustment and RADV audits are not duplicative because they serve different purposes—the former accounts for MAOs' incentive to fully report all applicable diagnoses for each Medicare Advantage enrollee (*i.e.*, diagnosis coding completeness), while the latter concerns recouping payments to MAOs for diagnosis codes that lack medical record documentation (*i.e.*, undocumented diagnosis codes). Humana MSJ at 33-34. The Final Rule does not explain how or why a statutory provision concerned with coding completeness has any bearing on the agency's obligation to satisfy actuarial equivalence when conducting RADV audits intended to recoup MAO payments based on undocumented diagnosis codes.

Rather than rebutting this argument directly, the Government seeks to minimize CMS's past statements distinguishing the Coding-Intensity Adjustment and RADV audits by pointing out that *one* of the relevant agency statements is from less than a week after Congress enacted a mandatory Coding-Intensity Adjustment. Gov't Br. at 39. It is unclear why that timing helps the Government's cause—unless the Government is suggesting, however implausibly, that CMS had no idea that Congress had enacted a major statutory provision regulating the benefit program administered by the agency. There is no reason to think that CMS's statement failed to account for the recently enacted legislation. In any event, on numerous occasions over the subsequent years—and as recently as 2024—the agency has continued to emphasize that the Coding-Intensity

Adjustment and RADV audits tackle distinct issues. App. 000647 (“The MA coding pattern adjustment is not intended to adjust for inaccurate coding, but it is intended to account for program-wide differences in coding patterns between MA and FFS.”); *see also, e.g.*, App. 000112, 000294-95. Humana inventoried this lengthy history in its motion, Humana MSJ at 33-34, and the Government offers no response, *see* Gov’t Br. at 39.

*b.* The Government’s position that the Coding-Intensity Adjustment limits actuarial equivalence makes no sense as a matter of statutory construction. Where, as here, two statutory provisions are “harmonious” and not “textually inconsistent,” courts decline to infer that one provision restricts the plain language of another. Humana MSJ at 35 (citing *Quarles v. St. Clair*, 711 F.2d 691, 700-01 (5th Cir. 1983)).

The Government does not contest this principle of statutory construction. Rather, it chiefly argues that the Medicare statute’s provision establishing the Coding-Intensity Adjustment reflects Congress’s “holistic” determination that MAO payments are “too high.” Gov’t Br. at 38-39; *see also id.* at 39-40 (describing Coding-Intensity Adjustment as a “holistic congressional assessment of the accuracy of Medicare Advantage payments”); *id.* at 37 (“Congress itself has evaluated the accuracy of the payments made to Medicare Advantage insurers under the CMS-HCC model, and has twice enacted its evaluation into law.”). From there, the Government leaps to the conclusion that applying an FFS Adjuster or otherwise addressing the actuarial-equivalence defect created by extrapolated RADV audits is inconsistent with the Coding-Intensity Adjustment because it would rest on the “opposite and inconsistent premise that [Medicare Advantage] payment rates are too low.” *Id.* at 38.

That overly simplistic argument fails for many reasons. To begin, it is not stated in the Final Rule. Though the Final Rule alleges that the existence of a Coding-Intensity Adjustment



renders the application of a FFS Adjuster unreasonable, *see* App. 007343, 007356, CMS did not find that the Coding-Intensity Adjustment represents a congressional judgment that payments to MAOs are too high in the abstract and therefore bars the agency from making any adjustments that would inure to MAOs' benefit. The Court may not sustain the Final Rule on the basis of "counsel's *post hoc* rationalizations" that appear nowhere in the Final Rule itself. *State Farm*, 463 U.S. at 50.

The argument is also wrong on the merits. First, there is nothing "textually inconsistent" between the Coding-Intensity Adjustment and Humana's reading of the actuarial-equivalence provision. *Quarles*, 711 F.2d at 700-01. The Coding-Intensity Adjustment does not prohibit adjustments that sustain, rather than reduce, risk-adjusted payments. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(ii). Second, the Government cites no support for its new contention that the Coding-Intensity Adjustment is a "holistic" assessment of MAO payment rates. On the contrary, as Humana previously explained in the motion, the legislative and regulatory history shows that Congress intended that provision to address MAOs' greater incentive to "find and report as many diagnoses as can be supported by the medical record" and thereby "*legitimately* increase [enrollees'] risk scores." Humana MSJ at 9-10 (quoting App. 008872-73); *see also id.* at 33. That objective is fully consistent with applying an FFS Adjuster: both the FFS Adjuster and the Coding-Intensity Adjustment aim to ensure that "risk scores . . . are consistent across both fee-for-service Medicare and Medicare Advantage settings." App. 007752. And nothing in the legislative history suggests that in seeking to achieve parity between Medicare Advantage and fee-for-service Medicare, Congress intended to bar CMS from accounting for a *different* potential discrepancy between the two programs. Humana MSJ at 35-36. Finally, the Government's position proves far too much—if by adopting the Coding Intensity Adjustment, Congress effectively barred CMS from any policies inuring to MAOs' financial benefit, the agency could adopt any policy that

lowered payments or increased costs to MAOs regardless of the actuarial consequences. No principled reading of the Medicare statute could justify that absurd proposition.

Separately, the Government maintains that because the Coding-Intensity Adjustment refers to “applying the adjustment under [42 U.S.C. § 1395w-23(a)(1)(C)(i)] for health status to payment amounts,” § 1395w-23(a)(1)(C)(i) must be read to apply only to “the establishment of risk adjustment factors,” not “audit recoveries.” Gov’t Br. at 38-39. But this argument thoroughly misunderstands the order of operations when CMS calculates a Medicare Advantage enrollee’s risk score. The Coding Intensity Adjustment does not alter the “risk adjustment factors” developed by CMS. As the Government elsewhere acknowledges, rather than deflating risk *factors*—that is, the risk coefficients—the Coding-Intensity Adjustment is an across-the-board reduction to an enrollee’s risk *score*, after CMS tabulates and applies the coefficients. *See id.* at 11. The enrollee’s risk score is tabulated using coefficients that include health status and other risk factors that the agency has determined predict future healthcare costs, such as whether the enrollee is under the care or custody of particular types of facilities like skilled nursing facilities or psychiatric hospitals. *See App. 008008, 007781.* The Coding-Intensity Adjustment simply reduces the tabulated risk score of each enrollee by a uniform percentage to account for the different coding incentives and patterns between fee-for-service Medicare and Medicare Advantage. Thus, rather than supporting the Government’s view that CMS’s statutory obligation to achieve actuarial equivalence ends after it establishes risk coefficients, the Coding-Intensity Adjustment demonstrates Congress’s intention to create an actuarially sound risk-adjustment system, beginning with the establishment of risk coefficients and extending through any subsequent “adjust[ments]” to MAOs’ “payment amount[s].” 42 U.S.C. § 1395w-23(a)(1)(C)(i); *see Humana MSJ at 25-27.*

c. Finally, because the Final Rule’s reliance on the Coding-Intensity Adjustment was entirely “conclusory,” it fails as a matter of administrative law. Humana MSJ at 34-35. The Government counters that the agency’s reasoning was “adequately laid out in the preamble” to the Final Rule. Gov’t Br. at 39 (citing App. 007356-57). But the cited passage merely recounts the history of the Coding-Intensity Adjustment and then asserts that, in light of this statutory adjustment, it is unreasonable to read the Medicare statute to limit CMS’s ability to “enforce longstanding documentation requirements” by requiring an offset for extrapolated RADV audit recoveries. App. 007356-57. The Government’s opposition does not—and cannot—identify any portion of the Final Rule that purports to explain *why* such a reading is unreasonable, or even how the Coding-Intensity Adjustment relates to RADV audits at all. *See* Humana MSJ at 34-35. Nor does the opposition argue that the Final Rule previewed the Government’s post hoc explanation that the Coding-Intensity Adjustment authorizes actuarially unsound extrapolated audits because it reflects a generic congressional judgment that MAO payments are too high. That deficiency alone confirms that the Coding-Intensity Adjustment rationale cannot support the Final Rule.

**B. The Government Offers No Credible Justification for CMS’s Decision to Abandon the FFS Adjuster, Confirming That the Final Rule Is Arbitrary and Capricious.**

Humana’s motion showed that, regardless of the Court’s reading of the Medicare statute, the Final Rule is arbitrary and capricious because it offers no reasonable explanation for CMS’s decision to abandon the FFS Adjuster. Humana MSJ at 36-40. The Government’s opposition confirms that the Final Rule contains no “satisfactory explanation” for CMS’s policy reversal, and thus must be set aside as arbitrary and capricious. *Dep’t of Commerce v. New York*, 588 U.S. 752, 773 (2019) (quoting *State Farm*, 463 U.S. at 43).

**1. The FFS Adjuster addressed a fundamental actuarial problem with extrapolated RADV audits that CMS acknowledged for years.**

For years before the publication of the Proposed Rule in 2018, CMS acknowledged the actuarial problem that arises when the agency calculates risk coefficients based on *unaudited* fee-for-service Medicare claims data but applies those coefficients to *audited* Medicare Advantage encounter data through extrapolated RADV audits. The agency concluded that it could not use “one documentation standard for RADV, which is perfection,” while at the same time using “another documentation standard for risk adjustment, which reflects a certain level of [fee-for-service Medicare diagnosis] codes that aren’t documented in a medical record.” App. 001702; *see* Humana MSJ at 15; Gov’t Br. at 13 (admitting that “some diagnoses reported in [fee-for-service Medicare] programs lack medical record support”). CMS further acknowledged that an FFS Adjuster that would “offset . . . recovery amounts under RADV” could “[e]nsure[] that RADV and [Medicare Advantage] payments are on the same documentation standard” and was “the right thing to do.” App. 001690, 001703; *see* Humana MSJ at 15-16. In February 2012, CMS publicly announced its policy adopting the FFS Adjuster to “account[] for” this difference in documentation standards. App. 007700, 007703-04; *see* Humana MSJ at 16.

The Government admits that CMS “reversed course” from its earlier view when it decided to abandon the FFS Adjuster in the Final Rule and “effectively withdrew the 2012 guidance[.]” Gov’t Br. at 20, 44. The Final Rule must be set aside unless that policy reversal was “reasonable and reasonably explained,” *Nat’l Tel. Coop. Ass’n v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009), meaning that 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 Commerce*, 588 U.S. at 773 (quoting *State Farm*, 463 U.S. at 43). Because CMS “chang[ed] its course,” it bears a heightened obligation to offer a reasoned explanation for that

reversal. *State Farm*, 463 U.S. at 42. Merely declaring that the new policy is statutorily *permitted* is not enough; under the APA, the Court must ensure that the agency has “engaged in reasoned decisionmaking *within* [the] boundaries” of its statutory authority. *Rest. L. Ctr. v. U.S. Dep’t of Labor*, 120 F.4th 163, 175 (5th Cir. 2024) (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 371 (2024)).

The Government does not meaningfully dispute Humana’s point that the purely *legal* rationale articulated in the Final Rule cannot supply the required reasoned explanation for CMS’s *policy* decision to abandon the FFS Adjuster given the acknowledged risk of “systematic payment error.” Humana MSJ at 37-38; *see* Gov’t Br. at 42. By “fail[ing] to respond” to Humana’s arguments in the motion, the Government “concedes” them. *Hull v. Kapstone Container Corp.*, 2018 WL 4409798, at \*2 (N.D. Tex. Sept. 17, 2018); *see also Sabal v. Anti-Defamation League*, 2024 WL 5113497, at \*9 n.52 (N.D. Tex. Dec. 13, 2024) (O’Connor, J.) (“Plaintiff tacitly concedes the [Defendant’s] arguments by failing to address them in his response[.]”).

The Government instead points to two related conclusions in the Final Rule to argue that CMS’s decision to abandon the FFS Adjuster was “reasonable” and “adequately explained.” Gov’t Br. at 41-42, 44. But neither conclusion provides any such explanation.

*First*, the Government contends that CMS reasonably concluded that “[t]he proper solution” to any actuarial problem resulting from the inconsistent documentation standards “is to correct the payment rates that apply throughout the Medicare Advantage program, and not to make a payment adjustment that would only apply to audited contracts.” *Id.* at 41. The opposition even characterizes the FFS Adjuster that the agency promoted for years as “a conceptual error.” *Id.* at 42. This contention fails to grapple with the actuarial defect at issue, which arises only with respect to *audited* Medicare Advantage contracts. There is nothing inherently problematic about CMS

choosing to develop risk coefficients for Medicare Advantage payments based on unaudited fee-for-service Medicare claims data. *See supra* at 16-17, 19. It is the application of the risk coefficients to audited Medicare Advantage encounter data through extrapolated RADV audits that creates the inconsistent documentation standards and threatens the systemic underpayments identified by both the American Academy of Actuaries and CMS itself. *See supra* at 17-18; App. 001702. CMS cannot justify abandoning its previous acknowledgment of that actuarial problem by—incorrectly—characterizing the issue as one that affects audited and non-audited contracts alike; Medicare Advantage contracts not subject to extrapolated audits do not face the inconsistent documentation standards introduced by the Final Rule. Nor can the agency ignore this actuarial defect by blithely suggesting that it might try to remedy the problem via some other mechanism at an unspecified future time.

*Second*, and relatedly, the Government repeats its assertion that any systematic payment error due to the inconsistent documentation standards should be addressed through a challenge to the risk coefficients, rather than before this Court. Gov't Br. at 41 (“CMS also concluded that, if there is any adjustment to be made, it should be made through payment rates rather than documentation standards.”). That argument is meritless for the reasons already explained *supra* at 17-19. CMS made a policy choice to build the CMS-HCC model using unaudited fee-for-service Medicare data, as the statute permitted. *See* Gov't Br. at 10 & n.9. The agency is free to alter that choice and instead pursue a policy of basing the risk coefficients on audited Medicare Advantage data. *See id.* But it cannot use its previous policy choice on that issue to justify ignoring actuarial problems created by its new, separate choice to adopt extrapolated RADV audits without an FFS Adjuster.

The Government also asserts in conclusory fashion that the “actuarially sound administration of the Medicare Advantage program is served by the recovery of overpayments,” and repeats its assertion that MAOs have never been entitled to payment on the basis of undocumented diagnosis codes. *Id.* at 42. The Government’s non-response elides the real issue: the Final Rule concedes the risk of “systematic payment error”—an actuarial concern by the agency’s own admission and as commenters repeatedly explained for years, *e.g.*, App. 001688, 001703, 003726, 003750, 003761, 007493, 007625—but disregards it, App. 007358. The opposition’s glib assertion does not reasonably explain CMS’s departure from its previous, considered view that extrapolated RADV audit recoveries without an FFS Adjuster would be actuarially *unsound* and that the FFS Adjuster “makes sense and from a technical point of view is the right thing to do.” App. 001703.

**2. The Final Rule offers no empirical basis to abandon the prior CMS policy adopting a FFS Adjuster.**

Nor does the Government’s opposition point to any attempt in the Final Rule to “examine[] ‘the relevant data’” and “articulate[] ‘a satisfactory explanation’ for [the agency’s] decision” based on the record facts. *Dep’t of Commerce*, 588 U.S. at 773 (quoting *State Farm*, 463 U.S. at 43). As the Government admits, CMS expressly disclaimed its empirical study as a basis for its decision to abandon the FFS Adjuster. Gov’t Br. at 42-43. The Government thus cannot rely on the study in this litigation to explain the agency’s policy reversal. Humana MSJ at 38-39. Nevertheless, the Government cites a brief passage from the Final Rule expressing disagreement with commenters who “claim[ed] that [CMS’s] study or [the commenters’] counter-studies provide[d] evidence that [Medicare] FFS errors systematically reduce payments to MAOs.” Gov’t Br. at 22, 42-43 (citing App. 007358-59). But Humana’s motion already explained in detail why that aside did not constitute a reasoned explanation justifying the Final Rule. Humana MSJ at 38-40. The opposition

merely repeats the Final Rule’s assertions, and provides no response to Humana’s arguments. *Id.* at 42-43; *see Hull*, 2018 WL 4409798, at \*2 (failure to respond effectively concedes arguments).

The opposition also proffers purported evidence that “insurers received almost \$2,000 more in payments than they paid out in claims for each covered beneficiary,” insinuating that MAOs are generally overpaid. Gov’t Br. at 24 & nn.14-15. Oddly, the Government does not tie this inference to any part of its argument, and it provides no support for CMS’s policy reversal. To start, the Government’s evidence does not support its insinuation. The purported \$2,000 difference between payments to MAOs and claims payments does not represent a profit margin—as the overage must cover all of the other non-benefit expenses of administering a Medicare Advantage plan, ranging from marketing to enrollment to claims systems. The Medicare statute itself limits MAOs’ expenditures on expenses other than clinical services and quality improvement through what is referred to as a “medical loss ratio.” *See* 42 U.S.C. § 1395w-27(e)(4).<sup>7</sup> CMS also regulates MAOs’ profit margins in their bids.<sup>8</sup> And in any event, the very premise of the Medicare Advantage program is that MAOs are financially rewarded “to the extent they achieve genuine efficiencies over traditional Medicare.” *UnitedHealthcare*, 16 F.4th at 874. As with the Coding-Intensity Adjustment, the general assertion that payments to MAOs are “too high”—if that is what

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<sup>7</sup> *See also* App. 008193 (defining “medical loss ratio” as a requirement for “health insurance companies” to spend . . . [a] percent of premium dollars on medical care and healthcare quality improvement, rather than on administrative costs”).

<sup>8</sup> *See* App. 001088 (“MA and Part D bid instructions require the aggregate [profit] margin of plans to be within 1.5 percent of the plan’s margin on fully insured health insurance business other than MA and Part D”); CMS, *Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2025*, <https://www.cms.gov/files/document/cy2025-ma-bpt-instructions20240405.pdf> (imposing cap on expected profit margins for MAOs by requiring detailed explanation and specific approval for annual bids that would allow MAO to collect more than 5.5 percent of “additional revenue . . . beyond benefit expenses and non-benefit expenses”).



the Government hopes to imply—cannot justify ignoring a specific actuarial defect resulting from the Final Rule.<sup>9</sup>

Finally, the opposition cites the Final Rule’s conclusion that “commenters had not shown that ‘FFS errors systematically reduce payments.’” Gov’t Br. at 43-44. But the Government has it exactly backward. Humana’s burden here is not to prove that the Final Rule causes systemic payment error that violates actuarial equivalence. *See supra* at 3 & n.2, 20 & n.6. Instead, its burden is to show that, on the administrative record, CMS’s decision to abandon the FFS Adjuster was arbitrary and capricious, either because it was based on erroneous legal rationales or because the agency offered no reasonable explanation for the reversal of its prior policy. Humana’s arbitrary-and-capricious challenge targets CMS’s *policy decision* to abandon the FFS Adjuster, and it is the *agency* that must supply a “satisfactory explanation” for that decision. *State Farm*, 463 U.S. at 43. The Final Rule’s cursory statement of disagreement with certain commenters, devoid of coherent accompanying reasons, supplies no defensible explanation, much less a “satisfactory” one. *See Humana MSJ* at 38.

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<sup>9</sup> In addition to the fact that the cited press report is inadmissible hearsay, the Government may not rely on it, or the MedPAC report cited in footnote 15, to sustain the Final Rule because those documents are outside the administrative record. It is black-letter administrative law that agency action must be judged based on the “grounds . . . upon which the record discloses that [the] action was based,” and that the agency is “not free to defend its decision by supplying new, *post hoc* rationalizations . . . when sued.” *Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 371 (5th Cir. 2024) (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)). The Government therefore may not introduce new empirical justifications in briefing to remedy the absence *in the Final Rule* of a “satisfactory explanation” for CMS’s policy reversal, including a “rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 43.

### C. The Government's Procedural Defense of the Final Rule Is Unpersuasive.

#### 1. The Final Rule is not a "logical outgrowth" of the Proposed Rule because it relies on entirely different justifications.

The Government admits that the Final Rule abandoned the Proposed Rule's first rationale: an "empirical analysis" grounded in the agency's study of diagnosis error in fee-for-service Medicare claims data. Gov't Br. at 44. And it points to no passage in the Proposed Rule articulating either of the two legal rationales proffered in the Final Rule: (1) CMS's assertion that the D.C. Circuit's decision in *UnitedHealthcare* "supports [its] conclusion that an FFS Adjuster is neither required nor appropriate in the context of RADV" audits because the actuarial-equivalence requirement does not apply as a matter of law, App. 007359, and (2) CMS's conclusion that the Coding-Intensity Adjustment forecloses use of an FFS Adjuster.

Instead, the Government contends that the Final Rule effectively adopted the Proposed Rule's second rationale—that an FFS Adjuster would inappropriately "introduce inequities between audited and unaudited" MAOs "by only correcting the payments made to audited" MAOs. App. 000731. The Government focuses on a statement in the Proposed Rule that "RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation." Gov't Br. at 45 (quoting App. 000731). But that statement in no way prefigures either of the legal conclusions on which the Final Rule explicitly relied.

Even if the Government's cited statement could in isolation be interpreted as somehow related to the rationales CMS ultimately adopted in the Final Rule, the context makes clear that the Final Rule does not satisfy the APA's requirement that "[t]he agency's rationale . . . 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). The language upon which the Government now relies was merely a premise supporting the Proposed Rule's now-abandoned rationale that

“correct[ing] any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts . . . would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.” App. 000731; *see* Gov’t Br. at 44-45. That conclusion appears nowhere in the Final Rule, having been supplanted by the two legal rationales described above. The opposition cites no case in which such an ambiguous, cherry-picked sentence was held sufficient to provide the “clear” notice the APA requires. *Tex. Ass’n of Mfrs.*, 989 F.3d at 381-82. On the contrary, such “an exercise in ‘looking over a crowd and picking out your friends’ does not advise interested parties how to direct their comments and does not comprise adequate notice under APA § 533(c).” *Env’t Integrity Project v. E.P.A.*, 425 F.3d 992, 998 (D.C. Cir. 2005) (quoting *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546 (2005)).

The Government also contends that it cured its procedural default by requesting comment on “whether 42 U.S.C. 1395w-23—and in particular clause (a)(1)(C) . . .—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology” after announcing the Proposed Rule but before the D.C. Circuit decided *UnitedHealthcare*. App. 000741; *see* Gov’t Br. at 45. It is undisputed that CMS never sought comment at all on its interpretation of or reliance on the *UnitedHealthcare* decision, a fact the Government ignores. And the agency’s request for supplemental comment never articulated that CMS was reconsidering whether actuarial equivalence applied to extrapolated RADV audits. *See* App. 007380 (explaining CMS’s previous position that RADV audits “further[] actuarial equivalence” by ensuring the “accuracy” of data and permitting corresponding “adjustments” to those payments). “[M]erely informing the public, in a generic sense, of the broad subjects and issues the Final Rule would address is insufficient.” *Mock v. Garland*, 75 F.4th 563, 583-84 (5th Cir. 2023). “Instead, agency notice must describe the

range of alternatives being considered with reasonable specificity.” *Id.*; cf. *Env’t Integrity Project*, 425 F.3d at 998 (final rule that “repudiate[d]” the agency’s previous interpretation of an unchanged regulatory text and “adopt[ed] its inverse” “violated the APA’s notice-and-comment requirements”). CMS did not satisfy that threshold obligation of fair notice, and thus, the Final Rule is procedurally defective under the APA.

**2. CMS’s failure to provide proper notice unfairly prejudiced Humana and thus was not harmless.**

CMS’s misdirection left commenters, including Humana, unable to provide “specific and credible objections” as to why the agency’s new interpretation of the actuarial-equivalence provision is incorrect and why the D.C. Circuit’s reasoning in *UnitedHealthcare* does not support the agency’s conclusions in the Final Rule. *See* Humana’s MSJ at 41-42. This procedural error was therefore prejudicial and requires vacating the Final Rule.

The Government asserts that “other commenters understood CMS to be seeking comment on the applicability of the actuarial-equivalence provision to extrapolated RADV audits.” Gov’t Br. at 46. But none of those commenters had the opportunity to address the Final Rule’s statutory analysis because CMS never articulated it—and even if they were able to “divine” the agency’s “unspoken thoughts,” that does not mean the agency satisfied its obligation to provide fair notice. *Mexican Gulf Fishing Co. v. U.S. Dep’t of Commerce*, 60 F.4th 956, 975 (5th Cir. 2023) (“These comments show only that a few members of the public happened to ‘divine’ the Government’s ‘unspoken thoughts.’”); *see also Tex. Ass’n of Mfrs.*, 989 F.3d at 383 (“The fact that one commenter suggested that data above the 95th percentile is too unstable for rulemaking does not relieve the Commission of its burden to provide notice and an opportunity to comment on the clearly articulated justification for its use of such data.”). Accordingly, a harmless-error analysis does not save the Final Rule.

**D. The Final Rule Is Retroactive and Congress Granted CMS No Authority to Engage in Retroactive Rulemaking.**

The Final Rule is both contrary to law and arbitrary and capricious because it is impermissibly retroactive. As explained in Humana’s motion, the Final Rule is retroactive because it expressly applies to past payment years and attaches new legal consequences to actions long since completed. *See* Humana MSJ at 42-45. That retroactive application is unlawful because Congress did not authorize it. *Id.* at 45-49. Moreover, even if legally authorized, the consequences of applying the Final Rule retroactively are “so unfair as to be arbitrary and capricious.” *Microcomputer Tech. Inst. v. Riley*, 139 F.3d 1044, 1050 (5th Cir. 1998); Humana MSJ at 49-50. To the extent the Government’s opposition even engages with Humana’s arguments, its responses are unavailing.

**1. The Government fails to refute the Final Rule’s retroactive effects or Humana’s reasonable reliance on CMS’s 2012 RADV Notice.**

The Final Rule plainly imposes “new legal consequences” on MAOs, including Humana. *Germain v. U.S. Bank Nat’l Ass’n*, 920 F.3d 269, 275 (5th Cir. 2019). Prior to adopting the Final Rule, CMS had not performed extrapolated RADV audits and, until it issued the Proposed Rule, had committed to apply an FFS Adjuster if it conducted such audits in the future. App. 001690-91, 007703-04. Humana’s Medicare Advantage bids for payment years 2018 to 2023 reflected and relied upon that commitment. *See* Humana MSJ at 44. Under the Final Rule, however, CMS will conduct extrapolated RADV audits without an FFS Adjuster, which materially alters the actuarial foundations of Humana’s already-submitted and accepted bids. Numerous courts have recognized that similar post hoc changes to payment methodologies, including in the Medicare program, constitute retroactive rulemaking. *See id.* (citing, *inter alia*, *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 17 (D.C. Cir. 2011), *Bowen*, 488 U.S. at 207, and *Regents of the Univ. of Cal. v.*

*Burwell*, 155 F. Supp. 3d 31, 47 (D.D.C. 2016)). The Government’s opposition does not squarely address the holdings of these cases, let alone their reasoning. *See* Gov’t Br. at 47-48.

Instead, the opposition principally argues that the Court should turn a blind eye to the obvious impact of the express policy change effected by the Final Rule because—according to the Government—the three pillars underpinning the Final Rule pre-dated its adoption: (1) the medical-record documentation requirement; (2) the existence of medical-record audits; and (3) “statistical sampling and extrapolation” as a “recognized means of calculating overpayments in the Medicare program.” *Id.* at 46-47. Humana agrees that the first two asserted pillars pre-dated the Final Rule, but neither is at issue here. The third, though, compares apples and oranges. Prior to the Final Rule, CMS had never extrapolated RADV audits of MAOs. *Id.* at 47 n.20; *see* App. 001690. The extrapolation process that the Government references in its opposition occurred in Medicare Parts A and B, which is subject to a different compensation scheme entirely. *See* Gov’t Br. at 46-47 (citing *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005) and *Ratanasen v. Cal. Dep’t of Health Servs.*, 11 F.3d 1467, 1469-71 (9th Cir. 1993), which concern only Part A and Part B audits); *id.* at 4-7 (describing different payment structure applicable to Parts A and B). The Government’s “business-as-usual” argument thus fails on its own terms. The Final Rule breaks new regulatory ground by “codif[ying] in regulation” extrapolation of RADV audits in Medicare Part C—and establishing a methodology to do so that categorically excludes an FFS Adjuster. App. 007342.<sup>10</sup>

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<sup>10</sup> Numerous commenters on the Proposed Rule disputed CMS’s statutory authority to extrapolate audit findings in the context of Medicare Part C—that is, Medicare Advantage—explaining that the Medicare statute confers on the agency the authority to extrapolate, but only for Medicare contractors auditing healthcare providers under Parts A and B, and only in certain circumstances. *See, e.g.*, App. 001437-38, 001579-80, 004227-28. The statutory provision conferring that authority does not apply to Medicare Part C. *See* App. 001579-80. While Humana did not raise that objection in its comment to the Proposed Rule, CMS has not previously

Alternatively, the Government attempts to downplay the significance of the 2012 RADV Notice in which CMS committed to apply an FFS Adjuster to any extrapolated RADV audits. *See* Gov't Br. at 47. The plain text of the 2012 RADV Notice speaks for itself. It purports to establish a “Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits.” App. 007700. It was the product of the agency’s “careful[] review[]” of “the more than 500 comments received on the draft methodology.” *Id.* And it made changes “[e]ffective with the [Calendar Year] 2011 RADV audit”—applying prospectively, without limitation. App. 007702; *see also* App. 001693 (CMS talking points: “Payment year 2011 will be *the first year* we will apply the extrapolation methodology that we outline in today’s notice.”).

While CMS explained that the methodology would “be applied to the next round of RADV contract-level audits, which will be conducted on payment year 2011,” App. 007700, nothing in the 2012 RADV Notice or the larger administrative record supports the Government’s new suggestion that CMS intended the methodology to apply *only* to those 2011 audits. *See* Gov’t Br. at 47. As far as Humana is aware, the opposition is the first occasion that CMS or the Government has ever even intimated that the policy announced in the 2012 RADV Notice was intended to apply to audits in only one payment year. Even the Final Rule itself acknowledges its broader scope. *See* App. 007346 (describing the 2012 RADV Notice as “a final methodology for RADV contract-level payment error calculation, *to begin with* PY 2011 RADV audits”); *see also id.* (“Although the use of an FFS Adjuster *beginning with* PY 2011 RADV audits was included in the 2012 methodology, CMS has not issued final RADV audit results for PY 2011 audits *or any subsequent*

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extrapolated audit results in Medicare Part C, and its claim to such authority is legally distinct from the limited statutory authority to extrapolate audit findings under Parts A and B. *See* App. 007347 (Final Rule’s explanation for extrapolation authority).

year, and therefore, an FFS Adjuster has not been applied to any RADV audits issued by CMS to date.”).

The Government now observes that in 2012, CMS took no position “on whether it would apply an FFS Adjuster to RADV audits using a significantly more modest form of sampling and extrapolation, such as those now being conducted for payment year 2018.” Gov’t Br. at 47. But the fact that CMS “took no position” on an audit methodology that the agency would not even propose for another twelve years is neither illuminating nor surprising. Nothing about CMS’s reasoning in 2012 suggests it would not also extend to the extrapolation methodology that the agency announced in 2023. Rather, the 2012 RADV Notice promised to apply an FFS Adjuster to “offset” *any* “preliminary recovery amount,” App. 007703, regardless of whether CMS was conducting a “broad” audit or a “more modest” one, Gov’t Br. at 47.

To accept the Government’s argument, the Court would need to effectively conclude that the Final Rule achieves nothing new and instead just reiterates existing program requirements. That conclusion is not only unreasonable on this record, but this Court has already implicitly rejected it in denying the Government’s motion to dismiss. *See* ECF No. 36 at 9 (discussing “new legal regime mandated by the Final Rule”); *id.* (“Now that the Final Rule eliminates the FFS Adjuster, Plaintiffs will incur costs to change their actuarial calculations.”); *id.* at 8 n.6 (“The Final Rule will require Humana to change its existing actuarial methodology.”). The Final Rule is plainly retroactive.

**2. Congress has not authorized retroactive application of the Final Rule, and retroactive application would be arbitrary and capricious in any event.**

Retroactive application of the Final Rule is contrary to law because it is not authorized by statute. *Bowen*, 488 U.S. at 208-09. The Medicare statute only permits the retroactive application of rules if (i) “necessary to comply with statutory requirements,” or (ii) “failure to apply the change



retroactively would be contrary to the public interest.” 42 U.S.C. § 1395hh(e)(1)(A). Neither ground applies here, and the Government’s contrary arguments simply parrot the Final Rule without addressing any of Humana’s explanations as to why those arguments fail. Moreover, even if it *were* authorized by the Medicare statute, retroactive application of the Final Rule is “so unfair as to be arbitrary and capricious.” *Microcomputer Tech. Inst.*, 139 F.3d at 1051.

First, the Government argues that retroactive application is “necessary” because the Payment Integrity Information Act of 2019 (“PIIA”) directs agencies to “conduct recovery audits . . . in a manner designed to ensure the greatest financial benefit to the Federal Government.” Gov’t Br. at 48 (citing 31 U.S.C. § 3352(i)(1)(A)-(B)). But as Humana already explained, the PIIA nowhere mandates *retroactivity*. Humana MSJ at 46. While traditional recovery audits seek to recoup payments based on the parties’ settled obligations such that recoupment is not truly retroactive, the Final Rule disrupts MAOs’ prior expectations. *Id.* Further, in the motion, Humana highlighted CMS’s internally inconsistent position: If the PIIA truly requires the agency to maximize all audit recoveries, CMS would lack discretion *not* to extrapolate for payment years 2011 through 2017. *Id.* (citing App. 007349). In the Final Rule, CMS relied on prudential considerations to decline retroactive application of the new policy to payment years before 2018. App. 007349. Since the Medicare statute authorizes retroactivity only when “necessary” to comply with *other* statutory obligations, 42 U.S.C. § 1395hh(e)(1)(A), and the Government concedes that the PIIA does *not* require retroactive application for any particular payment year, the Government’s necessity argument for payment years 2018 and beyond collapses. The opposition never answers any of these arguments. *See generally* Gov’t Br. at 47-48.

Nor does the Government respond to Humana’s point that CMS overreads the “public interest” prong by assuming it applies whenever the federal government would save money while

ignoring MAOs' significant reliance interests and the systemic risks to the Medicare Advantage program caused by the agency's unprincipled retroactivity determinations. *See* Humana MSJ at 48-49; *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020) (“[B]ecause [the agency] was not writing on a blank slate, it was required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns.” (emphasis omitted)). Instead, the Government simply doubles down, relying solely on the asserted “improper allocation of taxpayer dollars’ to Medicare Advantage insurers” and ignoring all countervailing interests. Gov’t Br. at 48 (citing App. 007352). That flawed reasoning assumes a limitless and atextual carveout to the Medicare statute’s general prohibition on retroactivity. Humana MSJ at 47-48.

Moreover, the impact of the retroactive aspects of the Final Rule is so severe that even if the Court finds that the Medicare statute authorizes retroactivity, it should not permit it here. *See id.* at 49-50. The Final Rule violates principles of “fair notice, reasonable reliance, and settled expectations” by “undermining the value of costs that parties incurred in reasonable reliance” on the continuation of CMS’s longstanding commitment to apply an FFS Adjuster to extrapolated RADV audits, and its consistent acquiescence to Humana’s Medicare Advantage bids that expressly incorporated that understanding. *Treasure State Res. Indus. Ass’n v. EPA*, 805 F.3d 300, 305 (D.C. Cir. 2015) (discussing the “typical form of unfairness that retroactivity may wreak” in determining whether a regulation had retroactive effect). This doctrine supplies a wholly separate ground for this Court to sever the Final Rule’s retroactive applications, regardless of the Court’s resolution of Humana’s other claims for relief. *See Microcomputer Tech. Inst.*, 139 F.3d at 1050-51 (interpreting the APA’s prohibition against “arbitrary and capricious” agency action to bar fundamentally “unfair” retroactive applications even when retroactivity is statutorily permitted).

And the Government's failure to directly answer these arguments in this litigation provides further confirmation of the indefensible regulatory overreach at issue in this case.

### **E. Vacatur Is the Appropriate Remedy.**

The Government asserts that the Court should decline to vacate the Final Rule as a matter of equitable discretion. Gov't Br. at 48-50. But the Government's opposition concedes that recent binding caselaw holds that the APA authorizes vacatur of unlawful rules. *Id.* at 48 n.21; *see, e.g., Tex. Med. Ass'n v. U.S. Dep't of Health & Human Servs.*, 110 F.4th 762, 779-80 (5th Cir. 2024) (noting that vacatur is "statutorily permissible[] and required in this circuit"); *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374-75 (5th Cir. 2022) ("Vacatur is the only statutorily prescribed remedy for a successful APA challenge to a regulation."); *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021) ("[B]y default, remand *with* vacatur is the appropriate remedy" in an APA case.); *Chamber of Commerce of the U.S. v. U.S. Dep't of Labor*, 885 F.3d 360, 363, 388 (5th Cir. 2018) (vacating challenged rule "*in toto*").

But even if the Court were inclined to entertain the Government's request for a more limited remedy, the opposition offers no factual or other basis on which the Court could rely to exercise its discretion. The Government provides no reason, much less evidence, why the Court should exercise its equitable discretion to provide narrow relief when the Final Rule cannot be lawfully applied as written. *See* Gov't Br. at 48-50. Nor is one readily apparent. Vacatur is therefore appropriate here.

### **III. CONCLUSION**

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

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 3, 2025, 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*  
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