# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

<b>HUMANA INC. and HUMANA</b>	§	
BENEFIT PLAN OF TEXAS, INC.,	§	
	§	
Plaintiffs,	§	
	§	
<b>v.</b>	§	Civil Action No. 4:23-cv-00909-O
	§	
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.	§	

## **ORDER**

Before the Court are Plaintiffs' Motion for Summary Judgment (ECF No. 43); Defendants' Cross-Motion for Summary Judgment (ECF No. 61); Plaintiffs' Combined Response and Reply (ECF No. 67); and Defendants' Reply (ECF No. 74). For the reasons stated below, Plaintiffs' Motion is **GRANTED** and Defendants' Motion is **DENIED**.

## I. BACKGROUND<sup>1</sup>

This case involves actuarial issues relating to how Medicare Advantage Organizations ("MAOs") are compensated for providing Medicare benefits. MAOs are private insurers who contract with the Medicare Advantage program to cover enrollees's Medicare benefits. The Centers for Medicare and Medicaid Services ("CMS") pays contracted MAOs a prospective fixed monthly amount based on risk-adjusted cost estimates for services provided to Medicare Advantage program enrollees.

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<sup>&</sup>lt;sup>1</sup> Unless otherwise cited, the Court's recitation of the facts is taken from Plaintiff's Complaint. *See* Pls.' Compl., ECF No. 1.

On February 1, 2023, CMS issued a final rule ("Final Rule") adopting a new policy for calculating payment recoveries in Medicare Advantage audits. The Final Rule allows CMS to recover suspected overpayments from audited Medicare Advantage contracts by sampling a small number of contract enrollees and statistically extrapolating these audit results across a contract's entire enrollee population. It then recovers contract-wide repayments based on those estimates.

Every June, MAOs, such as Humana Inc. and Humana Benefit Plan of Texas, Inc. (collectively, "Humana" or "Plaintiffs"), submit and negotiate bids with CMS for the following year's plans. Through this process, CMS and the MAOs determine each plan's benefits and pricing, which they later memorialize in Medicare Part C contracts. After this bidding and contracting process concludes, and during an enrollment period from October to December preceding the coverage year, Medicare beneficiaries can enroll in any Medicare Advantage plan covering the geographic area where they live.

Medicare Advantage programs use a different compensation structure from plans available under Medicare Parts A and B, which use a fee-for-service payment model. Unlike Medicare Parts A and B, which pay doctors directly, the Medicare Advantage program contracts with private insurers such as Humana to cover enrollees' Medicare benefits. MAOs commit to provide enrollees with benefits that match or exceed those available under Medicare Parts A and B. In exchange, CMS prospectively pays MAOs a fixed monthly amount based on the cost that the agency estimates it would incur to provide fee-for-service Medicare benefits to those same enrollees.

To harmonize these different compensation structures, the Medicare statute requires "actuarial equivalence" between payments to MAOs and the payments that CMS would expect to make for the same enrollees' healthcare expenses in the fee-for-service Medicare program.

42 U.S.C. § 1395w–23(a)(1)(C)(i). Ensuring actuarial equivalence requires CMS to apply an actuarially sound method of "risk adjustment." *Id.* § 1395w–23(a)(3)(A). Risk adjustment is a way of statistically estimating the healthcare costs of a particular pool of Medicare Advantage beneficiaries and then increasing or decreasing payment based on their unique risk factors. The Medicare statute requires CMS to adjust the base payment for each enrollee to account for certain "risk factors," including "age, disability status, gender, institutional status, and . . . health status . . . so as to ensure actuarial equivalence" with fee-for-service Medicare. *Id.* § 1395w–23(a)(1)(C)(i).

CMS bases its ultimate payment to insurers on (1) the base rate and (2) the risk source unique to each Medicare Advantage enrollee considering that enrollee's demographic and health characteristics. Each enrollee in a Medicare Advantage plan has the same "base rate"—an estimate of the expected cost to provide fee-for-service Medicare benefits to an enrollee with average health and demographic characteristics in the covered locale. CMS sets base rates through an annual bidding process. MAOs, including Humana, submit bids for each Medicare Advantage plan, stating the amount of revenue they estimate will be necessary to provide benefits to an enrollee of average risk in a given geographic area in the next calendar year. The MAOs must certify "based on generally accepted actuarial principles" that projected revenues will cover (1) an average enrollee's fee-for-service Medicare benefits, and (2) any supplemental benefits—services not covered by fee-for-service Medicare—that the MAOs commit to provide. 42 C.F.R. § 422.254(b)(5).

To determine how much to pay MAOs, CMS built its payment model on data from fee-forservice Medicare. The agency develops estimates of the expected marginal costs associated with particular types of diagnosis codes. These are based on how much CMS pays healthcare providers who submitted claims for services rendered to fee-for-service Medicare beneficiaries where the providers' claims included those same codes.

To confirm the accuracy of those codes, the United States Department of Health and Human Services ("HHS"), CMS's parent agency, implemented the Risk Adjustment Data Validation ("RADV"). Under the RADV, CMS and the Inspector General for HHS ("HHS-OIG") audit a subset of Medicare Advantage contracts. The contract administrator is required to submit medical records for a sample of enrollees. CMS or HHS-OIG subsequently reviews those medical records to ensure the documented conditions correspond with the diagnosis codes submitted to CMS. CMS then recoups payments from MAOs for any diagnosis codes it deems undocumented in the medical record.

Historically, CMS recouped only payments corresponding to individual diagnosis codes from the enrollee sample. But in 2010, CMS announced that it would start using RADV audits to calculate payment error estimates for the entire enrollee population of the audited Medicare Advantage contract and recover extrapolated contract-wide repayments based on those estimates. Under that proposal, CMS would audit diagnosis codes for only a sample of a contract's enrollees but would use the results to recoup an extrapolated payment associated with the statistically estimated rate of undocumented diagnosis codes for the entire contract.

Commenters identified a critical flaw in this approach. Humana and others explained that the agency's proposal was actuarially unsound because it would simultaneously use two very different sets of data to measure diagnoses—non-validated fee-for-service Medicare Claims Data for the development of payment rates, and validated Medicare Advantage Claims Data documented in medical records on the back end of the RADV audit.<sup>2</sup> In other words, CMS's

<sup>&</sup>lt;sup>2</sup> Pls.' App. Supp. Mot. Summ. J. (RADV Comment) App. 7493, ECF No. 45-11.

proposal would have estimated the agency's costs associated with a given diagnosis code based on claim forms submitted by fee-for-service Medicare providers but would pay audited MAOs based only on diagnosis codes documented in the enrollees' medical records. Humana and others contested that the proposal would systematically underpay audited MAOs and thus no longer compensate them for the risks they were accepting.

CMS agreed with the comments and, in February 2012, publicly adopted what it called a Fee-for-Service Adjuster ("FFS Adjuster") in a revised RADV audit methodology. The FFS Adjuster would account for the difference in the two data points by conducting a RADV-like review of records submitted to support fee-for-service Medicare claims data and applying the findings as an offset to any payments that it recovered in extrapolated RADV audits. From 2012 to 2018, the FFS Adjuster operated to ensure actuarial equivalence by offsetting the payments.

But, in 2018, CMS proposed a new rule which would get rid of the FFS Adjuster due to a study it had conducted<sup>3</sup> and a finding that it would be inequitable to correct the payments made to audited plans but not to non-audited plans. 83 Fed. Reg. 54982, 55037–41 (Nov. 1, 2018) ("Proposed Rule"). In 2023, CMS issued the Final Rule, which eliminated the FFS Adjuster on the grounds that RADV audits do not have to comply with the statute's actuarial-equivalence mandate and the Coding-Intensity Adjustment forecloses use of an FFS Adjuster. 88 Fed. Reg. 6643 (Feb. 1, 2023).

On September 1, 2023, Plaintiffs filed their complaint against Xavier Becerra in his official capacity as Secretary of U.S. Department of Health and Human Services, and United States Department of Health and Human Services ("Defendants") in the Northern District of Texas,

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<sup>&</sup>lt;sup>3</sup> When commenters asked to see the study, CMS informed them that it had been misplaced. Subsequently, CMS replicated the study to reach the same result. And after commenters poked many holes in the replicated study, CMS abandoned it entirely when promulgating the Final Rule.

where Humana Benefit Plan of Texas, Inc. resides. The Complaint brought three claims for relief under the Administrative Procedure Act ("APA"), alleging that (1) the Final Rule is arbitrary and capricious and contrary to law because it reverses CMS's FFS Adjuster policy without adequate explanation, (2) CMS abused its discretion in deciding to apply the new policy retroactively beginning in payment year 2018 because it relied solely on legal justifications that misinterpret the Medicare Statute, and (3) CMS promulgated the Final Rule without observance of procedure required by law.<sup>4</sup> The Parties filed cross-motions for summary judgment, which are now ripe for review.

## II. LEGAL STANDARD

In a case challenging an agency action under the APA, summary judgment "serves as the mechanism for deciding" whether the action "is supported by the administrative record and otherwise consistent with the APA standard of review." *Gadhave v. Thompson*, No. 3:21-cv-2938-D, 2023 WL 6931334, at \*1 (N.D. Tex. Oct. 19, 2023) (citation omitted). The agency resolves "factual issues to arrive at a decision supported by the administrative record." *Yogi Metals Grp. Inc. v. Garland*, 567 F.Supp.3d 793, 797–98 (S.D. Tex. 2021) (citation omitted), *aff'd*, 38 F.4th 455 (5th Cir. 2022). The district court then applies the APA standards of review to determine whether, as a matter of law, "the evidence in the administrative record permitted the agency to make the decision it did." *MRC Energy Co. v. U.S. Citizenship & Immigr. Servs.*, No. 3:19-cv-2003-K, 2021 WL 1209188, at \*3 (N.D. Tex. Mar. 31, 2021) (citation omitted). The entire case is thus a question of law, with the district court sitting as an appellate tribunal. *See Id.* If a court determines the contested agency action falls short of the APA's substantive or procedural

<sup>&</sup>lt;sup>4</sup> Pls.' Compl. 38–42, ECF No. 1.

requirements, the reviewing court "shall" set aside the unlawful agency action. 5 U.S.C. § 706(2)(A)–(D); *Data Mktg. P'ship v. U.S. Dep't of Lab.*, 45 F.4th 846, 859 (5th Cir. 2022).

## III. ANALYSIS

Plaintiffs contend that they are entitled to summary judgment on all three of their claims:

(1) the Final Rule is arbitrary and capricious and contrary to law because it reverses CMS's FFS Adjuster policy without an adequate explanation; (2) CMS abused its discretion in deciding to apply the new policy retroactively beginning in payment year 2018 because it relied solely on legal justifications that misinterpret the Medicare Statute; and (3) CMS promulgated the Final Rule without observance of procedure required by law. In contrast, Defendants claim that they are entitled to summary judgment on all three of Plaintiffs' claims. Because as discussed *infra*, the Court finds that the Final Rule is procedurally invalid as it was not a "logical outgrowth" of the Proposed Rule, the Court need not and will not address the other claims.

Plaintiffs claim that Defendants violated the APA's procedural requirements by abandoning their justifications for the Proposed Rule in favor of new justifications for the Final Rule. "In the Fifth Circuit, the logical-outgrowth rule requires [CMS] to provide 'fair notice' of the eventual Final Rule." *Mock v. Garland*, 75 F.4th 563, 583 (5th Cir. 2023) (quoting *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 381 (5th Cir. 2021)). To be a logical outgrowth, the proposed rule must "adequately frame the subjects for discussion such that the affected party should have anticipated the agency's final course in light of the initial notice." *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021) (citation modified). "If interested parties 'should have anticipated' that the change was possible, and thus reasonably

<sup>&</sup>lt;sup>5</sup> See generally Pls.' Br. Supp. Mot. Summ. J., ECF No. 44.

<sup>&</sup>lt;sup>6</sup> See generally Defs.' Br. Supp. Mot. Summ. J., ECF No. 62.

<sup>&</sup>lt;sup>7</sup> See Pls.' Br. Supp. Mot. Summ. J. 33, ECF No. 44.

should have filed their comments on the subject during the notice-and-comment period, then the rule is deemed to constitute a logical outgrowth of the proposed rule." *Id.* (quoting *Tex. Ass'n of Mfrs.*, 989 F.3d at 381). Here, as in *Texas Association of Manufacturers*, "[Plaintiffs] do not object to a substantive change in the text of the Proposed Rule and the Final Rule, but to the change in the justification for the Proposed Rule and the justification for the Final Rule." 989 F.3d at 382.

The notice of proposed rulemaking initially offered two rationales for its proposal not to include an FFS Adjuster in any sampling and extrapolation methodology: (1) an empirical analysis, and (2) the proposition that "correct[ing] any systematic payment error in the [Medicare Advantage] 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." While the comment period was still open, CMS requested 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 [its] proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology."

Ultimately, CMS offered two different justifications for the Final Rule: (1) 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; and (2) that the Coding-Intensity Adjustment forecloses use of an FFS Adjuster.<sup>10</sup>

Plaintiffs contend that the Defendants' violated the APA's logical-outgrowth rule by changing the justifications for the rule. <sup>11</sup> In response, Defendants' assert that the rational for the Final Rule was made clear by the first proposed justifications and the additional request for

<sup>&</sup>lt;sup>8</sup> Pls.' App. Supp. Mot. Summ. J. (Nov. 2018 Proposed Rule), App. 731, ECF No. 45-2.

<sup>&</sup>lt;sup>9</sup> Pls.' App. Supp. Mot. Summ. J. (June 2019 RADV Proposed Rule), App. 741, ECF No. 45-2.

<sup>&</sup>lt;sup>10</sup> Pls.' Consol. Resp. and Reply 32, ECF No. 68.

<sup>&</sup>lt;sup>11</sup> Pls.' Br. Supp. Mot. Summ. J. 40–42, ECF No. 44.

comment.<sup>12</sup> Additionally, Defendants assert that any error was harmless as there is no likelihood that the result would have been different as their interpretation of the statute is correct.<sup>13</sup> In rebuttal, Plaintiffs reassert their claim that the Final Rule's justifications did not logically flow from the Proposed Rule's justifications and argue that Defendants cannot save their procedural failures by "cherry-pick[ing]" generic and broad sentences from the Proposed Rule.<sup>14</sup> Plaintiffs further contend that the error was not harmless.<sup>15</sup> In their Reply, Defendants reassert their logical outgrowth and harmlessness arguments, and argue—for the first time—that they did not need to abide by the APA's notice-and-comment requirement for statutory interpretation.<sup>16</sup> The Court will address each of the preceding arguments.

The Court begins with the Parties' respective positions regarding the logical outgrowth rule. As discussed above, CMS's justifications for the Final Rule are (1) 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, and (2) that the Coding-Intensity Adjustment forecloses use of an FFS Adjuster. Defendants do not and cannot assert that their second justification (the Coding-Intensity Adjustment) logically flowed from the Proposed Rule's justifications. Thus, as the Parties do, the Court's analysis focuses on the first justification (the actuarial-equivalence requirement).

Defendants claim that their legal justification for the Final Rule logically flowed from one of the Proposed Rule's justifications and the request for additional comment. Specifically,

<sup>&</sup>lt;sup>12</sup> Defs.' Resp. 44–45, ECF No. 63.

<sup>&</sup>lt;sup>13</sup> *Id.* at 45–46.

<sup>&</sup>lt;sup>14</sup> Pls.' Consol. Resp. and Reply 32–33, ECF No. 68.

<sup>&</sup>lt;sup>15</sup> *Id.* at 34.

<sup>&</sup>lt;sup>16</sup> Defs.' Reply 26–28, ECF No. 74.

<sup>&</sup>lt;sup>17</sup> Pls.' Consol. Resp. and Reply 32, ECF No. 68.

<sup>&</sup>lt;sup>18</sup> See Defs.' Br. Supp. Mot. Summ. J. 44–45, ECF No. 62.

Defendants allege the following justification emanated from the Proposed Rule: "the proposition that 'a RADV-specific payment adjustment' would not be an 'appropriate' response to 'systematic payment error,' because 'RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation." But this abandons the Proposed Rule's stated 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." To support their assertion that the justifications for the Final Rule logically flowed from the Proposed Rule's first justification, Defendants selectively quote from the Proposed Rule. Because context is important, the Court includes the entirety of the relevant section below and bolds the parts Defendants quoted:

Moreover, even if we had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a RADVspecific payment adjustment would be appropriate. RADV audits are used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS. If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis. RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation. Consequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate. For this reason, we believe that it would not be appropriate to correct any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts. Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.

Because our study suggests that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program and because we believe it would be inequitable to correct any systematic errors in the payments made to audited plans

<sup>19</sup> *Id.* at 45 (citing 83 Fed. Reg. at 55,041).

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<sup>&</sup>lt;sup>20</sup> *Id.* (citing Nov. 2018 Proposed Rule, App. 731, ECF No. 45-2).

<sup>&</sup>lt;sup>21</sup> *Id*.

only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology. We welcome public comments on this study.<sup>22</sup>

This articulated reasoning, if true, may support a finding that it is "inequitable to correct any systematic errors in the payments made to audited plans only" or that RADV audits do not result in the systematic underpayment of MAOs. However, it does not give the reader any indication that CMS is reconsidering an over thirteen-year-old precedent regarding the application of the actuarial-equivalence provision to RADV audits.<sup>23</sup> Indeed, the Proposed Rule's justification (that FFS Adjusters introduce inequities) does not appear in the Final Rule, and thus could not have been a contributing factor for the new justification. CMS's discussion regarding whether FFS Adjusters correct payment errors or simply create inequities is not enough to connect the dots.

Defendants contend that any procedural defects were remedied when CMS requested 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 [its] proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology."<sup>24</sup> But this is not enough. *Mock*, 75 F.4th at 584 ("merely informing the public, in a generic sense, of the broad subjects and issues the Final Rule would address is insufficient."). Accordingly, the Court finds that Plaintiffs should not have reasonably anticipated that CMS's discussion regarding whether FFS Adjusters correct payment errors or simply create inequities would result in a finding that actuarial equivalence does not apply.<sup>25</sup>

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<sup>&</sup>lt;sup>22</sup> Nov. 2018 Proposed Rule, App. 731, ECF No. 45-2.

<sup>&</sup>lt;sup>23</sup> *Id.* The Court further notes that other courts regularly reject the cherry picking of sentences to satisfy the notice requirements of the APA. *See, e.g., Env't Integrity Project v. EPA*, 425 F.3d 992, 998 (D.C. Cir. 2005) (quoting *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005)) ("[A]n 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).").

<sup>&</sup>lt;sup>24</sup> *Id.* (citing 84 Fed. Reg. at 30,983)

<sup>&</sup>lt;sup>25</sup> This finding is bolstered by the fact that actuarial equivalence applies between Medicaid and MAOs, and CMS's discussion here involves equity between only MAOs. Therefore, it is not reasonably discernable

Defendants next claim that their request for additional comment should have made its intention to switch justifications "clear and subjected to public comment." That request for additional comment provides, in its entirety:

That proposal rested on two grounds. First, we conducted a study which indicated that diagnosis error in FFS claims data does not lead to systematic payment error in the Medicare Advantage (MA) program. Second, we suggested that it would be inequitable to correct any systematic errors made in the payments to audited plans only. We continue to welcome public comment on this proposal. We are also seeking comment on whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C), which requires risk adjustment in subclause (a)(1)(C)(ii), mandates a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C)(iii)—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.<sup>27</sup>

There is no specific indication here that would alert the reader to the fact that CMS was considering abandoning the just-mentioned justifications for a finding that actuarial equivalence does not apply. Rather, CMS cites all three sub-sections in a manner which signals to the reader that CMS believes the sub-sections are applicable to RADV audits.<sup>28</sup>

In an attempt to save the Final Rule from the APA's procedural requirements, Defendants point to one non-party comment to show that it was easily discernable that CMS was considering reversing their long-standing finding that actuarial equivalence applies.<sup>29</sup> But, the Fifth Circuit has directly addressed this contention, holding that even if "a few members of the public happened to divine the Government's unspoken thoughts, comments such as these do not satisfy the

that CMS's comments about inequities between MAOs would result in a finding that actuarial equivalence does not apply between Medicaid and MAOs for the purposes of these audits.

<sup>27</sup> June 2019 RADV Proposed Rule, App. 741, ECF No. 45-2.

<sup>&</sup>lt;sup>26</sup> Defs.' Br. Supp. Mot. Summ. J. 45, ECF No. 62.

<sup>&</sup>lt;sup>28</sup> See id. ("which **requires** risk adjustment in subclause (a)(1)(C)(i)" to ensure actuarial equivalence, "**mandates** a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C)(iii)") (emphasis added).

<sup>&</sup>lt;sup>29</sup> Defs.' Br. Supp. Mot. Summ. J. 46, ECF No. 62.

Government's obligation to afford the general public an opportunity to respond to clearly stated proposals."<sup>30</sup> Mexican Gulf Fishing Co. v. U.S. Dep't of Com., 60 F.4th 956, 975 (5th Cir. 2023) (citation modified) (citing Tex. Ass'n of Mfrs., 989 F.3d at 383). Thus, even though a few commenters submitted opinions regarding actuarial equivalence, the Court finds that Defendants' broad and affirmative reference to sub-sections of a statute did not satisfy their burden to notify the public with any reasonable specificity that they were considering finding actuarial equivalence inapplicable. 31 See Mock, 75 F.4th at 584 ("But merely informing the public, in a generic sense, of the broad subjects and issues the Final Rule would address is insufficient. Instead, the Proposed and Final Rule must be alike in kind so that commentators could have reasonably anticipated the Final Rule.").32

<sup>&</sup>lt;sup>30</sup> The Court notes that even though Defendants were able to identify at least one comment on whether actuarial equivalence is required for RADV audits, the entirety of the "comment and response" section of the Final Rule contains only one reference to "actuarial equivalence." See Pls.' App. Supp. Mot. Summ. J. (Final Rule), App. 7349–53, ECF No. 45-11. That reference is contained withing a series of other comments and states as follows: "Others commented that an extrapolation methodology based on sub-cohorts of enrollees would violate the statutory mandate of 'actuarial equivalence' between payments made under MA and Medicare FFS because it would generate recoveries based on random outcomes without regard to specific characteristics of MA plans' diagnostic mix, enrollment size, and risk scores." Id. at 7350. This comment does not address whether actuarial equivalence applies across RADV audits, but rather whether extrapolating the audit of a few patients across the entirety of the contract violates actuarial equivalence. And as best the Court can tell, the "response" does not address the comment.

<sup>&</sup>lt;sup>31</sup> This determination is strengthened by the fact that CMS seemingly based its reasoning on a D.C. Circuit opinion, dealing with a different statutory provision, which was issued well after the comment period closed. While Defendants assert that they did not rely on the case, by the Court's count, it was cited nineteen times to support CMS's new justification in the Final Rule. See Final Rule 7343–63, ECF No. 45-11 (citing UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. August 13, 2021, reissued November 1, 2021)). It cannot be said that the public had a fair opportunity to comment on a justification that is seemingly based on an opinion issued after the comment period closed. See June 2019 RADV Proposed Rule, App. 741, ECF No. 45-2 (providing that the comment period for the Proposed Rule "closes at 5 p.m. on August 28, 2019").

<sup>32</sup> The Court further notes that CMS seemingly failed to consider the relevant factors under the "surprise switcheroo" doctrine, given the sudden and absolute switch in interpretation. See R.J. Reynolds Vapor Co. v. FDA, 65 F.4th 182, 189 n.6 (5th Cir. 2023) (citing Azar, 587 U.S. at 571; Env't Integrity Project, 425 F.3d at 996).

Moreover, Defendants—for the first time in their Reply—assert that they did not have "an obligation to seek comment on [their] statutory interpretations." As a preliminary matter, this argument fails because courts do not consider arguments made for the first time in a reply. *Herrera v. United States*, No. 4:16-CR-107-A, 2019 WL 4806140, at \*3 (N.D. Tex. Oct. 1, 2019) (citing *United States v. Cervantes*, 132 F.3d 1106, 1111 (5th Cir. 1998)).

But even if the Court did consider it, it plainly fails. Defendants' assertion is based on the premise that interpretive rules, unlike legislative rules, need not be subjected to notice and comment. *See, e.g., Flight Training Int'l, Inc. v. Fed. Aviation Admin.*, 58 F.4th 234, 240–41 (5th Cir. 2023). However, the Fifth Circuit has held that when a rule "repudiates or is irreconcilable with a prior legislative rule, the second rule . . . must itself be legislative." *Id.* at 241. The "statutory interpretation" Defendants now rely upon is irreconcilable with the prior rule's longstanding principle that actuarial equivalence applies to RADV audits. Therefore, Defendants' argument that they had no obligation to participate in notice and comment also fails on the merits. *See Azar v. Allina Health Servs.*, 587 U.S. 566, 572–86 (2019) (rejecting a similar argument regarding the obligation to participate in notice and comment).

Finally, citing *Shinseki v. Sanders*, 556 U.S. 396, 411 (2009), Defendants assert that any error they committed was harmless as there is no likelihood that the result would have been different because their interpretation is the "the best reading of the statute" under *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024).<sup>34</sup> In essence, Defendants ask the Court to find that an agency need not comply with the APA's stringent requirements, as long as the agency's interpretation of a statute is the best reading. Defendants do not cite to a single case, and the Court

<sup>&</sup>lt;sup>33</sup> Defs.' Reply 27, ECF No. 74.

<sup>&</sup>lt;sup>34</sup> Defs.' Resp. 55, ECF No. 63; Defs.' Reply 32, ECF No. 74.

cannot find any in which a court considered this argument much less made such a holding. And this Court declines to be the first.

Moreover, holding that Defendants' failure to satisfy the APA's notice-and-comment requirement was harmless based on a finding that the interpretation was the best reading of the statute ostensibly violates the well-established principle that agencies must "consider... important aspect[s] of the problem," including, "of course, considering the costs and benefits associated with the regulation." *Chamber of Com. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) (citing *Mexican Gulf Fishing*, 60 F.4th at 973). And as part of that cost-benefit analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id*.

Here, because there was no meaningful notice of Defendants' ultimate finding that actuarial equivalence does not apply to RADV audits, there was no meaningful dialogue regarding the costs and benefits of the surprise changes. The harm caused by the lack of discussion—which is an independent ground for vacatur and remand—is exacerbated by the Final Rule's application back to 2018. While the Parties dispute whether this is impermissibly retroactive, it is undisputed that companies like Plaintiffs relied upon and operated under the old rule's guidance from 2018–2023. Consequently, Plaintiffs, and others, will potentially bear enormous unforeseen costs as a result of their reliance on CMS's nearly thirteen-year-old position from 2018–2023. Thus, the Court concludes that Defendants' error was not harmless.

As a result of the foregoing, the Court finds that Defendants' failure to comply with the procedural requirements of the APA was not harmless. Consequently, the Court must **VACATE** and **REMAND** the Final Rule for further consideration.

# IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Plaintiffs' Motion and **DENIES**Defendants' Motion. Therefore, it is **ORDERED** that the Final Rule is hereby **VACATED** and **REMANDED** for further consideration consistent with this opinion.

SO ORDERED on this 25th day of September, 2025.

eed O'Connor

CHIEF UNITED STATES DISTRICT JUDGE