UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELEVANCE HEALTH, INC., et al.

Plaintiffs,

v.

XAVIER BECERRA,
Secretary of Health and Human Services, et al.,

Defendants.

Civil Action No. 23-3902 (RDM)

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes and Legislative Materials

Regulations and Regulatory Materials

Defendants the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services ("CMS") respectfully submit this reply in further support of their cross-motion for summary judgment (ECF No. 17, "Defs. Mot.")

INTRODUCTION

Despite Plaintiffs' attempts to characterize their suit as an "as-applied" challenge to CMS's "violation" of other CMS rules, Plaintiffs' principle argument is that the Final Rule at issue is invalid because it was not codified in the Code of Federal Regulations. That is a facial challenge, not an as applied one. Neither the Administrative Procedure Act ("APA") nor the Medicare statute require publication in the Code of Federal Regulations for a rule to be binding—they require that a rule be adopted through the APA's procedures, which CMS followed when it adopted the challenged Final Rule. Plaintiffs' argument elevates form over substance to the extreme, and this Court should reject it.

ARGUMENT

I. Plaintiffs' Challenge to CMS's Application of Tukey Outlier Deletion Fails.

A. CMS Adopted the Final Rule Including the Rerunning of the Prior Year's Cut Points, Through Notice-and-Comment Rulemaking, and CMS Was Not Arbitrary and Capricious in Applying It Here.

1. The Final Rule Is Procedurally Proper.

Congress, through the Medicare statute and the APA, set forth the notice-and-comment procedures necessary for the rules governing the Medicare program. They require: (1) notice in the Federal Register, (2) a comment period, (3) consideration of the relevant matter presented, and (4) publication of the "rules adopted" with a "concise general statement of their basis and purpose." 42 U.S.C. § 1395hh(b)(1); 5 U.S.C. § 553(b)-(d). The Final Rule at issue here, including the decision to rerun the prior year's cut points, met all of these requirements.

> On February 18, 2020, CMS published the following in the Federal Register:
>
> > We request commenter feedback on Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. In the first year that this would be implemented, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years.

Contract Year 2021 & 2022 Policy & Technical Changes to the Medicare Advantage Program (the "Proposed Rule"), 85 Fed. Reg. 9,002, 9,043-44 (Feb. 18, 2020). CMS then received public comments, including one from Plaintiff Elevance (f/k/a Anthem, Inc.), objecting to Tukey outlier deletion generally, but not commenting on the rerun aspect of the methodology. *See* Comment of Elevance at 24 (certified rulemaking record ("R.R.") at 601). After due consideration, CMS published the Final Rule, including the rerun of the prior year's cut points, with a concise, general statement of the basis and purpose of the rerun:

> We explained that under our proposal in the first year of implementing this process, the prior year's thresholds would be rerun[.] . . .
>
> As noted in the [Proposed Rule], for the first year (2024 Star Ratings), we will rerun the prior year's thresholds using mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years.

Contract Year 2021 Policy & Technical Changes to the Medicare Advantage Program (the "Final Rule") 85 Fed. Reg. 33,796, 33,833, 33,835 (June 2, 2020). This was sufficient because the statutes do not require publication in the Code of Federal Regulations. *See* 42 U.S.C. § 1395hh(b)(1); 5 U.S.C. § 553(b)-(d).[1]

Many courts have held that rules set forth in Federal Register preamble are enforceable where the agency promulgated them though notice and comment and clearly intended them to be

[1] Congress has at times referred to rules promulgated only in Federal Register text as "regulations." Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5002, 120 Stat. 31 (2006).

binding. *See* Defs. Mot. (ECF No. 17) at 19-20; *Defs. of Wildlife v. Zinke*, 849 F.3d 1077, 1085 (D.C. Cir. 2017) ("This language manifests a clear intent by the Service to bind Wyoming, and therefore the preamble itself has the force of law."); *Chem. Waste Mgmt., Inc. v. EPA*, 869 F.2d 1526, 1534-35 (D.C. Cir. 1989) (preamble ripe for review where EPA published the policy in the Federal Register, provided for comment, and arrived at ultimate decision); *see also United States v. Acquest Transit LLC*, Civ. A. No. 09-0055, 2020 WL 3042673, at *24 (W.D.N.Y. June 4, 2020) ("[t]he fact that these agencies manifested their decision through a preamble published in the Federal Register is of no moment"); *Beaumont Hosp.-Wayne v. Azar*, Civ. A. No. 18-12352, 2019 WL 5455415, at *10 (E.D. Mich. Oct. 24, 2019) (upholding CMS's policy set forth in preamble).

The cases Plaintiffs cite involve situations where the text at issue did not go through notice and comment, was not clearly intended by the agency to be binding, or was directly contradicted by text in the Code of Federal Regulations (further evidence that the agency did not intend the text to be binding). *AT&T Corp. v. FCC*, 970 F.3d 344 (D.C. Cir. 2020), for example, involved "an explanatory document published not with the codified regulations, but shortly thereafter." *Id.* at 351. The December 28, 2011 Federal Register document at issue included the phrase "policy statement" in its caption and provided: "[t]his document provides additional information to the final rule document published on November 29, 2011." Connect America Fund, 76 Fed. Reg. 81,562, 81,562 (Dec. 28, 2011) (Final Rule; Policy Statement); *AT&T*, 970 F.3d at 350 (citing 76 Fed. Reg. 81,562). The statement in that document appeared in a paragraph seeking further comments after the publication of the final rule. 76 Fed. Reg. 81,630 ("the [FCC] seeks comment regarding the transition"); *AT&T*, 970 F.3d at 350 (citing 76 Fed. Reg. 81,630). It was in this context, that the court found that the Code of Federal Regulations text was "clear," that publication in the Federal Register alone did not suggest that it was "meant to be a regulation," and that it was

nonbinding. *AT&T*, 970 F.3d at 350 (quotation marks and citations omitted). This is nothing like the instant case, where CMS provided notice in the Federal Register from the beginning, responded to comments, published its final decision contemporaneously with the Code of Federal Regulations provisions, and clearly intended its decision to be binding.

In *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533 (D.C. Cir. 1986), the "enforcement guidelines" at issue were "replete with indications that the Secretary [of Labor] retained his discretion," were characterized as a "general policy," and, as recited in a statement accompanying the final rule, were published in the Federal Register only as an "appendix" to the regulation because, in part, the Secretary believed that a binding regulation was impractical. *Id.* at 538-39. The absence of the enforcement guidelines from the Code of Federal Regulations was but one of several facts further showing that the guidelines were not intended to be binding. Once more, this is not similar to the instant case, where the facts consistently show that CMS intended the Final Rule, including the rerun decision, to be binding.

Finally, *National Environmental Development Ass'n's Clean Air Project v. EPA*, 752 F.3d 999 (D.C. Cir. 2014), involved a directive sent from the Director of the EPA's Office of Air Quality and Standards to Regional Air Directors of the ten EPA regions, stating that the EPA would only follow a recent Sixth Circuit decision within that circuit. *Id.* at 1003. The court cited a lengthy series of EPA Code of Federal Regulations provisions designed to assure the uniform application and standardization of criteria, procedures, and policies by EPA Regional Offices in enforcing the agency's statute. *Id.* at 1009-10. It was in this context that the court found the directive "plainly contrary" to the regulations. *Id.* at 1003, 1009-10. Again, this is not similar to the instant case, where CMS used notice and comment rulemaking to promulgate an actual rule, intended that rule to be binding, and did not directly contradict existing regulations. *See also Tex. Children's Hosp.*

v. Burwell, 76 F. Supp. 3d 224, 237 (D.D.C. 2014) (preamble at issue was contradicted by other preamble and Code of Federal Regulations text; "the statements in the Preamble cited by the government are not representative[,] [t]he Preamble also stated on multiple occasions").

Plaintiffs cannot distinguish *St. Helena Clear Lake Hospital v. Becerra*, Civ. A. No. 19-0141 (CJN), 2021 U.S. Dist. LEXIS 62321 (D.D.C. Mar. 31, 2021), *aff'd*, 30 F.4th 301 (D.C. Cir. 2022), where the court upheld a 1998 statement by CMS in the Federal Register, on the basis that the Code of Federal Regulations provision did not foreclose CMS's interpretation of it. Plaintiffs' reply misses the significance of *St. Helena Clear Lake*. There, the district court found that the Code of Federal Regulations provision did not compel the plaintiff's reading and that CMS's reading was reasonable and entitled to deference. *Id.* at *16-17. The district court then proceeded to find that even if CMS needed to address the issue through "the notice and comment process," CMS's 1998 statement in the Federal Register satisfied that requirement. *Id.* at *18-19.

The D.C. Circuit affirmed, and in doing so, used CMS's 1998 statement in the Federal Register to determine not only the meaning of the Code of Federal Regulations provision at issue, but also the meaning of the relevant statute. *St. Helena*, 30 F.4th at 304-05. While it noted the plaintiffs' argument that the Secretary's policy for a prior time period had not been properly adopted through notice-and-comment rulemaking, *id*. at 304, it did not adopt that position and reverse the district court.

Here, CMS promulgated its decision to rerun the prior year's cut points for purposes of applying the guardrails through notice and comment rulemaking, and CMS's intent to make this implementing step in the Tukey methodology binding is clear. CMS proposed the prior year rerun in 2020: "In the first year that this would be implemented, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be

applied such that there is consistency between the years." 85 Fed. Reg. at 9,044. Nothing in this statement or the surrounding text indicated that CMS was presenting a general "statement of policy" or "interpretive rule." CMS's statement was not general, and it did not purport to interpret anything. Rather, it presented a specific methodological step and its purpose (alongside other specific methodological steps), which CMS "would" apply in a specific year ("the first year"), if CMS finalized the Tukey methodology.

The Final Rule stated CMS's decision in two places, definitively pronouncing: "we will rerun the prior year's thresholds." 85 Fed. Reg. at 33,835; *id.* at 33,833 ("the prior year's thresholds would be rerun . . . such that there is consistency between the years"). There was nothing hesitant or wavering, and if there was any doubt, it was resolved when CMS published the simulations referenced in the Final Rule illustrating that CMS would rerun the prior year's cut points, with the Memorandum stating just that. R.R. 2705-15; Defs. Mot. at 11-13. These simulations showed, in a very specific way, that CMS's finalized methodology reran the prior year's cut points because CMS believed that it would be inconsistent to remove Tukey outlier data for one year, while keeping it in for the prior year for purposes of the guardrails. Defs. Mot. at 12-13 ("Notably, the fourth tab did not present any scenario in which CMS implemented Tukey in the first year (2023) without rerunning the cut points from the prior year (2022) with Tukey.").

CMS also frequently described the preamble as the "final rule," even citing to the exact Federal Register pages finalizing the rerun step rather than the Code of Federal Regulations. Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 88 Fed.

Reg. 22,120, 22,295 (Apr. 12, 2023) ("In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 . . . (85 FR 33833–36)").[2]

Plaintiffs argue that CMS has chosen to promulgate other rules applicable to only one Star Ratings year in the Code of Federal Regulations. Pls. Opp. (ECF No. 21) at 15. That may be true, but it does not establish that CMS cannot promulgate other such rules without codifying them in the Code of Federal Regulations, as it did here. *See* Defs. Mot. at 22 ("CMS sometimes promulgates rules or large portions of rule without codifying regulations at all so as not to overly complicate the already voluminous Code of Federal Regulations.") (footnote omitted).

Plaintiffs also argue that CMS's decision to rerun the prior year's cut points violated 42 C.F.R. § 422.166(a)(2)(i) (calculation of Medicare Advantage cut points) and § 423.186(a)(2)(i) (calculation of Part D cut points), Pls. Opp. at 5-6, which address the operation of Tukey outlier deletion and the guardrails. That is incorrect, as the Final Rule specifically addressed how Tukey and the guardrails would interact in the 2024 Star Ratings. But regardless, even the guardrail provisions alone do not compel Plaintiffs' reading. As CMS has explained, those provisions state that CMS will remove Tukey outliers "prior to applying mean resampling with hierarchal clustering," and that CMS will apply guardrails so that the "cut points for non-[Consumer Assessment] measures do not increase or decrease more than the value of the cap from 1 year to the next." *See* Defs. Mot. at 22. Those provisions do not explicitly say whether in determining the guardrails, the "cut points" from the "1 year" and "the next" are calculated with Tukey outlier deletion "prior to applying mean resampling with hierarchal clustering," but the

[2] *See* 88 Fed. Reg. at 22,296 ("the June 2020 final rule . . . (85 FR 33891–33893)"); Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 87 Fed. Reg. 79,452, 79,634 (Dec. 27, 2022) ("In the June 2020 final rule, we finalized use of Tukey . . . (85 FR 33833–36)[.]").

natural reading is that they are. *Id.* at 22-23. Plaintiffs do not dispute that cut points in "the next" year are always calculated with Tukey outlier data removed. Nor do Plaintiffs dispute that cut points in the "1 year" are, after the first year, always calculated with Tukey outlier data removed. Thus, Plaintiffs do not dispute that in all years after the first year, when CMS determines the guardrails, CMS makes an apples-to-apples comparison of data from the "1 year" with Tukey outliers removed to data from "the next" year with Tukey outlier data removed.

The only dispute is whether in the first year of applying Tukey, CMS will make that same apples-to-apples comparison by consistently removing Tukey outliers from both data sets, or whether CMS will inconsistently compare data from the "1 year" *without* Tukey outliers removed to data from "the next" year *with* Tukey outliers removed. The better reading is that Tukey outliers are consistently deleted in both years for purposes of calculating the guardrails.

Plaintiffs also cite the definition section in the Code of Federal Regulations, which refers to the "prior year's . . . cut point" in defining the guardrails. Pls. Opp. at 5, 13 (citing 42 C.F.R. § 422.162). But Plaintiffs' interpretation of the definition section would introduce the same inconsistency noted above. And regardless, none of the provisions cited by Plaintiffs say "actual," "unadjusted," or "non-simulated cut points." Nor do any of the provisions Plaintiffs cite prohibit CMS from adjusting the prior year's cut points to account for updated data or methodological changes.

Plaintiffs argue that their approach is more consistent because it would have CMS using "actual" cut points for every prior year. That would be like comparing annual differences in temperature without regard to whether the measurements were taken in Maine or Florida, or like comparing sports statistics without regard to the number of games played in a season. Sometimes adjustments are needed for accurate comparisons. CMS's interpretation uses the prior year's "cut

points," and it ensures that CMS calculates them using the same methodology consistently in both years.

CMS implemented the Tukey outlier deletion methodology because of concerns "about extreme outliers influencing cut point determinations." 85 Fed. Reg. 33,833. It would make little sense to prevent extreme outliers in the ratings year from influencing that year's cut point determinations, while permitting extreme outliers from the prior year to influence those cut point determinations through their effect on guardrails. Moreover, removing outliers from the ratings year but not the prior year would fail to maintain consistency between the years, resulting in an apples-to-oranges comparison. 85 Fed. Reg. at 9,044.

Finally, Plaintiffs argue that CMS's rerun of the 2023 cut points "violated" the guardrail provisions "by applying the Tukey Methodology a year earlier than permitted by law," because 42 C.F.R. § 422.166(a)(2)(i) provides that Tukey will be implemented in the 2024 Star Ratings. *See* Pls. Opp. at 7. But CMS did not remove any Tukey outliers when it calculated the 2023 Star Ratings: not from the 2023 cut points, and not from the 2022 cut points either when it determined the guardrails. CMS, Medicare 2023 Part C & D Star Ratings Technical Notes, at 1, 138-39 (updated Jan. 19, 2023), *available at* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data. Rather, CMS applied the Tukey outlier methodology in the 2024 Star Ratings when it removed Tukey outliers from the 2023 cut points for purposes of determining the 2024 guardrails, just as CMS said it would. *See* Defs. Mot. at 17.

Plaintiffs also argue that the record does not include the "Guardrail Requirement," which "signals" that CMS did not consider it. Pls. Opp. at 10. As CMS has explained, neither Plaintiff nor any other commenters on the 2020 Proposed Rule specifically commented on the rerun step in the Tukey methodology. Defs. Mot. at 8; Comment of Elevance at 24 (R.R. 601). No commenters

objected to CMS's reasoning that the guardrails should be "applied such that there is consistency between the years." *See* 85 Fed. Reg. 9,044. And no commenters raised the argument Plaintiffs make now that rerunning the prior year's cut points "violates" the guardrail provisions.

Nevertheless, CMS considered the interaction between its proposed Tukey methodology and the guardrails. In the Proposed Rule, CMS described a simulation it ran on 2018 Star Ratings data with Tukey outlier deletion and "a 5 percent guardrail." 85 Fed. Reg. 9,044. In conducting this simulation, when CMS applied guardrails to the 2018 cut points relative to the prior year's (2017's) cut points, it reran the 2017 cut points with Tukey outliers removed. Declaration of Elizabeth Goldstein, attached hereto as Exhibit 1, ¶¶ 9-12 and Attachment A. This was consistent with CMS's statement: "[i]n the first year that this would be implemented, the prior year's thresholds would be rerun . . . so that the guardrails would be applied such that there is consistency between the years." 85 Fed. Reg. 9,044. And in the Final Rule, CMS discussed the 2018 simulation again and stated that CMS would later display "simulations of Tukey outlier deletion with . . . guardrails for contracts to view . . . the cumulative effect of all of these policies [including guardrails and Tukey outlier deletion]." 85 Fed. Reg. at 33,833, 33,835. CMS published these simulations on December 19, 2022, and they illustrated how CMS would rerun the prior year's cut points with Tukey outliers removed for purposes of the guardrails when CMS implemented Tukey in 2024. Defs. Mot. at 11-13; R.R. 2705-15.

Moreover, Plaintiffs' suggestion that the rulemaking record for this case should have included the entire promulgation and "regulatory history" of the guardrail provisions is incorrect. Plaintiffs did not challenge CMS's rulemaking procedure for the guardrail provisions, they challenged CMS's rulemaking procedure for the Final Rule's rerun step in the Tukey methodology. *See* Pls. Opp. at 2-3 ("CMS's argument violates a fundamental tenet of rulemaking,

which is that language in a preamble does not create law and certainly does not override regulatory text."); Pls. Mot. (ECF No. 23) at 19 ("To the Extent CMS Argues that it Stated in Rulemaking It Was Going to Simulate Cut Points for 2023, that is Irrelevant."); *see also infra* § I.B (Plaintiffs' case is a facial challenge).

As CMS has explained, it is no coincidence that CMS's interpretation of § 422.166(a)(2)(i) and § 423.186(a)(2)(i), as well as CMS's other Code of Federal Regulations provisions, sync with the Final Rule. Defs. Mot. at 23-24. In the 2020 Proposed Rule, CMS reproposed the entire text of 42 C.F.R. § 422.166(a)(2)(i) and § 423.186(a)(2)(i) with both the Tukey outlier deletion language and the guardrail language providing for the comparison of cut points "from 1 year to the next." 85 Fed. Reg. 9,220, 9,242-43. The entire text of these provisions was under CMS's consideration in the 2020 Rulemaking and re-finalized by CMS in the Final Rule. *See* 85 Fed. Reg. 33,907, 33,911. Thus, CMS's statements in the 2020 rulemaking are contemporaneous with § 422.166(a)(2)(i) and § 423.186(a)(2)(i), and, as CMS has explained, demonstrate that CMS did not intend for those provisions to prevent CMS from rerunning the prior year's cut points. *See* Defs. Mot. at 21-25; 85 Fed. Reg. at 33,833, 33,835; 85 Fed. Reg. at 9,044; *see also* R.R. 2705-15. This is not a case where an agency is trying to change the meaning of a Code of Federal Regulations provision with a new or long forgotten and obscure preamble statement.

The meaning and intent of § 422.166(a)(2)(i), § 423.186(a)(2)(i), and CMS's other relevant Code of Federal Regulations provisions are clear, and even if there were any ambiguity, the Court should find that CMS's reading is reasonable and entitled to deference. *See St. Helena*, 2021 U.S. Dist. LEXIS 62321, at *17. Thus, even without the clear statements in the Final Rule, CMS's decision to rerun the prior year's cut points would not be arbitrary and capricious. CMS did promulgate the Final Rule, and it did require that the prior year's cut points be rerun using Tukey

outlier deletion. *See id.* at *17-19. Accordingly, CMS's decision satisfied all the requirements of the Medicare statute and the APA, and CMS was not arbitrary and capricious in applying its decision to its calculations of the 2024 Star Ratings.

2. Plaintiffs' Argument That CMS Should Have Applied Guardrails Based on the 2022 Cut Points When Rerunning the 2023 Cut Points for Purposes of Applying the Guardrails in the 2024 Star Ratings Fails.

Plaintiffs' Reply does not respond to CMS's argument on this point. *See* Defs. Mot. at 25-26. As CMS has explained, it is essentially a sub-issue regarding how CMS should conduct the rerun step under the Final Rule. *Id.* at 25. Plaintiffs' method, *see* Pls. Mot. at 16, is also inconsistent with the applicable rule, which simply stated that CMS will rerun "the prior year's" cut points with Tukey outlier deletion and did not come anywhere close to suggesting that CMS will "rerun the prior year's cut points and apply guardrails to the prior year's cut points based on data from two years prior." *See id.*; 85 Fed. Reg. at 33,833, 33,835; 85 Fed. Reg. at 9,044.

Finally, CMS can hardly be expected to address this sub-issue in detail in the rulemaking when no commenters on the Proposed Rule, including Plaintiffs, specifically addressed CMS's proposed rerun step more generally. *See St. Helena Clear Lake*, 2021 U.S. Dist. LEXIS 62321, at *18 (CMS "is not required to address every conceivable . . . policy through notice-and-comment rulemaking); *see also ParkView Med. Assocs. v. Shalala*, 158 F.3d 146, 149 (D.C. Cir. 1998) (when no public commenter challenged a Medicare payment policy proposed in the Federal Register, the Secretary could not be faulted for "failure to refute the unvoiced attack"). That is especially true where, as here, Plaintiffs are trying to read in an additional, complex, and contradictory step to the simple rule CMS set forth. Thus, Plaintiffs' argument on this point fails.

3. The Technical Amendment Does Not Compel a Different Result.

Plaintiffs do not raise any arguments directly addressing this point. As CMS has explained, its inadvertent removal of the Tukey sentence, which it corrected with the Technical Amendment, was a nullity and had no effect on the Final Rule. *See* Defs. Mot. at 26-30.

B. Plaintiff Did Not Timely Raise the Rerun Issue in the Rulemaking Process.

"It is black-letter administrative law that 'absent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue.'" *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001) (quoting *Tex Tin Corp. v. EPA*, 935 F.2d 1321, 1323 (D.C. Cir. 1991)). "Generalized objections to agency action or objections raised at the wrong time or in the wrong docket will not do. 'An objection must be made with sufficient specificity reasonably to alert the agency.'" *Id.*; *see also Transp. Div. of the Int'l Ass'n of Sheet Metal v. Fed. R.R. Admin.*, 40 F.4th 646, 659 (D.C. Cir. 2022) ("because the Unions did not raise these objections during the rulemaking . . . they are forfeited").

This doctrine has deep roots and important purposes. "'Simple fairness to those who are engaged in the tasks of administration, and to litigants, requires as a general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice.'" *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 719-20 (D.C. Cir. 2016) (quoting *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)). This allows an agency to "consider the matter, make its ruling, and state the reasons for its action," and it prevents litigants from "sandbag[ging]," i.e., "withholding legal arguments for tactical reasons." *Okla. Dep't of Env't Quality v. EPA*, 740 F.3d 185, 192 (D.C. Cir. 2014) (internal quotation marks and citations omitted). It also lets an agency "discover and correct its own errors" so that some issues may be "resolved without the need for judicial intervention." *Ohio v. EPA*, 997 F.2d 1520, 1528-29 (D.C. Cir. 1993).

Plaintiffs argue that administrative waiver does not apply here because they bring an "as-applied" challenge, not a "facial" one. Pls. Opp. at 22. This argument fails. The concern driving the cases that Plaintiffs cite, that parties may be ill-represented at the rulemaking stage and thus lose their chance to ever challenge a rule, does not apply here. *See Koretoff v. Vilsack*, 707 F.3d 394, 401 (D.C. Cir. 2013) (Williams, J., concurring)); *see also Banner Health v. Burwell*, 126 F. Supp. 3d 28, 68-69 (D.D.C. 2015) (rejecting administrative waiver argument in part because 42 U.S.C. § 1395oo(a)(3), (f)(1) provided mechanism for provider having received fiscal intermediary's final determination to request administrative hearing and seek judicial review after obtaining agency's final decision). Here, Plaintiffs commented on the Proposed Rule generally, but chose to waive their opportunity to comment on the prior year rerun step, thereby preventing CMS from considering and responding to Plaintiffs' objections at that time. *See* Comment of Elevance at 24 (R.R. 601); *Appalachian Power*, 251 F.3d at 1036 (generalized objections will not do). Plaintiffs also cite their comment on the Proposed Technical Amendment, but that is equally unavailing. *See* Pls. Opp. at 24; Comment of Elevance at 25-26, 71-76 (R.R. 2257-58, 2303-08) (making no specific objections to the rerun); *see also Appalachian Power*, 251 F.3d at 1036 (objections that are generalized, raised at the wrong time, or raised in the wrong docket will not do).

Plaintiffs further argue that a different commenter specifically addressed the rerun step in response to the Proposed Technical Amendment and that CMS stated it responded in detail; thus, administrative waiver doesn't apply. Pls. Opp. at 24; Defs. Mot. at 16; Comment of UnitedHealth Grp. at 43 (R.R. 1937). As CMS has explained, the Proposed Technical Amendment did not reopen the Tukey methodology substantively, it proposed only a "technical amendment to fix" the "codification error," in addition to moving the Tukey sentence to "make[ ] the regulation text

clearer." *See* Defs. Mot. at 28-30; 87 Fed. Reg. at 79,635; *Select Spec. Hosp.-Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 26 (D.D.C. 2011) ("the effect of the correcting amendment was not to substantively change the final rule"); *see also Appalachian Power*, 251 F.3d at 1036 (objections raised at the wrong time or in the wrong docket will not do).

Moreover, the caselaw does not bear out Plaintiffs' distinction between "as-applied" and "pre-enforcement, facial" challenges. In *Alliance for Natural Health U.S. v. Sebelius*, 775 F. Supp. 2d 114 (D.D.C. 2011), the plaintiff scientists challenged an FDA rule that caused their licensee, a dietary supplement manufacturer, to incur $112,166.56 in compliance costs, which in turn rendered it unable to pay the scientists $67,752.62 due in royalties for the scientists' formulations. *Id.* at 120. The plaintiffs argued that the rule exceeded FDA's authority under the statute, but the comments plaintiffs had submitted during the rulemaking did not make that specific argument. *See id.* at 124-25. Despite plaintiffs' existing losses of $67,752.62, the court found that plaintiffs had waived the statutory argument:

> There was extensive public participation in the rulemaking process, including participation by [plaintiffs] as well as other industry participants. Under these facts, the Court concludes that the plaintiffs are precluded from contesting the FDA's regulatory authority [under the statute] . . . because that argument was not advanced during the rulemaking process.

Id. at 125-26; *see also Plunkett v. Castro*, 67 F. Supp. 3d 1, 21 n.8 (D.D.C. 2014) (noting the "inherent difficulty" with classifying APA challenges as "as applied" or "facial," when the concept derives from constitutional law and "scholars have recognized that often the as applied/facial dichotomy represents nothing more than a distinction without a difference").

Finally, even if the distinction were relevant, Plaintiffs' arguments in this case are in the nature of a facial challenge. The term "as-applied" generally refers to a challenge based on a "particular set of circumstances," whereas a "facial challenge" requires a plaintiff to establish that "no set of circumstances exist" under which the rule would be valid. *Id.* at 20 (quotation marks

and citations omitted). Here, Plaintiffs strain to characterize their suit as "as applied," but frequently make clear that the real gravamen of their challenge is their claim that the Final Rule including the rerun step in the Tukey methodology is invalid because CMS did not add it to the Code of Federal Regulations. *See* Pls. Opp. at 2-3 ("CMS's argument violates a fundamental tenet of rulemaking, which is that language in a preamble does not create law and certainly does not override regulatory text."); Pls. Mot. at 19 ("To the Extent CMS Argues that it Stated in Rulemaking It Was Going to Simulate Cut Points for 2023, that is Irrelevant."). Plaintiffs, by the very act of denying the existence of a valid, binding rule adopted by CMS through notice and comment containing the rerun step, challenge that rule and the rulemaking process.

Plaintiffs do not contend that the rerun step is invalid "as-applied" to their particular Star Ratings but potentially valid in other circumstances; instead, Plaintiffs attack the rerun wholesale. All of their challenges—i.e., the Final Rule conflicts with the guardrail provisions, the Final Rule does not appear in the Code of Federal Regulations, etc.—are issues that Plaintiffs could have and should have raised upon reviewing the February 18, 2020 Proposed Rule. By not doing so, Plaintiffs have waived their rights to bring those challenges now, four years later.

C. Plaintiffs Are Not Entitled to Relief for Harmless Errors.

The APA directs courts to take "due account" of the rule of "prejudicial error," also known as "harmless error." 5 U.S.C. § 706; *see also* Defs. Mot. at 35-36; *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 40-41 (D.C. Cir. 2005) (notice labeled "Petition for Declaratory Ruling" instead of "Notice of Proposed Rulemaking" was harmless error where "published in the Federal Register" and "crystal clear"); *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 311 (D.D.C. 2016) ("Few rulemakings are perfect, and a court should not set aside an agency's action under the APA based on procedural irregularities that constitute harmless error.")

Here, Plaintiffs cannot meet their burden in showing that they were harmed by the inadvertent deletion of the Tukey sentence, or, assuming that CMS was required to codify all rules in the Code of Federal Regulations, the failure to do so here. *See* Defs. Mot. at 32-34; *Combat Veterans for Cong. Political Comm. v. FEC*, 795 F.3d 151, 157 (D.C. Cir. 2015); *see also Ctr. for Biological Diversity v. Int'l Dev. Fin. Corp.*, 77 F.4th 679, 690 (D.C. Cir. 2023). Plaintiffs deflect by characterizing their lawsuit as "not challenging the rulemaking process to implement the Tukey methodology, including when CMS" inadvertently removed the Tukey sentence. Pls. Opp. at 18-19. As discussed above, *see supra* § I.B, the gravamen of Plaintiffs' suit is that CMS did not promulgate the rerun step in the Code of Federal Regulations; thus, it is Plaintiffs' burden to show that they were harmed by the alleged procedural error: CMS not promulgating the Final Rule in the Code of Federal Regulations.

Plaintiffs also argue that the amount of money they claim they will lose shows harm, *see* Pls. Opp. at 19, but that misses the point. Plaintiffs' 2024 Star Ratings may have decreased because CMS reran the 2023 cut points with Tukey outlier deletion, but that is not because CMS did not codify that aspect of the methodology in the Code of Federal Regulations text. The consequences of Plaintiffs' decreased ratings flow from CMS's decision to rerun the cut points itself, not from where the binding rule was located.

Plaintiffs' arguments in this case ask the Court to put formality above substance. The Court should reject this attempt and hold that any error on CMS's part was harmless.

II. Plaintiffs' Argument That CMS Used the Prior Year's Data for Measure C25 Fails.

Plaintiffs' opening brief argued that CMS violated 42 C.F.R. § 422.166(a)(2)(i) by calculating the cut points for measure C25, which measures enrollee-filed complaints against the plan, by using "the current year's" measure score distribution instead of the "prior year's" in the "restricted range cap." Pls. Mot. at 20-21. CMS responded to this argument in detail, citing record

evidence, relevant authority, and Plaintiffs' own declaration attached to its motion: CMS explained that Plaintiffs' argument was incorrect because CMS did use the prior year's data. Defs. Mot. at 34-37. CMS also explained that its contractor made a coding typo in the plans' favor that increased the restricted range cap, and in turn the cut points, by about 0.01. *Id.* at 35. Because this error only impacted cut points for C25, affected ratings for only a small number of plans, and increased those plans' ratings (since a lower score is better on C25), CMS did not correct the error. *Id.* Finally, CMS explained that this error was harmless, as it worked in the plans' favor and did not affect contract H5422's Star Rating in any event. *Id.* at 36.

Plaintiffs respond with a series of vague and extreme accusations, including that CMS's argument "does not meet the threshold for . . . summary judgment," and "it is impossible" for Plaintiffs to analyze the impact of CMS's position. Pls. Opp. at 25. These are curious arguments, considering that Plaintiffs have the burden of establishing that they are entitled to relief.

Moreover, it is possible to analyze the impact. As CMS explained, Plaintiffs seem to believe that CMS, instead of using the 2023 maximum and minimum values of 1.12 and 0, used the 2024 Star Ratings values of 1.41 and 0. *See* Defs. Mot. at 35. Further, because C25 measures member complaints about the health plan per 1,000 members, a lower score is better, and a higher cut point is easier for contracts to meet. *See id.* at 34. Thus, score of 1.41 is lower than 1.12, and the "current year's" (2024's) values represent a lower range than the "prior year's" (2023's) values, which translates into lower, easier cut points for contracts to meet.

Applying the formula, restricted range cap = (maximum score - minimum score) * 0.05, the current year's values yields a cap of .0705, while the prior year's values yield a cap of .056. *See id.* at 34-35. The .0705 cap based off the current year's numbers would be more beneficial to contracts because, as Plaintiffs' own declaration even shows, the larger guardrail would allow the

cut points for the 2024 Star Ratings to move higher, thus making them easier for contracts to meet. *Id.* at 35-36 (Abernathy Decl., Table 1 (at 11, ¶ 28)); CMS, Medicare 2024 Part C & D Star Ratings Technical Notes at 157 (updated Mar. 13, 2024), *available at* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data (2023 Star Ratings cut points for C25 with Tukey outliers removed); *id.* at 153 (2024 Star Ratings pre-guardrail cut points for C25); *id.* 76 (2024 Star Ratings post-guardrail cut points for C25).

Thus, even if Plaintiffs were correct that CMS used the current year's data instead of the prior year's data, all that would mean is that the guardrail would be .0705 instead of .056, resulting in higher, easier to meet final cut points, which could not harm Plaintiffs in any way. *See* Defs. Mot. at 35-36. In other words, even under Plaintiffs own theory, CMS's alleged error would be harmless. *See* 5 U.S.C. § 706; *U.S. Telecom Ass'n*, 400 F.3d at 40-41.

Nevertheless, CMS showed that it did use the prior year's data, Defs. Mot. at 35, and that its contractor's .01 coding error explains why the cap may have been off by close to .0705 or about 7%. *See id.* at 35-36. Adding the effect of the coding error (.01) to the cap CMS calculated of .056 yields .66, which is close to .0705 or about .07, and thus explains why Plaintiffs might have believed that CMS used the current year's data and applied a "Guardrail" of .07. *See id.*; Abernathy Decl., Table 1. This is harmless error.

Plaintiffs' briefs do not argue that the alleged C25 error "alone" negatively impacted Contract H5422 "in excess of a hundred million dollars," as Plaintiffs' Amended Complaint did. Am. Compl. (ECF No. 13) ¶ 70. Thus, far from showing that CMS's Tukey implementation was "fatally flawed," *see* Pls. Opp. at 25, this issue gives reason to doubt Plaintiffs' claims, and the court should find that any CMS error was harmless.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion and grant Defendants' Motion.

Dated: April 16, 2024

Respectfully submitted,

MATTHEW M. GRAVES, D.C. Bar #481052
United States Attorney

BRIAN P. HUDAK
Chief, Civil Division

OF COUNSEL:

SCOTT SASJACK
Attorney
U.S. Dept. of Health and Human Services
330 Independence Ave., S.W.
Washington, D.C. 20201
(202) 619-0435
scott.sasjack@hhs.gov

ALEXANDER R. WHITE
Attorney
U.S. Dept. of Health and Human Services
330 Independence Ave., S.W.
Washington, D.C. 20201
(202) 619-0182
alexander.white@hhs.gov

SAMUEL R. BAGENSTOS
General Counsel

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

Department of Health and Human Services

By: /s/ *Douglas C. Dreier*
DOUGLAS C. DREIER
D.C. Bar #1020234
Assistant United States Attorney
601 D Street, NW
Washington, DC 20530
(202) 252-2551

Attorneys for the United States of America

Exhibit 1

Declaration of Elizabeth Goldstein

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELEVANCE HEALTH, INC., et al. Plaintiffs, v. XAVIER BECERRA, Secretary of Health and Human Services, et al., Defendants.	Civil Action No. 23-3902 (RDM)

DECLARATION OF ELIZABETH GOLDSTEIN

I, Elizabeth Goldstein, declare that the following statements are true and correct to the best of my knowledge and belief, that they are based on my personal knowledge, or they are based on information supplied to me in the ordinary course of my job duties:

1) I am employed by the Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS"), located at 7500 Security Boulevard, Baltimore, MD 21244.

2) I am the Director of the Division of Consumer Assessment and Plan Performance, a component of the CMS Office of the Center for Medicare ("CM"). I have held this position since 2001. Before I was named Director, I served as a social science research analyst. I served in that capacity for over eight years. I first joined CMS in 1993 and have spent over thirty years performing the responsibilities of a social science research analyst or supervisory social science research analyst.

3) As Director of the Division of Consumer Assessment and Plan Performance, I am familiar with and responsible for implementing the quality ratings that determine Quality Bonus Payments for the Medicare Advantage program, formerly known as Medicare+Choice, which Congress established in Part C of the Medicare statute, 42 U.S.C. §§ 1395w-21 to 1395w-29. Under Medicare Advantage, the federal government pays insurers to provide the coverage that participating beneficiaries would otherwise receive through Parts A and B (sometimes known, collectively, as "traditional" Medicare). *Id.* § 1395w-22(a). These insurers, known as Medicare Advantage Organizations ("MAOs"), contract to provide coverage in a particular geographic area.

4) I am also familiar with and responsible for implementing the Medicare Part C and Part D Star Ratings, which are a means by which CMS measures the quality of MAOs (and Part D Prescription Drug Plans) on a scale of one to five "stars," based on Medicare Advantage and Part D data collected and used by CMS. 42 U.S.C. § 1395w-23(o)(4)(A); *see also* § 1395w-22(e)(3) and 42 CFR §§ 422.162(c) and 423.182(c). Star Ratings reflect the care provided and experiences of beneficiaries in these plans and assist beneficiaries in finding the best plans for their needs.

5) CMS publishes the Star Ratings each October for the upcoming year at the contract level, with each plan offered under that contract assigned the contract's rating. To calculate the ratings, CMS scores Medicare Advantage contracts on approximately thirty to forty-two quality measures, depending on whether the plan is Medicare Advantage-only or also includes Part D coverage. CMS, Medicare 2024 Part C & D Star Ratings Technical Notes at 13 (updated Mar. 13, 2024), *available at* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data. I am a subject matter expert on calculating the Star Ratings.

6) To determine ratings on measures other than the measures based on information from the Consumer Assessment of Healthcare Providers and Systems survey, CMS uses a clustering algorithm that creates four cut points in the Medicare Advantage Organization data, resulting in five separate levels with one typically being the worst and five being the best. Since the 2023 Star Ratings, CMS has applied a guardrail that prevents the cut points for each non-Consumer Assessment of Healthcare Providers and Systems measure from increasing or decreasing more than five percent from one year to the next for measures on a 0 to 100 scale. 42 C.F.R. § 422.166(a)(2)(i).

7) In a February 18, 2020 proposed rule, CMS proposed using Tukey outlier deletion in the calculation of the 2023 Star Ratings. *See* Contract Year 2021 & 2022 Policy & Technical Changes to the Medicare Advantage Program (the "Proposed Rule"), 85 Fed. Reg. 9,002, 9,043-44 (Feb. 18, 2020). CMS explained that Tukey outlier deletion removes scores above and below cutoff points that are identified by taking the interquartile range and multiplying it by a factor. *Id.*

8) In the Proposed Rule, CMS proposed that in the first year that Tukey outlier deletion would be implemented, the prior year's cut points would be rerun, including mean resampling and Tukey outer fence deletion, so that the guardrails would be applied such that there is consistency between the years. *Id.*

9) CMS also discussed, in the Proposed Rule, a simulation it ran on 2018 Star Ratings data with Tukey outlier deletion and a five percent guardrail. *Id.* CMS's contractor, the RAND Corporation ("RAND"), helped CMS perform this simulation.

10) Based on this simulation, CMS concluded, as it discussed in the Proposed Rule, that had it implemented Tukey outlier deletion and a five percent guardrail in the 2018 Star Ratings, two percent of combined Medicare Advantage and Part D contracts would have seen their

Star Ratings increase by half a star, while sixteen percent would have decreased by half a star, and one contract would have decreased by a full star. *Id.*

11) In conducting this simulation, CMS and RAND applied guardrails to the 2018 cut points, based off cut points in the 2017 Star Ratings data. In doing so, CMS reran the 2017 cut points in the 2017 Star Ratings data by applying CMS's proposed Tukey outlier deletion methodology, which included identifying and removing Tukey outliers by taking the interquartile range and multiplying it by a factor, as CMS proposed in the Proposed Rule. CMS reran the cut points this way for 2017 because CMS was proposing that in the first year it would implement Tukey outlier deletion, it would rerun the prior year's cut points, including mean resampling and Tukey outer fence deletion, so that the guardrails would be applied such that there is consistency between the years. *Id.*

12) CMS did not use or rerun data from the 2016 Star Ratings or any other Star Ratings year in this 2018 simulation, because CMS was only proposing to rerun the cut points for the year prior to the first year CMS would implement Tukey outlier deletion.

13) On or about April 9, 2024, CMS contacted employees at RAND who had assisted CMS with the 2018 simulation and other related work, including Maria DeYoreo. They verified that they performed the 2018 simulation by rerunning the 2017 cut points and applying the guardrails as described above, *see* paragraphs ¶¶ 9-12. They also sent a copy of an August 20, 2019 email from Adam Scherling at RAND to Maria DeYoreo at RAND, attached hereto as Attachment A, which states that RAND performed the 2018 simulation as described above. *See* paragraphs ¶¶ 9-12.

14) Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on:

Date: April 15, 2024

Elizabeth H. Goldstein -S Digitally signed by Elizabeth H. Goldstein -S
Date: 2024.04.15 15:09:09 -04'00'

Elizabeth Goldstein
Director of the Division of Consumer Assessment and Plan Performance
Center for Medicare
Centers for Medicare & Medicaid Services

ATTACHMENT A

From: Scherling, Adam <ascherli@rand.org>
Date: Tuesday, August 20, 2019 at 11:14 AM
To: DeYoreo, Maria <mdeyoreo@rand.org>, Damberg, Cheryl <damberg@rand.org>
Cc: Susan Paddock <Paddock-Susan@norc.org>
Subject: Re: 2018 simulations

Upon closer inspection the 2018 simulation with non-cumulative guardrails and Tukey outlier removal has guardrails based on a 2017 sim with Tukey outlier removal. That said, changing the run that the guardrails are based on is just a matter of changing the path in the code, so that should be easy. The bulk of the work may be just cleaning up the Excel output.

What is our timeline for this? I'm pretty busy right now but I could plausibly do this later this afternoon or tonight.