UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCAN HEALTH PLAN,

Plaintiff,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Civil Action No. 23-3910 (CJN)

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

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Defendants the Department of Health and Human Services (the "Department"), its Secretary, the Centers for Medicare & Medicaid Services ("CMS"), and its Administrator respectfully submit this reply in further support of their cross-motion for summary judgment (ECF No. 23, "Defs. Mot.").

I. Plaintiff's 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 Administrative Procedure Act ("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 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, that cited and discussed specific material from the two pages containing the proposed rerun of the prior year's cut points. Comment of SCAN Health at 5 (certified rulemaking record ("R.R.") at 382) (citing 85 Fed. Reg. 9,043 and commenting on a

2018 Star Ratings simulation discussed at 85 Fed. Reg. 9,044); *see also* Comment of SCAN Found. (R.R. 264-70). 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: "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.[1]

Plaintiff argues that publication in the Federal Register and notice and comment are not enough because CMS frequently publishes nonbinding statements of policy and interpretive rules in the Federal Register. *See* Pl.'s Opp. (ECF No. 27) at 8-9. What Plaintiff misses, however, is the importance of the agency's intent, both in the caselaw and in CMS's Final Rule, as a key factor distinguishing binding rules from other statements. *See id.* at 12 (whether CMS intended the Final Rule to be binding is "beside the point" and "irrelevant"). As CMS has explained, 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 binding. *See* Defs. Mot. at 22; *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.").

[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).

The cases Plaintiff cites 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.

Another case relied on by Plaintiff 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. *Nat'l Env't Dev. Ass'ns Clean Air Project v. EPA*, 752 F.3d 999, 1003 (D.C. Cir. 2014). 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 dissimilar to the case at bar, 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.

Finally, 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 a binding regulation was impractical. *Id.* at 538-39. The absence of the 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 dissimilar to this case, where the facts consistently show that CMS intended the Final Rule, including the rerun step, to be binding.

Plaintiff 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 this 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. *See* Pl.'s Opp. at 11. This 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. *See St. Helena*, 2021 U.S. Dist. LEXIS 62321, at *16-17. But the 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.

Plaintiff argues that, on appeal, the D.C. Circuit "expressly refused" to defer to CMS's Federal Register statement and instead reaffirmed that the preamble is not binding. *See* Pl.'s Opp. at 11-12. That is incorrect. In affirming, the D.C. Circuit used the 1998 Federal Register statement to determine not only the meaning of the Code of Federal Regulations provision at issue, but also the meaning of the statute. *St. Helena*, 30 F.4th at 304-05. While it noted the plaintiff's argument that the Secretary's policy for a prior time period had not been properly adopted through notice and comment rulemaking, it did not adopt that position and reverse the district court. *Id.*

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 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)").

Plaintiff quotes a December 3, 2020 advisory opinion from the Department's Office of the General Counsel, supposedly showing that text not appearing in the Code of Federal regulations is binding only where the agency uses the phrase, the Department "intends to bind itself." *See* Pl.'s Opp. at 12-13, at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101111604-mh-advisory-opinion-20-05-on-implementing-allina_12.03.2020_signed.pdf. This document states: "This advisory opinion sets forth the current views of the Office of the General Counsel. It is not a final agency action or a final order. Nor does it bind the Department or the federal courts. It does not have the force or effect of law." Advisory Opinion 20-05 at 1 (footnote omitted). It also states that the Department will speak to its intent to make a rule binding, "such as by using the phrase '[the Department] intends to bind itself' to the rule." *Id.* at 3. Thus, the advisory opinion did not state that using this phrase was the only way the Department could make its intent clear. Most importantly, the discussion in the advisory opinion further shows that the

Department's Office of General Counsel interpreted the applicable statutes and caselaw as allowing the Department to promulgate binding rules outside of the Code of Federal Regulations where the Department made its intent clear. *See id.*

Plaintiff argues that CMS has chosen to promulgate other rules applicable to only one Star Ratings year in the Code of Federal Regulations. Pl.'s Opp. at 12. 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 24.

Plaintiff also argues that CMS's decision to rerun the prior year's cut points violated 42 C.F.R. § 422.166(a)(1)-(2) (calculation of Medicare Advantage cut points) and § 423.186(a)(1)-(2) (calculation of Part D cut points), Pl.'s Opp. at 6-7, 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 Plaintiff's 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 25 (citing 42 C.F.R. § 422.166(a)(2)(i)); *see also* § 423.186(a)(2)(i) (containing the same relevant language). 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 natural reading is that they are. Defs. Mot. at 25-26. Plaintiff does not dispute that cut points in "the next" year are always calculated with Tukey outlier data removed. Nor does Plaintiff dispute that cut points in the "1 year" are, after the first year, always calculated with Tukey

outlier data removed. Thus, Plaintiff does 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.

Plaintiff responds that the phrase "from one year to the next" refers to the same variable in two years, here, the "measure-threshold-specific cut points." Pl.'s Opp. at 10 (citing *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 523 (D.C. Cir. 2009)). But CMS's interpretation does not change the variable (the cut points); rather, it ensures that CMS calculates that same variable using the same methodology consistently in both years. Plaintiff's reading and idea of consistency would be like comparing annual differences in temperature without regard to whether the measurements are 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. This would fail to maintain consistency, resulting in an apples-to-oranges comparison.

Plaintiff also cites definition sections in the Code of Federal Regulations that refer to "the prior year's . . . cut point" in defining certain caps and guardrails. Pl.'s Opp. at 11 (citing 42 C.F.R. §§ 422.162(a), 423.182(a)). But Plaintiff's interpretation of the definition sections would introduce the same inconsistency noted above. And regardless, none of the provisions cited by Plaintiff say "actual," "unadjusted," or "non-simulated cut points." Nor do any of the provisions Plaintiff cites prohibit CMS from adjusting the prior year's cut points to account for updated data or methodological changes.

This is no coincidence. Defs. Mot. at 26. 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 either of those provisions to prevent CMS from rerunning the prior year's cut points. *See* Defs. Mot. at 26; 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 sections 422.166(a)(2)(i) and 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. Plaintiff's 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.

Plaintiff's motion argued "even if the Court were to conclude that CMS's Federal Register preamble controls," that preamble never mentioned the removal of the guardrails that restricted the 2023 cut points from moving more than five percent from the 2022 cut points. Pl.'s Mot. (ECF No. 26), at 31. As CMS has explained, this is essentially a sub-issue regarding how CMS should conduct its rerun of the prior year's cut points under the Final Rule. Defs. Mot. at 28. Plaintiff is arguing that even if CMS can rerun the 2023 Star Ratings cut points for purposes of the 2024 guardrails, CMS should have, within the 2023 rerun, applied guardrails based on the 2022 cut points. *See id.*

This is inconsistent with the applicable rule, which stated that CMS will rerun "the prior year's" cut points with Tukey outlier deletion. *See id.*; 85 Fed. Reg. at 33,833, 33,835; 85 Fed. Reg. at 9,044. Nowhere did CMS come anywhere close to suggesting that it 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." Further, by arguing that CMS must use the "actual" 2022 cut points, Plaintiff reintroduces the same inconsistency in its original argument because it would have CMS calculate 2023 and 2024 cut points without Tukey outliers, but apply guardrails affected by 2022 cut points calculated with Tukey outliers. *See* Defs. Mot. at 28; Pl.'s Opp., at 31 n.17; *id.* at 15. Plaintiff's argument that CMS's methodology will allow "cut points to balloon 30%, 40%" upwards only highlights

that inconsistency. Pl.'s Opp. at 15. Under Plaintiff's method, the 2023, 2024, and all later cut points would initially be calculated free from Tukey outliers, but to some extent could still be affected by the most extreme outliers in the 2022 data, for eight years or longer (i.e., forty-percent divided by five percent equals eight). *See also* Defs. Mot. at 28.

Plaintiff also argues that "CMS affirmatively represented that guardrails would apply to limit changes of the simulated 2023 Star Rating cut points relative to the actual 2022 Star Rating cut points, on five occasions." Pl.'s Opp. at 15. CMS stated that "[i]n the first year that this would be implemented," CMS would rerun "the prior year's" cut points. 85 Fed. Reg. at 9,044. The "first" Star Ratings year Tukey is implemented is 2024, *see* 85 Fed. Reg. 33,836, and the "prior" Star Ratings year is 2023. In calculating the 2024 Star Ratings, CMS did apply guardrails to the cut points based on the 2023 cut points rerun with Tukey outliers removed, just as CMS said it would. Defs. Mot. at 18. CMS, Medicare 2024 Part C & D Star Ratings Technical Notes at 157 (updated Mar. 13, 2024) ("Technical Notes"), *available at* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.

CMS's simulations reran 2022 and 2023 cut points with Tukey outliers removed and applied guardrails between those two sets of cut points. Defs. Mot. at 11-12; R.R. 2711-15. This served only to illustrate what would happen in the 2024 Star Ratings when CMS would rerun the 2023 cut points prior to the application of the guardrails. Defs. Mot. at 12; R.R. 2705. Plaintiff does not rely on these simulations, because Plaintiff argues that CMS represented it would apply guardrails "relative to the actual" 2022 cut points, not to rerun 2022 cut points. Pl.'s Opp. at 15.

Plaintiff persists that "[n]o commenter would reasonably read 'guardrails would be applied' in the 'rerun' to actually mean 'no guardrails apply.'" *Id.* (quoting 85 Fed. Reg. at 33,833; Fed. Reg. at 9,044). But CMS did apply guardrails in the 2024 Star Ratings: it applied guardrails

to the 2024 cut points based on 2023 cut points rerun with Tukey outliers removed, just as it said it would. *See* Defs. Mot. at 18; Technical Notes, *supra*, at 157. CMS also applied guardrails in the 2023 Star Ratings: it applied them to the 2023 cut points based on the 2022 cut points. 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. Thus, it is incorrect to say that CMS applied "no guardrails" in the 2024 or 2023 Star Ratings.

Plaintiff also argues that CMS "hoodwinked the Medicare Advantage industry" by providing "no notice, much less opportunity for comment" that CMS would, in the 2024 Star Ratings, apply no guardrail between the 2023 and 2022 cut points, thereby allowing cut points to balloon upwards. Pl.'s Opp. at 14-17. Plaintiff bases this argument in part on the simulation using 2018 Star Ratings data that CMS discussed in the Proposed Rule. *Id.* at 15. Plaintiff claims that this discussion "misled the public" by "telling them" CMS would apply guardrails relative to the prior year's "actual" cut points, because CMS simulated its proposal "exactly that way." *Id.*; *see also* 85 Fed. Reg. 9,044.

The same discussion of the 2018 simulation that Plaintiff references from the Proposed Rule put the public on notice that had CMS removed Tukey outliers and applied a five percent guardrail in the 2018 Star Ratings—"16 percent" of Medicare Advantage-Part D contracts "would have decreased by half a star"—exactly the result that Plaintiff bases its lawsuit on here. 85 Fed. Reg. 9,044; Pl.'s Opp. at 1. Further, when CMS conducted that simulation and applied guardrails to the 2018 data, it removed Tukey outliers from the prior year's cut points (the 2017 Star Ratings cut points), consistent with CMS's statement that "[i]n the first year that this would be implemented, the prior year's thresholds would be rerun." 85 Fed. Reg. 9,044; Declaration of Elizabeth Goldstein, attached as Exhibit 1, ¶¶ 9-13 and Attachment A.

Moreover, the Proposed Rule presented, in two places, estimates that Tukey outlier deletion would create $808.9 million in savings for the federal government by decreasing payments to plans in 2024, increasing to $1.4492 billion in annual savings for 2030. *Id.* at 9,044, 9,186; Defs. Mot. at 8. Although CMS also estimated that this would be partially offset, especially in the first few years of Tukey outlier deletion, by another proposal, Defs. Mot. at 8, 11, 27, it is hard to imagine that an entire industry as sophisticated the Medicare Advantage industry would have missed this. CMS's proposal to rerun the prior's year's cut points and the sentence requesting comments appear in the very same paragraph as a sentence stating: "Tukey outlier deletion would create a savings of $808.9 million for 2024, increasing to $1,449.2 million by 2030." 85 Fed. Reg. 9,044. And that paragraph appears right after the paragraph discussing the 2018 simulation. *Id.*

CMS received numerous comments on its proposed Tukey methodology, including from Plaintiff, it just did not receive any comments specifically addressing the rerun step. Defs. Mot. at 8-9; Comment of SCAN Health at 5 (R.R. 382) (referencing the 2018 simulation); *see also* Comment of SCAN Foundation (R.R. 264-70). Plans like Plaintiff had the information and opportunity to comment but did not. In that context, CMS can hardly be expected to address in detail the sub-issue of whether, in the prior year's rerun, CMS would also use data from two years prior. *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, Plaintiff is trying to read in an additional, complex, and contradictory step to the simple rule CMS set forth. Plaintiff's argument that CMS should

have applied guardrails based on the 2022 cut points when rerunning the 2023 cut points with Tukey outlier deletion for purposes of calculating the 2024 guardrails fails.

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

Plaintiff's motion argued that CMS's inadvertent removal of the Tukey outlier deletion sentence from the Code of Federal Regulations "overturned" or "vacated" the Final Rule, requiring CMS to restart rulemaking completely from scratch for all aspects of the Tukey methodology including the prior year rerun. *See* Pl.'s Mot. at 31-33. Plaintiff now argues that CMS "revoked" the Final Rule. Pl.'s Opp. at 18. As CMS has explained, an inadvertent deletion of regulatory text does not repeal a rule, nor can a rule be repealed without additional notice-and-comment making. *See* Defs. Mot. at 14-15, 29-30. CMS's inadvertent removal of the Tukey sentence was therefore a nullity and had no effect on the Final Rule.

Plaintiff argues that only private parties can take advantage of an agency's ineffective revocation of a rule; an agency "obviously" cannot enforce a rule it invalidly revoked. Pl.'s Opp. at 19. Plaintiff cites only one authority for this proposition, a Federal Circuit case where Congress repealed the statute authorizing the regulation at issue. *See id.*; *Aerolineas Argentinas v. United States*, 77 F.3d 1564, 1570 (Fed. Cir. 1996).

Plaintiff's theory is incorrect. *See Ball Mem'l Hosp. v. Leavitt*, Civ. A. No. 04-2254, 2006 U.S. Dist. LEXIS 68226, at *36 (D.D.C. Sept. 22, 2006) (Secretary's Program Memorandum issued without notice and comment purporting to reverse Secretary's prior authoritative interpretation of CMS rule was "unlawful" and a "nullity," and thus provided no basis for the relief sought by plaintiffs against CMS); *see also Humane Soc'y of the U.S. v. Dep't of Agric.*, 41 F.4th 564, 567-68 (D.C. Cir. 2022).

Further, Plaintiff merely assumes that CMS intended to "revoke" the Final Rule in May 2022. But as *Select Specialty Hospital-Akron v. Sebelius*, 820 F. Supp. 2d 13 (D.D.C. 2011),

demonstrates, when CMS offers the logical explanation that it "inadvertently omitted" language from the Code of Federal Regulations text and an opposing party offers no alternative explanation, CMS is not arbitrary and capricious when it fixes that error with a "correcting amendment." *See id.* at 20, 26; Defs. Mot. at 29-32.

Here, despite Plaintiff's attempts to characterize the Final Rule as being "overturned," "vacated," or "revoked" by CMS in the May 9, 2022 final rule, Plaintiff has offered no alternative explanation or evidence of anything other than a simple mistake. *See* Pl.'s Mot. at 31-33; Pl.'s Opp. at 18; Defs. Mot. at 14; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage Program, 87 Fed. Reg. 27,704, 27,766, 27,895, 27,900 (May 9, 2022) (removing the Tukey sentence but also stating that "Tukey outlier deletion will be implemented beginning with the 2024 Star Ratings"). Thus, under *Select Specialty*, CMS would not have been arbitrary and capricious even if it added the Tukey sentence back to the Code of Federal Regulations without taking comments. *See Select Specialty*, 820 F. Supp. 2d at 23-24. But CMS did take comments, and it responded to them in detail, satisfying the requirements of the APA. *See id.*; 88 Fed. Reg. at 22,295-97.

CMS was not arbitrary and capricious. It was diligent and cautious. Plaintiff has not met its burden to show otherwise, and the Court should uphold CMS's decision to rerun the 2023 cut points with Tukey outlier deletion for purposes of applying the guardrails in the 2024 Star Ratings.

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)). 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)).

Relying on a concurring opinion, Plaintiff argues that administrative waiver does not apply here because Plaintiff brings an "as-applied" challenge, not a "pre-enforcement, facial challenge to an agency's final rule." Pl.'s Opp. at 20 (citing *Koretoff v. Vilsack*, 707 F.3d 394, 399 (D.C. Cir. 2013) (Williams, J., concurring)). The concern raised by the *Koretoff* concurrence—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*, 707 F.3d at 401. Here, Plaintiff commented on other parts of the Proposed Rule but chose to waive its opportunity to comment on the prior year rerun step, thereby preventing CMS from considering and responding to Plaintiff's objections at that time. *See* Comment of SCAN Health at 5 (R.R. 382) (criticizing the 2018 data).

Moreover, the caselaw does not bear out Plaintiff's 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. *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, Plaintiff's 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. *Plunkett*, 67 F. Supp. 3d at 20 (quotation marks and citations omitted). Here, Plaintiff strains to characterize its suit as "as applied," but frequently makes clear that the real gravamen of its challenge is its 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* Pl.'s Opp. at 9 ("In short, *AT&T* and *Brock*'s admonitions that a Federal Register preamble alone does not give rise to a binding legislative rule, even with an opportunity for notice and public comment, hold doubly true for CMS."); *id.* at 18 ("CMS revoked those preambles in 2022, and never attempted to revive them."); *id.* at 22-23 (CMS used the wrong methodology "drawn from the wrong source of law [the Final Rule]"); Pl.'s Mot. at 30 ("CMS knows full well that it needs to codify regulations in the Code of Federal Register for them to have the force and effect of law: it just chose not to do so here."). Plaintiff, by the very act of denying the existence of a valid, binding rule adopted by CMS through notice and comment containing the rerun step, challenges that rule and the rulemaking process.

Plaintiff does not contend that the rerun step is invalid "as-applied" to its Star Ratings but potentially valid in other circumstances; instead, Plaintiff attacks the rerun step wholesale. All of its challenges (that the Final Rule conflicts with the guardrail provisions, that the Final Rule does not appear in the Code of Federal Regulations, etc.), are issues that Plaintiff could have and should

have raised in the rulemaking after reviewing the February 18, 2020 Proposed Rule. By not doing so, Plaintiff has waived its right to bring those challenges now, four years later.

C. Plaintiff Is 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." Defs. Mot. at 35-36; *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 40-41 (D.C. Cir. 2005); *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 311 (D.D.C. 2016). Here, Plaintiff cannot meet its burden in showing that it was 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 36-37; *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). Plaintiff again deflects by characterizing its suit as an "as-applied" challenge. *See* Pl.'s Opp. at 22. But Plaintiff's makes a facial challenge. *See supra* § I.B.

The gravamen of Plaintiff's suit is that CMS did not promulgate the rerun step in the Code of Federal Regulations; thus, it is Plaintiff's burden to show that it was harmed by the alleged procedural errors, but the best Plaintiff can do is argue again that CMS did not give notice. Pl.'s Opp. at 23-24. CMS did give notice, and Plaintiff commented on the Proposed Rule. *See* Comment of SCAN Health at 5 (R.R. 382) (criticizing the 2018 data); *supra* § I.A.2.

Plaintiff also argues that the amount of money it claims it will lose shows harm, *see* Pl.'s Opp. at 23, but that misses the point. Plaintiff's 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. CMS's Conclusion That the February 9, 2023 Call Required More Than Eight Minutes to Connect to an Interpreter Is Consistent with the Record and Relevant Guidance.

Much like the arguments in its opening brief, Plaintiff's arguments on reply fail because they ask this Court to apply the wrong standard and displace CMS's reasoned factual judgment.

A. CMS Applied the Proper Standard to the February 9, 2023 Call.

The Secretary's opening brief (Def. Mot. at 38) discussed CMS's regulation governing the process for "[a]dding, updating, and removing measures." *See* 42 C.F.R. § 422.164. There is no doubt that the Secretary followed the procedures outlined in his own regulations by "list[ing] the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings." *Id.* § 422.164(a); *see* SCAN-AR00191-92.

Plaintiff insists that the regulation at 42 C.F.R. § 422.111(h)(1)(iii) is the "governing regulation." Pl.'s Opp. at 25. In support of this, Plaintiff notes that the Reconsideration Official and Hearing Officer cited that provision in their respective decisions. *Id.* at 25-26. As Plaintiff acknowledges in a parenthetical, the Hearing Officer's "final and binding" decision states that "CMS in the December 1, 2022 Call Center Monitoring [Health Plan Management System memo] defines interpreter availability and when the 8-minute measure is met." SCAN-AR00006; *see* Pl.'s Opp. at 26. That guidance—which does not mention or purport to implement 42 C.F.R. § 422.111(h)(1)(iii)—describes how measure C30 will be assessed.[2] This is not a post-hoc

[2] Plaintiff cites "other guidance that Defendants rely upon." Pl.'s Opp. at 27. But it quotes only the portions of those documents that refer to Section 422.111(h), ignoring the portions that accurately describe how the interpreter availability measure would be tested. The first such document, "Call Center Monitoring Accuracy and Accessibility Study Technical Notes," refers to the annual Call Center Monitoring Memo and notes "[t]he annual memo supersedes any definitions contained in this document." SCAN-AR00481. It nonetheless defines "Interpreter Availability" exactly as Measure C30 defines it: "The measure is considered completed when contact has been established with an interpreter and the introductory question has been correctly answered within eight minutes of reaching a [Customer Service Representative]." SCAN-AR00489-90. So too

explanation: the Hearing Officer applied the measure specifications found in the guidance. Same with the Reconsideration Official. SCAN-AR00026 ("Completed contact with an interpreter is when the [Customer Service Representative], via an interpreter, provides an affirmative response to the introductory question."). Nor does Plaintiff attempt to argue that there was any genuine confusion with respect to the relevant measure specifications. As the Secretary showed, measure specifications for foreign language interpreter availability have been consistent for years, and plans have long known about those standards. *See* Defs. Mot. at 39.

Plaintiff responds that Section 422.111(h)(1)(iii) should control because it was subject to notice and comment rulemaking and CMS's guidance was not, an alleged violation of *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019), and *AT&T Corp. v. FCC*, 970 F.3d 344 (D.C. Cir. 2020). *See* Pl.'s Opp. at 28. This claim fails because Congress explicitly authorized CMS to make annual announcements related to the Medicare Advantage via a specific procedure. *See* 42 U.S.C. § 1395w-23(b).

Plaintiff invokes *Allina* talismanically, urging this court to find that it stands for the proposition "that CMS must provide 'notice and a chance to comment on' non-binding 'Medicare interpretive rules' and 'policies.'" Pl.'s Opp. at 9 (quoting *Allina*, 139 S. Ct. at 1816). Not so. In *Allina*, the Supreme Court interpreted the statutory requirement at 42 U.S.C. § 1395hh(a)(2), which requires the Secretary to act "by regulation" when he "changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities,

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with the December 1, 2022 Health Plan Management System Memo, which cites the regulation but also clearly and accurately describes the standard used for measuring interpreter availability. SCAN-AR00457-58. The full text of these documents supports the government's position. It was clear in advance that, for a secret shopper call testing the availability of foreign language interpretation services to be marked successful, a caller would have to confirm "that the [Customer Service Representative] is able to answer questions about plan benefits via an interpreter" and not merely be connected to an interpreter. SCAN-AR000458.

or organizations to furnish or receive services or benefits under [Medicare]." *Allina*, 139 S. Ct. at 1809. Plaintiff has not shown that the methodology for calculating Star Ratings even falls within the ambit of Section 1395hh(a)(2). Indeed, Plaintiff has not even attempted to argue that the Star Ratings calculations themselves govern "the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services" under Medicare, meaning it has not met the threshold for invoking *Allina*.

Further indication that section 1395hh(a)(2) does not apply to agency communication about the Star Ratings methodology is found in a more specific statute, in which Congress instructed CMS on how to convey information about the Medicare Advantage program to "interested parties." 42 U.S.C. § 1395w-23(b). That statute contains its own notice and comment provision. *See id.* § 1395w-23(b)(2). In a 2018 rulemaking, CMS described how it had historically "used the draft and final Call Letter, which are attachments to the Advance Notice and final Rate Announcement respectively, to propose for comment and finalize changes to the quality Star Ratings system." 83 Fed. Reg. 16,440, 16,524 (Apr. 16, 2018) (footnote omitted). CMS finalized its proposals—which relied heavily on Section 1395w-23(b)(2)—to modify Star Ratings measures either via rulemaking (for new measures and substantive changes) or via the Advance Notice and Rate Announcement process (for non-substantive changes). 83 Fed. Reg. at 16,533, 16,537; *see also* 42 C.F.R. § 422.164.

This statutory and regulatory authority undercuts Plaintiff's claim that the agency somehow meant to revise the Star Ratings measure specification for Measure C30 via the 2021 final rule, which—as is undisputed—does not reference the Star Ratings (much less Measure C30 specifically) at all in the relevant section. The agency in 2018 explained via regulation how it would modify the Star Ratings measurement criteria in the future. Critically, it announced that it

would use a statutory notice and comment procedure (either the APA rulemaking procedure or the procedure in section 1395w-23(b)) to make such future changes. Plaintiff's claim that Section 422.111 established a new governing standard for Measure C30 amounts to an argument that CMS violated its own regulations and changed the measure without providing the notice to affected parties that its own regulations require.[3] This Court should not adopt that claim.

B. CMS Did Not Act Arbitrarily and Capriciously in Determining That the February 9, 2023 Call Failed Measure C30.

Plaintiff's argument amounts to a request that this Court displace the agency's factual determination. Defs. Mot. at 40. Most of the relevant facts here are undisputed: that no interpreter was connected until six minutes and thirty-five seconds had elapsed, and that Plaintiff failed to achieve "completed contact with an interpreter" within the required eight minutes.

Plaintiff would have this Court hold that because a different French call required forty-one seconds between an interpreter coming on the line and "completed contact," the minute-and-twenty-five second duration for the challenged call was CMS's fault. But this Court cannot do that without adopting Plaintiff's characterization of the factual record. Plaintiff makes two core claims: that twenty-five seconds was too long for the secret shopper to ask the question, and the question was asked in a non-standard way, which is why the translator asked for it to be repeated. Neither claim is supported by the record. As the Secretary showed in his opening brief, there is a

[3] Plaintiff asserts that "CMS has never articulated any rationale for measuring C30 under a different and far stricter standard than its own compliance regulation." Pl.'s Opp. at 29. But the "compliance regulation" was promulgated only in 2021, and the C30 measure has been in effect for longer. Plaintiff has cited no evidence that any commenter raised the issue during the 2021 notice-and-comment. Plaintiff also ignores that CMS annually solicits comments under Section 1395w-23(b) for changes to the Star Ratings methodology. There is no evidence that anyone has raised the issue via the statutory procedure.

mere seven- or eight-second difference between the time required to ask the initial question in the call that Plaintiff believes is exemplary and the call at issue that Plaintiff failed.

Plaintiff's argument that the phrasing of the failed call was somehow "non-standard" is contradicted by the record. As the Reconsideration Official found: "CMS asks the same question on all calls. We use the same translation for each foreign language call that is placed." SCAN-AR00030. Plaintiff seems to imply that any human factor (i.e., different people speaking a different way) renders suspect CMS's assessment of the disputed call. But there is no legal basis for interpreting the "arbitrary and capricious" standard to require absolute uniformity. Plaintiff cites no authority in support of such an unrealistic standard.

Plaintiff resorts to accusations that CMS's transcription of the call was somehow "secret." Pl.'s Opp. at 31-32. But the transcript—which was produced to Plaintiff during the administrative proceeding at issue and as part of the administrative record that was provided in this matter under a schedule agreed to by both parties, *see* ECF No. 19—does not need to conclusively establish interpreter error. Nor did Defendants suggest so in their opening brief: "[N]either CMS nor this Court is obliged to rely on Plaintiff's characterization, particularly where the record here indicates that SCAN Health's translator failed to take notes and had to ask the caller to repeat key information." Defs. Mot. at 41. To succeed in its argument, Plaintiff must persuade this Court—contrary to the deferential substantial evidence standard of review, *see id.* at 21—to adopt fully Plaintiff's characterization of the record. Neither the Reconsideration Official nor the Hearing Officer agreed with Plaintiff's view that an error by the secret shopper was the cause of Plaintiff's failure to complete the measure specifications within the required eight minutes.

Plaintiff asks this Court to contradict the Reconsideration Official's finding when it says that Plaintiff should not be held accountable for the failure of the translator service it hired. Pl.'s

Opp. at 32-33. The Reconsideration Official was clear: "How SCAN elects to provide interpreters is within SCAN's control and SCAN is thus responsible for how well its chosen approach works." SCAN-AR00030. Nor should this Court countenance Plaintiff's continued reliance on statements made during a live question-and-answer session that CMS promptly clarified. *See* Pl.'s Opp. at 33; Defs. Mot. at 42. Plaintiff's dissatisfaction with its performance on Measure C30 does not amount to an arbitrary-and-capricious violation.

* * *

CONCLUSION

Accordingly, the Court should deny Plaintiff's Motion and grant Defendants' Motion.

Dated: April 16, 2024

Respectfully submitted,

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Exhibit 1

Declaration of Elizabeth Goldstein

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCAN HEALTH PLAN, Plaintiff, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civ. A. No. 23-3910 (CJN)

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 14:12:41 -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.