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)

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiff challenges the final decision of the Centers for Medicare & Medicaid Services ("CMS") to apply "Tukey" outlier deletion (a standard statistical method for removing outlier data), to 2023 data for the purposes of calculating certain measures in the Medicare Part C 2024 Star Ratings. While the details of Tukey outlier deletion are complex, the basic issue here is not. CMS promulgated the challenged rule through notice and comment rulemaking in 2020 and did not receive comments from anyone including Plaintiff specifically challenging it, even though Plaintiff did submit a comment in that rulemaking. CMS illustrated how the challenged rule would work in simulations it posted to its website in December 2022. CMS's intent to make the challenged rule a binding step in the 2024 Star Ratings was at all times absolutely clear, and Plaintiff's main argument is based merely on CMS publishing the rule in the Federal Register and it not being found in the Code of Federal Regulations, a compilation maintained by the Office of the Federal Register of the National Archives and Records Administration and published by the Government Publishing Office. Nat'l Archives, *What is the eCFR, and what is the legal status of this publication?*, available at: https://www.ecfr.gov/reader-aids/understanding-the-ecfr/what-is-the-ecfr.

But neither the Administrative Procedure Act (the "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 procedures set out in the APA. Moreover, the rule does not contradict the plain text of the Code of Federal Regulations, which instead is consistent with CMS's use of the Tukey outlier deletion methodology. Plaintiff's argument elevates form over substance to the extreme: Plaintiff had full notice of, and in fact commented on, the proposed rule. And the rule specifically provided that CMS would apply Tukey outlier deletion to 2023 data in calculating the 2024 Star Ratings. In sum, nothing about CMS's calculation of the Star Ratings was arbitrary or

capricious; CMS merely followed rules it had properly promulgated, and Plaintiff does not like the result.

Plaintiff also separately challenges CMS's determination that it was entitled to four stars (out of a possible five) on a measure of its call center's ability to provide translation and foreign language interpretation services in a timely manner. Plaintiff SCAN Health Plan ("SCAN Health") takes issue with a single call, alleging both that CMS did not apply the proper standard and acted arbitrarily and capriciously in determining that the call was not timely connected under the relevant criteria. The legal challenge fails because SCAN Health urges this Court to apply an inapposite regulation, ignoring longstanding and clear guidance for how CMS would calculate the measure. The arbitrary and capricious claim amounts to little more than an effort to have this Court overturn a well-supported factual finding by the agency. CMS correctly applied the proper standards to the disputed call, and there is no basis for SCAN Health's challenge to its rating on the measure.

I. Statutory and Regulatory Background

Medicare is a federal health insurance program for the elderly and persons with disabilities. *See* 42 U.S.C. § 1395 *et seq*. Medicare covers hospitalizations under Part A of the statute, *id.* §§ 1395c to 1395i-6, outpatient medical care under Part B, *id.* §§ 1395j to 1395w-6, and prescription drugs under Part D, *id.* §§ 1395w-101 to 1395w-154. This case concerns Medicare Advantage, formerly known as Medicare+Choice, which Congress established in Part C of the statute, *id.* §§ 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 ("Advantage Organizations" or "MAOs"), contract to provide coverage in a particular geographic area. Beneficiaries can then choose among the plans available where

they reside. *Id.* § 1395w-21(b). Advantage Organizations receive a predetermined sum for providing coverage to each beneficiary, based in part on the demographic and health characteristics of that beneficiary. *Id.* § 1395w-23(a)(1)(A), (C).

To calculate payments to Advantage Organizations, the Centers for Medicare & Medicaid Services ("CMS") first determines its "benchmark," based on the per capita cost of covering Medicare beneficiaries under Parts A and B in the relevant geographic area. *Id.* § 1395w-23(n); 42 C.F.R. § 422.258. Each Advantage Organization then submits a "bid," telling CMS what payment the Advantage Organization will accept to cover a beneficiary with an average risk profile in that area. 42 C.F.R. § 422.254. If the insurer's bid is less than the benchmark, the bid becomes its "base payment"—the amount it is paid for covering a beneficiary of average risk—and the insurer receives a portion of the difference between its bid and the benchmark as a "rebate" that the Advantage Organization can use to fund supplemental benefits for beneficiaries or reduce plan premiums. 42 U.S.C. § 1395w-24(b)(1)(C); 42 C.F.R. § 422.260. If the Advantage Organization's bid is greater than the benchmark, then the benchmark becomes its base payment, and the insurer must charge beneficiaries a premium to make up the difference. *See* 42 U.S.C. §§ 1395w-23(a)(1)(B)(ii), 1395w-24(b)(2)(A).

Star Ratings are a means by which CMS measures the quality of Medicare Advantage plans (and Part D Prescription Drug Plans) on a scale of one to five "stars," based on Medicare Advantage data collected by CMS. 42 U.S.C. § 1395w-23(o)(4)(A); *see also* § 1395w-22(e)(3). Star Ratings reflect the experiences of beneficiaries in these plans and assist beneficiaries in finding the best plans for their needs. Advance Notice of Methodological Changes for 2025 for Medicare Advantage Capitation Rates & Part C & Part D Payment Policies at 111 (Jan. 31, 2024),

available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

CMS has released Star Ratings for Medicare Advantage contracts since 2008. Contract Year 2019 Policy & Technical Changes to the Medicare Advantage Program, 83 Fed. Reg. 16,440, 16,520 (Apr. 16, 2018). In a 2018 rulemaking, CMS adopted the regulatory framework for the Star Ratings and has since then used rulemaking to adopt changes in the methodology and addition of new measures. *Id.*; *see also* 42 C.F.R. § 422.164(c), (d). The 2018 final rule describes the purpose of the Star Ratings system: it "is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care." 83 Fed. Reg. at 16,520.

Star Ratings affect payments to Advantage Organizations in two main ways. First, Medicare Advantage plans that earn a rating of four stars or higher qualify for Medicare Advantage Quality Bonus Payments in the form of an increased benchmark for the contract year following the ratings year (*e.g.*, the 2024 Star Ratings can increase the Medicare Advantage bidding benchmarks for contract year 2025). 42 U.S.C. § 1395w-23(o)(1) (increasing, for qualifying plans, the applicable percentage that calculates the benchmark); § 1395w-23(o)(3)(A)(i) (a qualifying plan is one that earns a rating of four stars or higher). This in turn can allow a Medicare Advantage plan to increase its bid, receive higher rebates, or lower premiums. *See id.* § 1395w-24(b)(1)(C); 42 C.F.R. § 422.260.

Second, Star Ratings affect the level of rebate received by plans that bid below their benchmarks for the contract year following the ratings year (e.g., the 2024 Star Ratings are used to set plans' rebate percentages for contract year 2025). Plans that earn a rating of four-and-a-half stars or higher receive a rebate of seventy percent of the difference between their bid and the

benchmark, while plans that earn three-and-a-half or four stars receive a rebate of sixty-five percent of that difference, and plans that earn less than three-and-a-half stars are eligible for a rebate of fifty percent of that difference. 42 U.S.C. § 1395w-24(b)(1)(C)(v) (listing the "final applicable rebate percentage[s]" by rating); 42 C.F.R. § 422.266(a)(2)(ii) (same).

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. *See* 42 C.F.R. §§ 422.162(b), 422.166, 423.182(b), 423.186. It published the 2024 Star Ratings, for example, in October 2023. CMS, Fact Sheet – 2024 Medicare Advantage and Part D Star Ratings (Oct. 13, 2023) ("Fact Sheet"), *available at* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data. 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) ("Technical Notes"), *available at* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data. These measures relate to five broad categories (outcomes, intermediate outcomes, patient experience, access, and process), *see id.* at 10, and CMS uses a variety of data including administrative and medical record review data collected as part of the Healthcare Effectiveness Data and Information Set ("Healthcare Effectiveness Data") and survey-based data from the Health Outcomes Survey and from the Consumer Assessment of Healthcare Providers and Systems ("Consumer Assessment"). 83 Fed. Reg. at 16,520, 16,525.

To determine ratings on measures other than the measures based on information from the Consumer Assessment, CMS uses a clustering algorithm that creates four cut points in the Advantage Organization data, resulting in five separate levels with one typically being the worst

and five being the best. Technical Notes, *supra*, at 18. Since the 2023 Star Ratings, CMS has applied a guardrail that prevents the cut points for each non-Consumer Assessment measure from increasing or decreasing more than five percent from one year to the next. 42 C.F.R. § 422.166(a)(2)(i). CMS determines each plan's overall rating by calculating a weighted average of its measure-level Star Ratings. Technical Notes, *supra*, at 20-21.

CMS regulations permit Advantage Organizations to "appeal quality bonus payment status determinations." 42 C.F.R. § 422.260(a). An Advantage Organization must first seek reconsideration "by providing written notice to CMS within 10 business days of the release of its [quality bonus payment] status." *Id.* § 422.260(c)(1)(i). The Advantage Organization may appeal an adverse decision by the reconsideration official via an informal hearing request. *Id.* § 422.260(c)(2). "The hearing officer's decision is final and binding." *Id.* § 422.260(c)(2)(vii).

II. Factual and Procedural Background

A. CMS's Promulgation of the Tukey Outlier Deletion Methodology

1. The Proposed Rule Including the Rerun of the Prior Year's Cut Points

In a 2018 and 2019 rulemaking finalizing steps for calculating the cut points for Star Ratings measures, some commenters suggested that CMS do more to address outlier data and provide cut point stability, i.e., they were concerned that extremely high or low performing contracts were causing wide swings in cut points from year to year, making it difficult for all contracts to predict cut points and plan accordingly. *See* Policy & Technical Changes to the Medicare Advantage Program for Years 2020 and 2021, 84 Fed. Reg. 15,680, 15,755 (Apr. 16, 2019). They suggested that CMS remove outlier data prior to clustering, and CMS began evaluating methods for doing so, including Tukey outer fence outlier deletion ("Tukey outlier deletion"), which is a standard statistical method for removing outlier data. *Id.* at 15,755-56. Recognizing that "the public ha[d] not had an opportunity to comment" on outlier deletion

methods, CMS stated that it would evaluate the issue further and "consider proposing outlier deletion in future rulemaking." *Id.* at 15,756.

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 while trimming is simple in that it removes all scores below the 1st percentile and above the 99th percentile, it would fail to remove true outliers that appear between the chosen percentiles, while removing values that are not true outliers when they appear above or below the percentiles. *Id.* at 9,044. 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 (here, that factor is 3). *See id.*

CMS made clear that "[i]n the first year that [Tukey outlier deletion] would be implemented, the prior year's thresholds [(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.* CMS did not hide this in the details. It presented it within the two pages containing the main Tukey discussion, right after the sentence requesting comments:

> 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.

Id. In its proposed Code of Federal Regulations text, CMS did not include a re-recitation of this part of the methodology, which applies only to one year's Star Ratings calculations. *Id.* at 9,220.

CMS also made clear in the Proposed Rule that, in addition to increasing the stability of cut points, CMS expected Tukey outlier deletion to decrease overall payments to Advantage

Organizations. CMS noted that in the simulations it ran, "[i]n general, there tend to be more outliers on the lower end of measure scores," and, "[a]s a result, the 1 to 2 star thresholds often increased . . . when outliers were removed compared to the other thresholds that were not as impacted." *Id.* at 9,044. CMS also noted that had it implemented Tukey outlier deletion and a five percent guardrail in the 2018 Star Ratings, more contracts would have seen a decrease in their Star Ratings than an increase. Specifically, 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 would have decreased by a full star. *Id.*

And CMS presented, in two places, estimates that Tukey outlier deletion would create $808.9 million in savings for the federal government by decreasing payments to Advantage Organizations in 2024, increasing to $1.4492 billion in annual savings for 2030. *Id.* at 9,044, 9,186. CMS estimated that this would be partially offset, especially in the first few years of Tukey outlier deletion, by another proposal, which was to increase the weight of patient experience and access measures to four. *See id.* at 9,049, 9,184-86. CMS estimated that in 2024, for example, this would increase payments to Advantage Organizations by $391.4 million, thereby reducing the government's estimated $808.9 million in Tukey savings to $417.5 million ($368.1 million adjusted for inflation). *See id.* at 9,186. For 2025, CMS estimated $305.4 million in increased payments to Advantage Organizations, reducing the government's estimated $935.0 million in Tukey savings to $629.6 million ($537.9 million adjusted for inflation). *Id.* For 2026, CMS estimated $296.1 million in increased payments, reducing the government's estimated $1.029 billion in Tukey savings to $732.9 million ($606.7 million adjusted for inflation). *Id.*

2. Public Comments on the Proposed Rule

Some commenters offered general support for CMS's proposal to apply Tukey outlier deletion. *See* Comment of Ass'n for Cmty. Affiliated Plans at 3 (Certified Rulemaking Record

("R.R.") at 389); Comment of UCare at 3 (R.R. 274); Comment of All. of Cmty. Health Plans at 7 (R.R. 832) (agreeing that Tukey outlier deletion "appears to produce more appropriate and accurate cut points," but requesting that CMS further test the methodology and provide simulated data). Many commenters generally opposed the proposal. *See* Comment of Blue Cross Blue Shield Ass'n ("Blue Cross") at 23-24 (R.R. 414-15) (Tukey would "dramatically decrease payments to plans").

No commenters however, including Plaintiff, specifically commented on the proposal to rerun the prior year's cut points for purposes of applying the guardrails in the first year of Tukey outlier deletion. Plaintiff, for example, cited the Proposed Rule at 85 Fed. Reg. 9,043 and commented that the "outlier removal" and guardrail methodologies will not likely improve predictability and that "[i]n the federal registry" CMS uses "CY2018" Star Ratings data, "which is at least two years old." Comment of SCAN Health at 5 (R.R. 382). The simulations using the 2018 Star Ratings data Plaintiff referenced are discussed at 85 Fed. Reg. 9,044, the same page that proposed rerunning the prior year's cut points. Yet, Plaintiff did not specifically comment on the rerun aspect of the methodology. *See also* Comment of SCAN Foundation (R.R. 264-70) (not commenting on Tukey at all). Elevance (f/k/a Anthem, Inc.) commented that there is no reason to believe outlier values in the Star Ratings are invalid and that CMS should return to its previous policy of determining cut points prior to the measurement period. *See* Comment of Elevance at 24 (R.R. 601). But it too did not specifically comment on the rerun aspect. *See id; see also* Comment of Blue Cross at 23-24 (R.R. 414-15). No comments criticized CMS's reasoning for the rerun—that the guardrails should "be applied such that there is consistency between the years"—and certainly no comments objected that the rerun proposal appeared in the preamble and not the proposed Code of Federal Regulations text. *See* 85 Fed. Reg. at 9,044.

3. CMS Adopts the Final Rule Including the Prior Year Rerun

In a June 2, 2020 final rule published[1] in the Federal Register (the "Final Rule"), CMS responded to comments and finalized its Tukey outlier deletion proposal. Contract Year 2021 Policy & Technical Changes to the Medicare Advantage Program, 85 Fed. Reg. 33,796, 33,830-36 (June 2, 2020). The Final Rule delayed the implementation of Tukey one year, to the calculation of the 2024 Star Ratings, so that the impacts of COVID-19 on measure scores could play out. *Id.* at 33,831. And it stated in two places CMS's decision to rerun the prior year's cut points for the purposes of the guardrails. *Id.* at 33,833 ("We explained that under our proposal in the first year of implementing this process, the prior year's thresholds would be rerun[.]"); *see id.* at 33,835 ("As noted in the [notice of proposed rulemaking], for the first year (2024 Star Ratings), we will rerun the prior year's thresholds using mean resampling and Tukey outer fence deletion[.]").

The Final Rule also stated that CMS would display "simulations of Tukey outlier deletion with mean resampling and guardrails for contracts to view in [the Health Plan Management System] for the 2021, 2022, and 2023 Star Ratings prior to implementing the Tukey outlier change effective with the 2024 Star Ratings." *Id.* at 33,835. The Health Plan Management System is a web-enabled information system that CMS uses to communicate and exchange data with Advantage Organizations and Part D plans. It explained that the "simulations will illustrate the cumulative effect of all of these policies [mean resampling effective in the 2022 Star Ratings, guardrails effective in the 2023 Star Ratings, and Tukey outlier deletion effective in the 2024 Star Ratings]." *Id.* And it repeated this twice. *Id.* at 33,836.

[1] CMS's proposed and final rules typically appear on display on the Office of the Federal Register website before they appear in the Federal Register. This brief frequently refers to the date of publication in the Federal Register, but in many cases, the proposed or final rule referenced will have appeared on display, available to the public, at an earlier date.

Having provided these explanations, CMS chose again in the Final Rule, as it had in the Proposed Rule, not to unnecessarily complicate the regulation found in the Code of Federal Regulations by codifying the methodological step that the prior year's cut points would be rerun. That policy was clearly set out in three places in the Federal Register, applied only to calculations for one year, and would be later illustrated in simulations available for contracts to view. *Id.* at 33,907.

In the impact analysis of the final rule, CMS estimated that because it was delaying Tukey implementation until the 2024 Star Ratings, the federal government would no longer save $417.5 million ($368.1 million adjusted for inflation) in 2024 for the combined effects of Tukey and the change to the weight of patient experience and complaint measures, but rather would incur a cost of $391.4 million ($345.1 million adjusted for inflation). *Id.* at 33,891-92; *see also* 85 Fed. Reg. 9,186. The Final Rule, by delaying Tukey one year, effectively gave Advantage Organizations back the $808.9 million ($713.2 million adjusted for inflation) that CMS expected the federal government to save in 2024. *Id.*

The estimates for the individual years 2025 to 2030 did not change for either Tukey or the re-weighting decision. Later, in 2023, CMS would decrease the weight of patient experience and access measures back down to two, but that decision would not take effect until the 2026 Star Ratings, thus leaving all estimates for years 2024 to 2026 including the partial offsets to Tukey for those years unchanged. Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 88 Fed. Reg. 22,120, 22,272-77, 22,322-23 (Apr. 12, 2023).

4. CMS's Simulations Illustrating that the Prior Year Would Be Rerun

On December 19, 2022, CMS published on its website the simulations it had announced in the Final Rule. *See* 85 Fed. Reg. at 33,835-36. CMS notified "[a]ll Part C and D Plan Sponsors" about the simulations in a Health Plan Management System memorandum (the "Memorandum")

it sent that day, which included a link to the simulations and technical notes. R.R. 2705. The simulations recalculated 2022 and 2023 Star Ratings with Tukey outlier deletion, mean resampling, and guardrails. R.R. 2707-15. CMS did not simulate effects on the 2021 Star Ratings because it did not have updated Healthcare Effectiveness Data and Consumer Assessment data for 2021 due to COVID-19. *See* Medicare & Medicaid Programs Policy & Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule with Comment Period, 85 Fed. Reg. 19,230, 19,271 (Apr. 6, 2020) (eliminating the Healthcare Effectiveness Data 2020 submission requirement covering the 2019 measurement year); 42 C.F.R. § 422.166(j)(1) (providing for the use of older Healthcare Effectiveness Data and Consumer Assessment data in the 2021 Star Ratings).

The Memorandum explained that pursuant to the policy adopted in the 2020 Final Rule, CMS would rerun the prior year's (2023's) cut points with Tukey outlier deletion for purposes of applying the guardrails in the 2024 Star Ratings; thus, CMS reran the 2022 cut points with Tukey outlier deletion in the simulations. The Memorandum explained:

> As we stated in the . . . Final Rule, for the first year that Tukey outlier deletion is implemented (2024 Star Ratings), we will rerun the prior year's thresholds using mean resampling and Tukey outlier deletion so that guardrails will be applied consistently between years. Therefore, in the simulations, the 2022 Star Ratings thresholds were recalculated applying mean resampling and Tukey outlier deletion.

R.R. 2705. The simulations themselves for the 2023 Star Ratings showed that before calculating guardrails for the 2023 Star Ratings, CMS reran the measure-level cut points for the 2022 Star Ratings. R.R. 2714-15. CMS was essentially illustrating what would happen in the 2024 Star Ratings with the 2023 cut points being rerun prior to the application of the guardrails, by showing what would happen in the 2023 Star Ratings if the 2022 cut points were rerun prior to the application of the guardrails.

The first tab in the excel file that was publicly posted as part of the simulations, "Part C Outlier Cutoffs," shows for each measure, in each year, the upper and lower Tukey outlier cutoffs. R.R. 2707-08. If CMS applied Tukey in these years (2022 and 2023), CMS would remove Advantage Organization scores above the upper cutoff and below the lower cutoff. The second tab in the excel file presents this for Part D. R.R. 2709-10. The third tab, "2022 Star Ratings Cut Points," shows for each measure, what all four cut points: (1) actually were—shown in blue, and (2) would be if CMS reran the cut points for the 2022 Star Ratings using Tukey outlier deletion—shown in white. R.R. 2711-13, cols. B, C. The fourth tab, "2023 Star Ratings Cut Points," shows for each measure, what all four cut points: (1) actually were using guardrails based on the actual 2022 cut points—shown in blue, and (2) would be if CMS applied Tukey in the 2023 Star Ratings and used guardrails based on rerunning the 2022 cut points with Tukey—shown in white. R.R. 2714-15, cols. B, C, D.

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. Tukey was either in for both years or out for both years. *See id.* As CMS had now stated many times, this was for consistency. CMS believed that removing outliers for one year but keeping the outliers in for the prior year for purposes of the guardrails would be inconsistent. Having already finalized this part of the methodology in the Final Rule, CMS's simulations simply compared the results of applying it to the results of not applying it. But applying Tukey in its first year without rerunning the prior year's cut points was never part of any CMS methodology.

5. The Technical Amendment Adding the Inadvertently Removed Tukey Sentence Back to the Code of Federal Regulations

In 2020, after CMS published the Final Rule on June 2nd, the Code of Federal Regulations contained, verbatim, the exact sentence that CMS had finalized for it: "Effective for the Star

Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed." 42 C.F.R. § 422.166(a)(2)(i) (2020), *compare with*, 85 Fed. Reg. at 33,907. In a January 19, 2021 "second final rule," CMS noted that in "the June 2020 final rule," it had "finalized" the application of Tukey outlier deletion starting with the "2024 Star Ratings." Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, 86 Fed. Reg. 5,864, 5,916-17 (Jan. 19, 2021). The above Tukey sentence from the Final Rule and the 2020 Code of Federal Regulations remained in the Code, verbatim, throughout 2021. 42 C.F.R. § 422.166(a)(2)(i) (2021).

In a May 9, 2022, final rule, CMS again noted that Tukey outlier deletion "will be implemented beginning with the 2024 Star Ratings." Contract Year 2023 Policy and Technical Changes to the Medicare Advantage Program, 87 Fed. Reg. 27,704, 27,766 (May 9, 2022). Yet, that same final rule, with no discussion and no explanation as to why it also stated Tukey "will be implemented beginning with the 2024 Star Ratings," also inadvertently removed the Tukey sentence from 42 C.F.R. § 422.166(a)(2)(i) in finalizing other changes to that paragraph. *See* 87 Fed. Reg. at 27,766, 27,895; *see also* 88 Fed. Reg. at 22,295-96; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 87 Fed. Reg. 79,452, 79,634-35 (Dec. 27, 2022). Nowhere in that rulemaking, however, or anywhere else did CMS propose and request comments on removing any aspect of the Tukey methodology that it had finalized in 2020. *See* 88 Fed. Reg. 22,295 ("At no point did CMS propose removal of the Tukey outlier provision and CMS has, since its adoption in the June 2020 final rule, discussed implementation and application of the Tukey outlier provision when applicable."); 87 Fed. Reg. at 79,634-35 ("In the rulemakings since that time [2020], we have not proposed to eliminate the Tukey outlier deletion aspect of the Star Ratings methodology.").

The removal of the Tukey sentence from the Code of Federal Regulations was simply a mistake. And without a proposal to remove Tukey, a comment period, and final decision explaining CMS's rationale—none of which happened—it was a nullity. *See* 42 U.S.C. § 1395hh(b)(1) (requiring notice in the Federal Register and a sixty-day comment period); 5 U.S.C. § 553(b)-(d) (requiring notice in the Federal Register; an opportunity to submit written comments, and publication of the rules adopted with a concise general statement of their basis and purpose); *id.* § 551(5) (an "agency process" for "repealing a rule" is a rulemaking); *Humane Soc'y of the U.S. v. Dep't of Agric.*, 41 F.4th 564, 572 (D.C. Cir. 2022) ("[L]ongstanding precedent holds that once an agency prescribes a rule, it must provide notice and comment before repealing it[.]"); *Consumer Energy Council of Am. v. FERC*, 673 F.2d 425, 446 (D.C. Cir. 1982) (notice and comment is needed to repeal a rule); 88 Fed. Reg. 22,296 ("After the adoption of the Tukey outlier deletion provision in the June [2020] final rule (85 FR 33833-36), CMS would need additional rulemaking to change that policy and change the Star Ratings methodology to eliminate that provision, which did not happen.").

Realizing its mistake, in December 2022 (within the same two-week period that CMS published its simulations of the 2022 and 2023 Star Ratings), CMS, in an abundance of caution, proposed and requested comment on a "technical amendment" to add the Tukey sentence back and move it to an earlier place within 42 C.F.R. § 422.166(a)(2)(i). *See* 87 Fed. Reg. at 79,634-35 (the "Proposed Technical Amendment"). CMS also proposed removing the guardrails completely beginning with the 2026 Star Ratings, because evidence showed they were limiting the ability of cut points to shift with actual changes in industry performance and thus inflating some measures and diluting the value of the ratings. *Id.* at 79,625-26. CMS stated that Tukey and mean

resampling would improve the predictability and stability of cut points, thus minimizing the need for guardrails. *Id.*

Again, some commenters supported or opposed Tukey generally. One comment argued that CMS could not add the Tukey sentence back to the Code of Federal Regulations with a mere technical amendment but needed to start from scratch with yet another proposed rule. *See* Comment of Alignment Health at 6-7 (R.R. 2153-54).

Other comments acknowledged that CMS's Tukey methodology was already in place. *See* Comment of the Pharm. Care Mgmt. Ass'n ("Pharm. Care") at 46 (R.R. 2215) ("CMS is proposing to maintain its previously published final rule") (citing 87 Fed. Reg. 27,766); Comment of Cigna Grp. at 3 (R.R. 2452) (Tukey was "already finalized to take effect"), *id.* at 18 (R.R. 2467) (Tukey "will remain in place"); Comment of Blue Shield of Cal. at 12 (R.R. 2325) ("While we expected codification of the Tukey outlier deletion methodology for the 2024 Star Ratings, we encourage CMS to delay implementation"); Comment of AHIP at 52-53 (R.R. 1821-22) (Tukey was "set to take effect" with the 2024 Star Ratings). Numerous comments discussed the Tukey simulations CMS released on December 19, 2022. *See* Comment of Elevance at 71-76 (R.R. 2303-08); Comment of Pharm. Care at 46 (R.R. 2215); Comment of Alignment Health at 9 (R.R. 2156); Comment of CVS at 14 (R.R. 1988) ("CMS should provide simulations [of Health Equity Index rewards] to health plans (similar to the information provided for Tukey's outlier calculations)."); Comment of Blue Shield of Cal. at 12 (R.R. 2325); Comment of Village MD at 2 (R.R. 2311).

One comment did specifically object to the rerun aspect, arguing that CMS should use the actual 2023 cut points for purposes of applying the guardrails in the 2024 Star Ratings. *See* Comment of UnitedHealth Grp. at 43 (R.R. 1937); *see also* Comment of Alignment Health at 10 (R.R. 2157) (noting that CMS had stated in the 2020 rulemaking that the prior year's cut points

would be rerun). In its comment, UnitedHealth Group acknowledged that Tukey is intended to stabilize cut points but argued that using "adjusted" 2023 cut points could cause substantial movement in the cut points, removing year-over-year consistency and stability. Comment of UnitedHealth Grp. at 43 (R.R. 1937). It proposed temporarily keeping guardrails to ease the transition to Tukey. *Id.* Plaintiff, however, did not specifically criticize or object to the Final Rule's decision to rerun the prior year's cut points. *See* Comment of SCAN Health at 6 (R.R. 1748) (discussing only re-weighting patient experience and access measures).

CMS responded to these comments in detail. At the outset, CMS noted that it had already "finalized the application of Tukey outlier deletion . . . beginning with the 2024 Star Ratings in the . . . final rule published in June 2020," so the Technical Amendment was "not a new enhancement" or feature in the Star Ratings calculations, and contracts had been on notice of the upcoming change. 88 Fed. Reg. at 22,295 (the "Technical Amendment"). CMS then discussed Tukey's impacts, explaining that based on the simulations using 2022 and 2023 Star Ratings data, Tukey had no significant impact on the three, four, and five-star cut points for most measures. *Id.* at 22,296. Rather, most of the impact was on the one and two-star cut points, bringing these cut points more stability. *Id.* Further, out of twenty non-Consumer Assessment measures in the 2023 Star Ratings, eight measures had no Tukey outliers to remove, ten measures required removal of three-and-a-half percent or less of the data, and only two measures required removal of more than four percent. *Id.* Finally, CMS compared year-over-year cut point stability in simulations of the 2022 and 2023 Star Ratings without guardrails and found that out of twenty non-Consumer Assessment measures, ten changed by more than five percent from 2022 to 2023 when CMS did not apply Tukey compared to only five that changed by that amount with Tukey. *Id.* Thus, Tukey increased overall stability year-over-year.

CMS finalized the Technical Amendment on April 12, 2023, reaffirming that Tukey would "begin[] with the 2024 Star Ratings." *See id.* at 22,120-21, 22,297. The Tukey sentence reappeared in the Code of Federal Regulations, verbatim, later in 2023. *Id.* at 22,332; 42 C.F.R. § 422.166(a)(2)(i) (2023).[2]

6. The 2024 Star Ratings

In October 2023, CMS published the 2024 Star Ratings, calculated with Tukey outlier deletion, "[a]s finalized in rulemaking in 2020." Fact Sheet, *supra*, at 2. This included rerunning the cut points from the 2023 Star Ratings with Tukey for purposes of applying the 2024 guardrails as CMS had described "[w]hen [CMS] proposed and finalized Tukey outlier deletion in the [Final Rule]." Technical Notes, *supra*, at 157. On December 29, 2023, Plaintiff filed this action challenging CMS's decision to calculate the 2024 guardrails using the rerun cut points.

B. The Foreign Language Interpreter and TTY Availability Call Center Measure

Each year, CMS circulates to plans (and displays on its website) Technical Notes that provide details about the current year's Part C & D Star Ratings. *See* SCAN-AR00108 (2024 Technical Notes). Among other things, these Technical Notes include details about the measures that comprise the Star Ratings, how the measures are weighted, what the cut points for each measure are, and how CMS assesses each measure. *See generally id.* Plans are informed about the measures in upcoming Star Ratings through the rulemaking process and the Advanced Notice process. *See* 42 C.F.R. § 422.164(c), (d); 42 U.S.C. § 1395w-23(b)(2).

CMS has included an assessment of contracts' Call Center Foreign Language Interpreter and Teletypewriter (or "TTY") Availability in the annual Star Ratings since the 2016 Star Ratings.

[2] CMS did not at that time finalize its proposal to remove the guardrails in the 2026 Star Ratings and continues to consider its guardrails policy. *See id.* at 22,121.

See Medicare 2016 Part C & D Star Rating Technical Notes, First Plan Preview at 47, *available at* https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovGenIn/Downloads/2016-Technical-Notes-Preview-1-v2015_08_05.pdf. The metric has been identical since the 2018 Star Ratings, including in 2024, where it is listed as Measure C30 in the Technical Notes. SCAN-AR00191. CMS contractors, colloquially known as "secret shoppers," dial the Plan's number and request assistance in foreign language or by TTY. *Id.* The contractor measures the amount of time until a completed contact occurs. *Id.* "Completed contact with an interpreter is defined as establishing contact with an interpreter and confirming that the customer service representative can answer questions about the plan's Medicare Part C benefit within eight minutes." *Id.* The measure is expressed as a percentage: the number of completed contacts divided by the number of attempted contacts. SCAN-AR00191-92. Star Ratings for the measure are then assigned based on cut points. SCAN-AR00192.

For 2024 Star Ratings, the cut point between four and five stars for Measure C30 is ninety-seven percent, meaning a contract will receive five stars on the measure if at least ninety-seven percent of attempted interpreter contacts are completed. *Id.* SCAN Health achieved a score of ninety-five percent on C30; 61 of the 64 calls were successful. SCAN-AR00014. SCAN Health challenges only one of its three unsuccessful calls—Call C0600900. SCAN-AR00015. On February 9, 2023, a CMS contractor called SCAN Health's customer service line and requested assistance in French. SCAN-AR00321. After six minutes and thirty-five seconds, a French interpreter came on the line. SCAN-AR00006. The CMS contractor requested assistance with a SCAN Health plan, reading off the name of the plan. SCAN-AR000321. SCAN Health's interpreter responded (in French), "I failed to take notes," and asked the contractor to repeat the name of the plan. *Id.* By the time the customer service representative had confirmed (through the

interpreter) that he or she was able to answer questions about the plan, more than eight minutes had elapsed. SCAN-AR000017. The interaction was therefore marked as an attempted but not completed contact. *Id.*

On November 10, 2023, after its preliminary Quality Bonus Payment ratings (which incorporated the February 9, 2023, call) became available, SCAN Health sought reconsideration on the basis of "incorrect data," alleging that "there was a technical issue caused by the CMS caller's deviation from protocol that ultimately caused the call to exceed the 8 minute threshold." SCAN-AR01002. On February 22, 2024, the CMS Reconsideration Official declined to change the rating for SCAN Health's contract. SCAN-AR000022. SCAN Health requested an informal hearing, and on March 25, 2024, the CMS Hearing Officer upheld the reconsideration official's determination. SCAN-AR00007.

STANDARD OF REVIEW

In this action proceeding under the Medicare statute, judicial review is governed by the standards of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and decided on an administrative record. *Se. Ala. Med. Ctr. v. Sebelius*, 572 F.3d 912, 916-17 (D.C. Cir. 2009). Accordingly, "'the district court does not perform its normal role' but instead 'sits as an appellate tribunal'" resolving legal questions. *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999) (quoting *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). Although the parties move for summary judgment, the "standard set forth in Rule 56(c) . . . does not apply." *Gentiva Healthcare Corp. v. Sebelius*, 857 F. Supp. 2d 1, 6 (D.D.C. 2012), *aff'd*, 723 F.3d 292 (D.C. Cir. 2013). Rather, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Id*.

The APA provides for courts to "hold unlawful and set aside agency action, findings, and conclusions" if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C). Under the APA's "arbitrary or capricious" standard, the Court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). An agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). Even a decision that is not fully explained may be upheld "if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

The "arbitrary or capricious" standard is "narrow . . . as courts defer to the agency's expertise." *Ctr. for Food Safety v. Salazar*, 898 F. Supp. 2d 130, 138 (D.D.C. 2012) (quoting *Motor Vehicle*, 463 U.S. at 43). The Court "is not to substitute its judgment for that of the agency." *Id*. In Medicare cases, the "'tremendous complexity of the Medicare statute" "adds to the deference which is due to the Secretary's decision.'" *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 60 (D.C. Cir. 2015) (quoting *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994)). The question is not whether the agency's policy is the "best" or only solution, but whether it is a "reasonable solution." *See Petal Gas Storage, L.L.C., v. FERC*, 496 F.3d 695, 703 (D.C. Cir. 2007). When reviewing an agency's factual findings, courts accord deference. *Bellion Spirits, LLC v. United States*, 393 F. Supp. 3d 5, 13 (D.D.C. 2019); *see also* 5 U.S.C. § 706(2)(E) ("substantial evidence" standard).

ARGUMENT

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. CMS Was Not Arbitrary and Capricious in Applying the Final Rule.

The Medicare statute and the APA set forth the notice-and-comment procedures necessary for the rules governing the Medicare program, and 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). Nowhere do these authorities require publication in the Code of Federal Regulations for a rule to be effective.

Thus, as many courts have held, rules set forth in preamble are enforceable if the agency promulgated them though notice and comment and clearly intended them to be binding. *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 was ripe for review where EPA had published the challenged policy in the Federal Register, provided opportunity for comment, and arrived at its 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).

In *St. Helena Clear Lake Hospital v. Becerra*, for example, CMS finalized language in the Code of Federal Regulations in 2001 stating that the reasonable costs of outpatient Critical Access

Hospitals ("CAHs") can include the costs of on-call emergency room ("ER") physicians. *St. Helena Clear Lake Hosp. v. Becerra*, Civ. A. No. 19-0141 (CJN), 2021 U.S. Dist. LEXIS 62321, at *6-7 (D.D.C. 2021), *aff'd*, 30 F.4th 301 (D.C. Cir. 2022). The preamble to the final rule explained that this was to comply with a congressional directive, and that before that directive, CMS did not allow CAHs to include the costs of *any* on-call physicians. *Id.* at *7. That prior policy appeared not in the Code of Federal Regulations, but in the preamble to a 1998 CMS final rule.

The plaintiff in that action sought reimbursement for on-call costs of non-ER physicians and argued that the 2001 Code of Federal Regulations provision did not bar such costs merely by leaving them out of the text. *Id.* at 8-9, 16. This Court, however, found that the Code of Federal Regulations provision did not compel plaintiff's reading and that CMS's reading, which was that *only* costs of on-call ER physicians were allowed, was reasonable and entitled to deference. *Id.* at 17. Further, the Court looked to the 1998 preamble statement and found that even if the plaintiff was correct that CMS needed to adopt an explicit rule barring costs of on-call non-ER physicians through notice and comment rulemaking, the 1998 preamble statement satisfied that requirement and remained unaltered except for the narrow 2001 exception. *Id.* at *17-19.

In the case at bar, CMS promulgated its decision to rerun the prior year's cut points through notice and comment rulemaking, and its intent to make this step in the Tukey methodology binding is absolutely clear. CMS first proposed to rerun the prior year's cut points in the Proposed Rule in 2020, in the two main pages describing the methodology, directly after the sentence requesting comments. 85 Fed. Reg. at 9,043-44. In the Final Rule, CMS stated its decision on the rerun in two places. The first referenced CMS's earlier proposal to rerun the prior year, 85 Fed. Reg. at 33,833, and the second definitively stated: "we *will* rerun the prior year's thresholds." *Id.*

at 33,835 (emphasis added). There was nothing hesitant or wavering about this pronouncement, 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, along with the Memorandum explicitly stating just that. *See id.* at 33,835-36; R.R. 2705-15; *supra* § II.A.4; *see also St. Helena Clear Lake Hosp. v. Becerra*, 30 F.4th 301, 304 (D.C. Cir. 2022) ("[T]he preamble of the key regulation can be used to explain the regulation even if the preexisting policy turned out to be legally defective.").

CMS also frequently described the preamble as the "final rule," even directly citing to the exact preamble pages finalizing the rerun decision rather than the Code of Federal Regulations text. 88 Fed. Reg. 22,295 ("In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 and subsequent years. (85 FR 33833–36)"); *id.* at 22,296 (In addition, the June 2020 final rule adopting the Tukey outlier deletion step in the Star Ratings methodology (85 FR 33891–33893) adequately discussed the cost estimates for the implementation of Tukey outlier deletion."); 87 Fed. Reg. 79,634 ("In the June 2020 final rule, we finalized use of Tukey outlier deletion . . . (85 FR 33833–36)"). The Final Rule itself even describes preamble pages in an earlier rule as the "final rule." 85 Fed. Reg. 33,801 ("As explained in the April 2018 final rule (83 FR 16480 through 16485) . . . ."). Indeed, 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.[3]

[3] For example, the measures used for the Alternative Payment Model Performance Pathway within the Quality Payment Program are listed in the applicable final rule for the year but are not listed in regulation text. *See* CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; MA; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program Final Rule, 88 Fed. Reg. 78,818, 79,112-13, Table 29 (Nov. 16, 2023).

Nor can there be any doubt that the public, including Plaintiff, had an opportunity to comment on the proposal to rerun the prior year. Plaintiff submitted a comment on the Proposed Rule citing the preamble at 85 Fed. Reg. 9,043 and referencing 2018 simulations discussed at 85 Fed. Reg. 9,044, the very same page that proposed the rerun. Comment of SCAN Health at 5 (R.R. 382). Plaintiff just did not address the rerun. *See also* Comment of SCAN Foundation (R.R. 264-70) (not commenting on Tukey at all).

Plaintiff argues that the decision to rerun violated 42 C.F.R. § 422.166(a)(2)(i).[4] But that provision does not compel Plaintiff's reading. It states both that CMS will remove Tukey outliers "prior to applying mean resampling with hierarchal clustering," and that CMS will apply a guardrail 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." *Id.* It does not explicitly say whether 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.

Plaintiff agrees that "the next" year is calculated with Tukey (otherwise, no years would ever be calculated with Tukey for the purposes of the guardrail). Plaintiff also agrees that in all later years, the "1 year" is calculated with Tukey. The only dispute is whether in the first year of applying Tukey, both the "1 year" and "the next" year are consistently calculated with Tukey,

[4] The cases Plaintiff cites involve situations where the Code of Federal Regulations text directly contradicts the preamble. *See, e.g.*, *AT&T Corp. v. FCC*, 970 F.3d 344, 350 (D.C. Cir. 2020) ("'[B]ecause the regulation itself is clear, we need not evaluate' either the regulatory 'preamble' or any other document that 'itself lacks the force and effect of law.'") (quoting *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018)). Plaintiff has failed to establish the necessary predicate—i.e., nothing in the regulation contradicts the preamble.

allowing for an apples-to-applies comparison when applying the cap, or inconsistently calculated *without* Tukey in the "1 year" and *with* Tukey in "the next" year.

The latter reading would have CMS inconsistently comparing one set of data with outlier values removed, to another set of data that still had outlier values affecting its cut points. The better reading is that Tukey is consistently applied in both years. Indeed, Plaintiff wishes to read additional words into the regulatory text; critically however, § 422.166(a)(2)(i) does not say "*actual, unadjusted* cut points," nor does it say "*that CMS applied in the prior year's Star Ratings* to the next," no matter how much Plaintiff endeavors to read in those words. Section 422.166(a)(2)(i) says "cut points" from the "1 year," and nothing in the text of that section prohibits CMS from satisfying this by adjusting the prior year's cut points to account for updated data or methodological changes.

This is no coincidence. As shown above, CMS's contemporaneous statements in the 2020 rulemaking show undoubtedly that CMS did not intend for § 422.166(a)(2)(i) to prevent it from rerunning the prior year's cut points. *See* 85 Fed. Reg. at 33,833, 33,835 ("we *will* rerun the prior year's thresholds") (emphasis added); 85 Fed. Reg. at 9,044; *see also* R.R. 2705-15 (simulations and the Memorandum). 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. CMS's intent at the time it drafted § 422.166(a)(2)(i) is obvious. Plaintiff's reading contradicts the plain language of the final rule and CMS's contemporaneous intent, and it creates the exact inconsistency CMS was trying to avoid: "we will rerun the prior year's [cut points] using [Tukey] . . . such that there is consistency between the years." 85 Fed. Reg. at 33,835; *see also id.* at 33,833; 85 Fed. Reg. at 9,044.

Plaintiff also makes much of the financial impacts, arguing that rerunning the prior year undermines the stability the guardrails were meant to provide. But the Proposed Rule gave notice of these effects, and CMS, by delaying Tukey for one year in the Final Rule, gave Advantage Organizations back $808.9 million that CMS expected the federal government to save in 2024. *See* 85 Fed. Reg. at 33,831, 33,891-92; 85 Fed. Reg. 9,186. CMS also estimated that Tukey's impact would be partially offset by changes to patient experience and complaint measures by $305.4 million and $296.1 million in 2025 and 2026, respectively, thus even further easing the transition to Tukey in its first years and providing stability. *See id.* The financial impacts therefore do not contradict CMS's intent to rerun the cut points from the prior year for purposes of applying the guardrail. *See supra* § II.A.3.

The meaning and intent of section 422.166(a)(2)(i) 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 Clear Lake*, 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 would not be arbitrary and capricious. Of course, CMS did promulgate the Final Rule, and it did clearly require that the prior year's cut points be recalculated using the 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 argues that "even if the Court were to conclude that CMS's Federal Register preamble controls," the 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 Memorandum in Support of Pl.'s Mot. ("Pl.'s Mem."), at 31. This, according to Plaintiff, violated CMS's

statement that "guardrails would be applied such that there is consistency between the years." *Id.* at 30; 85 Fed. Reg. at 33,835. This is essentially a sub-issue regarding how CMS should conduct its rerun of the prior year's cut points if CMS does in fact rerun the prior year's cut points. Plaintiff is arguing that even if CMS could, under the Final Rule, rerun the 2023 Star Ratings cut points with Tukey outlier deletion and generate simulated cut points for the 2024 guardrails, CMS should have, *within the 2023 simulation*, applied guardrails based on the 2022 cut points.

This is inconsistent with the applicable rule. First, the rule stated that "the prior year's" cut points would be rerun with Tukey outlier deletion. 85 Fed. Reg. at 33,833, 33,835; 85 Fed. Reg. at 9,044. Nowhere did it say anything about using data from *two years prior* to the Star Ratings year to calculate measure-level cut points.

Second, Plaintiff is reintroducing the same inconsistency in its original argument, because it appears to argue that the guardrails on the simulated 2023 cut points must be based on the "actual 2022 Star Rating cut points." Pl.'s Mem., at 31 n.17. Presumably, this means CMS would *not* apply Tukey outlier deletion to the 2022 Star Ratings cut points. Thus, the 2023 and 2024 cut points would be free from Tukey outliers, but to some extent would still be affected by 2022 cut points containing the most extreme outliers—those pulling measures up or down by ten percent or more such that their effects would persist after applying a five percent guardrail in two consecutive years—exactly the kind of inconsistency CMS was trying to avoid.

Finally, when no commenters on the Proposed Rule specifically addressed CMS's proposal to rerun the prior year's cut points with Tukey for purposes of the guardrails, CMS can hardly be expected to address in detail the sub-issue of whether, in that 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"). Thus, Plaintiff's argument that CMS should have applied guardrails based on the actual 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 argues 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 Mem. at 31-33. Because CMS's proposal to add the Tukey sentence back in did not also propose to "revive" the rerun decision, Plaintiff argues, that decision supposedly "had no further force or effect." *Id.* at 32-33. This is incorrect. An inadvertent deletion of regulatory text does not repeal a rule, nor can a rule be repealed without additional notice-and-comment making. *See supra* at 15 and authorities cited therein.

Here, *Select Specialty Hospital-Akron v. Sebelius* is instructive on the effects of an inadvertent omission of Code of Federal Regulations text and correcting amendment. *Select Spec. Hosp.-Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13 (D.D.C. 2011). In *Select Specialty*, CMS issued a final rule after notice and comment changing the requirements for Medicare-certified long term care hospitals operating as a hospital-within-a-hospital and receiving payment under the long term care hospital system. *Id.* at 17-19. Under the final rule, hospital-within-a-hospital admissions from its host hospital could not exceed twenty-five percent of its discharges, or else CMS would adjust its payment. *Id.* at 18-19. But the rule created a "grandfather" or "hold harmless" exception for existing hospitals-within-a-hospital that exempted them for cost reporting periods from October 1, 2004, through September 30, 2005 (fiscal year "FY" 2005). *Id.* at 19. The preamble

in the final rule stated that even for grandfathered hospitals-within-a-hospital, "in the first cost reporting period" the percentage of discharges from host hospital admissions could not exceed what it was in the hospital-within-a-hospital FY 2004 period. *Id.* But the Code of Federal Regulations text in the final rule was "inconsistent" with the preamble, stating only that existing hospitals-within-a-hospital received "no adjustment" under the new rule. *Id.* at 19-20. Four months after publishing the final rule, CMS issued a "correcting amendment" explaining that CMS had "inadvertently omitted" from the Code of Federal Regulations the requirement that the percentage of discharges from admissions could not exceed FY 2024 levels. *Id.* at 20. The correcting amendment revised the Code of Federal Regulations text, and CMS did not give the public a second opportunity to comment. *Id.*

A group of hospitals-within-a-hospital challenged the correcting amendment because CMS did not give an opportunity for comment. *Id.* at 21. The court held first that CMS did give an opportunity for comment because it took comments in the original rulemaking, and the substance of the correcting amendment was a logical outgrowth of those comments. *Id.* at 23-24. Next, the court held that although there were "technical inconsistencies" between the final rule's preamble and Code of Federal Regulations text, the preamble "was an unequivocal expression of the agency's intended meaning of the final rule," which served as evidence of "CMS's contemporaneous understanding of the final rule," and was thus "sufficient to bind plaintiffs." *Id.* at 25-26. The court explained: "the effect of the correcting amendment was not to substantively change the final rule, but rather to correct the language of the final rule so that it was consistent with the agency's intent as expressed in the preamble to the rule." *Id.* at 26. Finally, the court held that CMS's explanation that it had "inadvertently omitted" the language was logical, and plaintiffs offered no alternative explanation. *Id.* Thus, CMS was not arbitrary and capricious. *Id.*

Here too, CMS gave the public a full opportunity to comment on the proposal to apply Tukey outlier deletion in the 2020 rulemaking. *See supra* §§ II.A.1.–II.A.3. Here too, CMS's Technical Amendment was not an attempt to substantively change the Final Rule, but rather to correct section 422.166(a)(2)(i) to reflect CMS's intent as expressed in the Final Rule (and elsewhere)[5] to apply Tukey outlier deletion in the Star Ratings. That intent was clear not only in the Final Rule CMS published June 2, 2020,[6] but also in the preamble in the very same May 9, 2022 final rule that Plaintiff claims "overturned" or "vacated" Tukey from the Star Ratings: "Tukey outlier deletion *will* be implemented beginning with the 2024 Star Ratings." 87 Fed. Reg. at 27,766 (emphasis added). And here too, the Tukey sentence in the Code of Federal Regulations was "inadvertently removed" from the Code of Federal Regulations text, and Plaintiff has offered no alternative explanation or evidence of anything other than a simple mistake. 88 Fed. Reg. at 22,295; 87 Fed. Reg. at 79,635.

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*

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[5] On January 19, 2021, CMS noted that it had "finalized" Tukey in "the June 2020 final rule" starting with the "2024 Star Ratings." *See* 86 Fed. Reg. at 5,916-17.

[6] The Final Rule stated:

> After consideration of the comments and for the reasons indicated in the proposed rule and our responses to the related comments, we are finalizing as proposed the definition ''Tukey outer fence outliers'' and the specific formulae used. We are finalizing revisions to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the Tukey outlier deletion methodology prior to applying mean resampling with hierarchal clustering as proposed with one modification. . . . we are delaying the addition of Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures until the . . . 2024 Star Ratings.

85 Fed. Reg. at 33,836; *see also id.* at 33,907, 33,911 (adding Tukey to the C.F.R.).

Select Specialty, 820 F. Supp. 2d at 23-24. But CMS did take comments, and it responded to them in detail, going above and beyond what the APA required. *See id.*; 88 Fed. Reg. at 22,295-97.

Moreover, after finalizing Tukey in 2020, CMS never proposed removing it. 88 Fed. Reg. at 22,295; 87 Fed. Reg. at 79,634-35. There was no notice, no comment period, and no final decision explaining CMS's rationale. Thus, the absence of the Tukey sentence from the Code of Federal Regulations had no effect at all. *See Consumer Energy Council*, 673 F.2d at 446 (notice and comment is needed to repeal a rule; this "ensures that an agency will not undo all that it accomplished through its rulemaking without giving all parties an opportunity to comment on the wisdom of repeal."); *see also supra* at 15. Just as the inadvertent omission of the requirement from the Code of Federal Regulations in *Select Specialty* did not repeal that requirement, the inadvertent removal of the Tukey sentence from the Code of Federal Regulations did not repeal any aspect of the Tukey methodology. *See Select Specialty*, 820 F. Supp. 2d at 25-26.

The Final Rule and the Tukey methodology it finalized, including the prior year rerun, remained in effect even after May 9, 2022. Many of the commenters on the Proposed Technical Amendment correctly noted this. *See* Comment of Pharm. Care at 46 (R.R. 2215) ("CMS is proposing to maintain its previously published final rule"); Comment of Cigna at 3 (R.R. 2452) (Tukey was "already finalized to take effect"), *id.* at 18 (R.R. 2467) (Tukey "will remain in place"); Comment of Blue Shield of Cal. at 12 (R.R. 2325) ("we expected codification of the Tukey outlier deletion methodology for the 2024 Star Ratings"); Comment of AHIP at 52-53 (R.R. 1821-22) (Tukey was "set to take effect" with the 2024 Star Ratings). Thus, there was no need to "revive" the rerun decision in the Technical Amendment, and whether the Technical Amendment specifically addressed the prior year rerun is irrelevant.

The Proposed Technical Amendment of course did not reopen the Tukey methodology substantively. It proposed only a "technical amendment to fix" the "codification error" from the May 9, final rule, in addition to moving the Tukey sentence to "make[] the regulation text clearer." 87 Fed. Reg. at 79,635.

Nevertheless, even if the Proposed Technical Amendment could be read to reopen Tukey substantively, it would have to be read as reopening the entire methodology, including the rerun. The very first sentence of the Proposed Technical Amendment states that CMS finalized "Tukey outlier deletion" in the Final Rule, and it cites 85 Fed. Reg. at 33,833-36, which contains the rerun decision. 87 Fed. Reg. at 79,634. The second sentence states that CMS never proposed to eliminate "Tukey outlier deletion." *Id.* Thus, when the Proposed Technical Amendment used the term "Tukey outlier deletion," it meant the entire Tukey methodology, and if it was proposing to reinstate Tukey substantively, it was proposing to reinstate all of it, including the prior year rerun. CMS published its simulations illustrating the prior year rerun and Memorandum stating the rerun on December 19, 2022, which was five days after the Proposed Technical Amendment went on display on December 14, 2022, and eight days before the Technical Amendment appeared in the Federal Register on December 27, 2022. This further shows that CMS had no intention of dropping its rerun decision. *See* R.R. 2705-15. As discussed above, CMS gave full notice and comment on the Technical Amendment, thus effectively reinstating the entire methodology to the extent necessary. *See supra* § II.A.5.

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 Appropriate Rulemaking.

"It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review." *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004). This is the doctrine of administrative waiver, and it holds that "absent exceptional circumstances, failure to raise arguments before an agency, such as in comments during a public-comment process, usually waives a litigant's rights to make those arguments in court." *All. for the Wild Rockies v. Petrick*, 68 F.4th 475, 487-88 (9th Cir. 2023); *see also Transp. Div. of the Int'l Ass'n of Sheet Metal v. FRA*, 40 F.4th 646, 659 (D.C. Cir. 2022) ("because the Unions did not raise these objections during the rulemaking . . . they are forfeited"); *Koretoff v. Vilsack*, 707 F.3d 394, 397-98 (D.C. Cir. 2013) ("the Secretary never considered [plaintiff's objection] for one simple reason: no one suggested during the rulemaking that such a determination was required."); *ParkView*, 158 F.3d at 149 (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").

Importantly, challengers to agency action cannot avoid waiver with obscure objections or by presenting issues at a "very high level of generality." *All. for the Wild Rockies*, 68 F.4th at 489. Rather, they must present timely and particular objections that allow the agency to give the issue meaningful consideration. *Id.; see also Nat. Res. Def. Council, Inc. v. EPA*, 937 F.2d 641, 647-48 (D.C. Cir. 1991) ("a zero argument deserves a zero response").

Here, no commenters in the 2020 rulemaking, including Plaintiff, specifically commented on the proposal to rerun the prior year's cut points. No comments engaged in any way with CMS's reasoning for the rerun (that the guardrails should "be applied such that there is consistency between the years," *see* 85 Fed. Reg. 9,044), and no comments objected that the rerun proposal

appeared in the preamble and not the proposed Code of Federal Regulations text. Plaintiff cited the Proposed Rule at 85 Fed. Reg. 9,043 and commented on 2018 data discussed at 85 Fed. Reg. 9,044, the same page that proposed the prior year rerun, but Plaintiff did not comment on the rerun itself. Comment of SCAN Health at 5 (R.R. 382). Nor did Plaintiff raise any specific objections to the rerun in its comments on the Proposed Technical Amendment. *See* Comment of SCAN Health at 6 (R.R. 1748).

Plaintiff had full notice of CMS's proposal to rerun the prior year's cut points in the Proposed Rule published on February 18, 2020, almost four years before Plaintiff filed this suit. Plaintiff submitted a comment in that rulemaking but did not raise the rerun issue. Plaintiff has waived its right to bring that challenge now, and the Court should reject Plaintiff's claims.

C. Any Error on CMS's Part Was Harmless.

The APA directs courts reviewing agency action to take "due account" of the rule of "prejudicial error." 5 U.S.C. § 706. This is also known as the "harmless error rule." *See Combat Veterans for Cong. Political Comm. v. FEC*, 795 F.3d 151, 156-57 (D.C. Cir. 2015); *First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1015 (D.C. Cir. 2000). Reviewing courts consider whether an agency's error affected the outcome of the underlying proceedings. *See Nw. Immigrant Rights Project v. U.S. Citizenship & Immigr. Servs*., 496 F. Supp. 3d 31, 60 (D.D.C. 2020). "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." *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 311 (D.D.C. 2016).

For example, where an agency mislabels a notice of proposed rulemaking, but the public nevertheless has notice and an opportunity for comment, this is harmless error. *See U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 40-41 (D.C. Cir. 2005) (agency labeling notice as "Petition for Declaratory Ruling" instead of "Notice of Proposed Rulemaking" was harmless error because the

proposal "published in the Federal Register made the issue under consideration crystal clear" and the labeling did not affect the comments made). A plaintiff seeking to invalidate agency action bears the burden of showing that "an error is harmful." *See Combat Veterans*, 795 F.3d at 157; *see also Ctr. for Biological Diversity v. Int'l Dev. Fin. Corp.*, 77 F.4th 679, 690 (D.C. Cir. 2023).

Here, Plaintiff cannot meet its burden in showing that it was harmed by CMS's alleged errors. Plaintiff had notice of CMS's proposal to rerun the prior year's cut points in the February 18, 2020 Proposed Rule. *See* 85 Fed. Reg. 9,044. CMS's intent to rerun the prior year's cut points was clear, and Plaintiff had the opportunity to comment on it, and did choose to comment on other aspects of the Proposed Rule. *See* Comment of SCAN Health at 5 (R.R. 382) (citing 85 Fed. Reg. 9,043; criticizing 2018 data discussed at 85 Fed. Reg. 9,044). CMS's decision in the Final Rule was equally clear, and Plaintiff was in no way harmed by the fact that the proposal and final decision were not codified in the Code of Federal Regulations. *See* 85 Fed. Reg. at 33,833, 33,835.

Nor was Plaintiff harmed by CMS's inadvertent removal of the Tukey sentence from the Code of Federal Regulations text in 2022. CMS's December 19, 2022 simulations illustrated the prior year rerun, and CMS's December 27, 2022 Proposed Technical Amendment explained that the removal of the Tukey sentence was inadvertent. *See* 87 Fed. Reg. 79,634-35; R.R. 2705-15. Plaintiff again had an opportunity to comment and did. *See* Comment of SCAN Health at 6 (R.R. 1748).

True, Plaintiff's Star Ratings may have decreased because CMS reran the 2023 cut points with Tukey outlier deletion for purpose of the guardrails in the 2024 Star Ratings, but that is not because CMS did not codify that aspect of the methodology in the Code of Federal Regulations text or later inadvertently removed the sentence providing that CMS would apply Tukey outlier deletion. The consequences of Plaintiff's decreased ratings flow from the decision to rerun the cut

points using Tukey outlier deletion itself, not from where it was located. Had CMS codified its policy in the Code of Federal Regulations and never inadvertently removed the Tukey sentence from the regulation—the result would be the same. Neither alleged error caused Plaintiff to lose the opportunity to comment, and neither affected the math that caused Plaintiff's Star Ratings to decrease. Thus, these "errors" are both procedurally and substantively harmless.

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.

SCAN Health separately urges this Court to overturn CMS's factual determination that the February 9, 2023, call exceeded the eight-minute threshold described in Measure C30. This Court should reject the invitation because SCAN Health relies on an inapposite regulation and urges this Court, contrary to precedent, to reverse the agency's factual findings. CMS provides extensive descriptions to health plans of how it will use so-called "secret shoppers" to develop the data that forms part of the Star Rating calculation. The detailed guidance is consistent with the regulatory text. This Court should not countenance SCAN Health's effort to avoid the guidance based on little more than its preferred dictionary definition of a word in a regulation that does not apply to the calculation of Star Ratings. CMS applied the technical specifications for Measure C30 in determining that the challenged call was connected to an interpreter after more than eight minutes, and Plaintiff has not shown why this Court should not defer to the agency's factual finding.

A. The 2021 Rulemaking Cited By Plaintiff Is a Red Herring

Plaintiff asks this Court to treat as the "governing regulation," Pl.'s Mem. at 34, a provision (42 C.F.R. § 422.111(h)(1)) that was added in 2021 (well after the methodology for calculating

Star Ratings had been established by a different regulation) that does not even mention Star Ratings. This Court should reject the invitation.

The regulation governing the calculation of Star Ratings is found at 42 C.F.R. § 422.166, captioned (unsurprisingly) "Calculation of Star Ratings." That regulation describes at a high level how Star Ratings are calculated and displayed, and (as described above) much of the detailed information underlying data gathering and annual cut points is provided to plans on an annual basis. Section 422.111, by contrast, "add[ed] greater specificity and clarity to our requirements for [Medicare Advantage] and Part D plans by delineating more explicit minimum performance standards for [Medicare Advantage] and Part D customer service call centers, as well as ensur[ed] greater protections for beneficiaries." 86 Fed. Reg. at 6,005. The regulation does not mention Star Ratings at all, nor does the relevant portion of the final rule preamble. See *id.* at 6,005-08.[7] It is in no sense the regulation "governing" Star Ratings calculations. As the agency established in 2018, updates to Star Ratings measures are enacted either through rulemaking or via the annual announcement of payment rates. *See* 42 C.F.R. § 422.164(d) (citing 42 U.S.C. § 1395w-23(b)).

To be sure, CMS has acknowledged that there is overlap between measure C30, its Call Center Foreign Language Interpreter and TTY Availability score for Star Ratings purposes, and 42 C.F.R. § 422.111(h)(1)(iii), which describes the "mechanisms for providing specific information on a timely basis," including interpreter availability. But SCAN Health is wrong to suggest that the Star Rating measure should do nothing more than test the regulatory minimum standards. The text of Section 422.111(h) is irrelevant to the calculation of Measure C30.

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[7] Elsewhere in the same 2021 rulemaking, the agency did finalize changes to the Star Ratings methodology, none of which concerned the foreign language interpreter issue raised here. *See* 86 Fed. Reg. at 5,916-31. This is further evidence that the amendments to section 422.111 had nothing to do with changes to the foreign language interpreter measure of the Star Ratings.

CMS has described its method for assessing wait times for foreign language translators since before the 2021 Rule, using virtually identical language. *See* Medicare 2020 Part C & D Star Ratings Technical Notes at 63, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Star%20Ratings%20Technical%20Notes%20%28Oct%2010%202019%29.pdf. Had CMS meant to use the 2021 Rule to modify its existing practice with respect to measuring a plan's foreign language interpreter availability for the purposes of calculating Star Ratings, it would have presumably amended the section of the Code of Federal Regulations governing Star Ratings calculations or, at the very least, mentioned Star Ratings in the relevant Federal Register preamble. It did neither—a strong indication that the 2021 Rule has nothing to do with Star Ratings.

It is entirely sensible that CMS might choose to impose a minimum standard—on what is essentially a pass-fail basis—for foreign language interpreter availability (80% of calls within eight minutes), but nonetheless assign quality ratings—on a curve—based on a spectrum of outcomes. *Accord AvMed, Inc. v. Becerra*, Civ. A. No. 20-3385 (JDB), 2021 WL 2209406, at *5 (D.D.C. June 1, 2021) ("Star Ratings are graded on a curve"), *see* Pl.'s Mem. at 10.[8]

Because Plaintiff cites the wrong regulatory text as the "governing regulation," this Court could disregard its arguments based on exegesis of that text and in particular Plaintiff's preferred definition of the word "available." *See id.* at 34-37. But that argument also fails on its own merits. It is by no means obvious that an interpreter is "available" the moment he or she connects to a call.

[8] Plaintiff urges this Court to apply a different standard to one call—out of thousands—without modifying the grading curve. It is highly unlikely that the February 9, 2023, call to SCAN Health was the only secret shopper call in the dataset in which an interpreter was on the line before eight minutes but did not complete the activity required by Measure C30 until more than eight minutes had passed. SCAN Health here is seeking special treatment (i.e., to be treated unlike other analogous cases) in asking this Court to order the agency to mark its wrong answer correct or disregard the question altogether, without modifying anyone else's grade.

To the contrary—it is fully consistent with the meaning of "available" to require that an interpreter demonstrate that he or she can provide relevant service—here, helping the beneficiary receive answers from a customer service representative. Foreign language interpretation is not analogous to a database in this regard. *Cf. United States v. Soybel*, 13 F.4th 584, 595 (7th Cir. 2021).[9]

There is no conflict between any "governing regulation" and the CMS guidance describing how foreign language interpreter data are included in the Star Ratings, because the regulation that Plaintiff repeatedly insists is "governing" has nothing to do with the Star Ratings. But even if Section 422.111 were somehow relevant here, the agency's guidance on the meaning of "available" would control over Plaintiff's imprecise and inapplicable dictionary definition.

B. CMS Correctly Assessed Call C0600900 Under Its Published Measure

Plaintiff does not dispute that it took six minutes and thirty-five seconds to connect a caller requesting French interpretation services to a translator. Nor does Plaintiff deny that call C0600900 failed the criteria laid out in measure C30—the plan failed to accomplish "completed contact with an interpreter" within eight minutes. This should end the matter, but Plaintiff insists that someone else should bear the blame for the shortcomings of its own system. Plaintiff's argument fails because it amounts to little more than a request that this Court review the agency's factual determination.

CMS produced its own translation of the call, which differs from Plaintiff's translation in one key respect. Plaintiff says that, beginning at 7:34 of the call, the interpreter said, "I missed that." Pl.'s Mem. at 38. CMS, on the other hand, translated "I missed that" as "I failed to take notes." SCAN-AR000321. Plaintiff would have this Court hold that the translator "missed that"

[9] Plaintiff also cites *Fischbein v. Olson Research Group, Inc.*, 959 F.3d 559, 565 (3d Cir. 2020) (Jordan, J., dissenting), for the definition of "available," but fails to note that the opinion cited is a dissent.

due to some error by the CMS contractor placing the call—"noticeably struggling to state her question." Pl's Mem. at 38. But neither CMS nor this Court is obligated 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.

Plaintiff has not acknowledged the translation upon which CMS relied, offering this Court only its own preferred translation. It further implies that because a different call required only forty-one seconds between an interpreter being connected and the requirements of measure C30 being fulfilled, it is somehow unreasonable (and CMS's fault) that the call at issue took longer. Of course, nothing in the statute, regulations, or guidance requires that each call be identical, or that the shortest time between an interpreter being on the line and a call being successfully connected be used as a "baseline" for other calls. This is not a failure to treat "like cases alike." *Id.* at 41 (citing *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007)). Presumably the interpreter on the shorter call did not fail to take notes when a customer was reading plan information. Under Plaintiff's theory, as long as one interpreter does so, other interpreters should be deemed (by some unstated alchemy) to have done the same.

SCAN Health's briefing on this issue is self-contradictory. On the one hand, SCAN Health complains that "[t]he secret shopper used an ambiguous French term—which has multiple and confusing English meanings—to refer to 'medical benefits.'" *Id.* at 18. But SCAN Health acknowledges that "[a]nother secret shopper called SCAN [Health] to pose exactly the same question in French, and took just 18 seconds to state the question (not over 25 seconds)." *Id.* at 19; *see also id.* at 38. If the allegedly "ambiguous French term" had been an impediment to translation, presumably it would have affected multiple calls. In light of the record, a far likelier explanation

is that the translator's failure to take notes on February 9, 2023, contributed more to the delay than any issues with CMS's contractors.

Plaintiff's remaining arguments fail. Its reliance on 2016 Guidance, for example, cites a purported question and answer. *See id.* at 41. But Plaintiff relies on statements made in a webinar, quoting a document entitled "Clarifications to Questions and Answers During the Webinar." *Id.* (citing Ex. 10 to Plumb Decl. at 4). Plaintiff quotes a portion of the "Webinar Answer" (i.e., what the presenters said during the webinar), ignoring the "Clarified Answer" (i.e. the clarification that CMS put in writing to resolve confusion). *Id.* The "Clarified Answer" does not remotely support Plaintiff's position, and states that "we would separate the interpreter availability component from this question." Ex. 10 to Plumb Decl. at 4. In other words, the "interpreter availability component"—the issue in this litigation—was not even addressed by the question raised in the Q&A, putting aside Plaintiff's effort to portray the unclarified "Webinar Answer" as CMS's official position. The "accuracy test" described in the Q&A is not part of the Star Ratings call center measures.

Ultimately, Plaintiff failed to achieve a five-star rating for a quality measure and attempts, post hoc, to take issue with CMS's implementation of the measure as it applies to one "secret shopper" call. But the rules were clear in advance, and CMS implemented them exactly as it said it would. Plaintiff's arbitrary-and-capricious challenge therefore fails.

* * *

CONCLUSION

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

Dated: March 29, 2024

Respectfully submitted,

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

BRIAN P. HUDAK
Chief, Civil Division

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

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

U.S. Dept. of Health and Human Services

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)

[PROPOSED] ORDER

UPON CONSIDERATION of Plaintiff's Motion for Summary Judgment, Defendant's Cross-Motion for Summary Judgment, and the entire record, it is hereby

ORDERED that Plaintiff's Motion for Summary Judgment is DENIED;

ORDERED that Defendant's Cross-Motion for Summary Judgment is GRANTED; and

ORDERED that summary judgment is entered in Defendant's favor on Plaintiff's claims in this action.

This is a final appealable Order.

SO ORDERED, this _____ day of _____, 202__.

_____
CARL J. NICHOLS
United States District Judge