IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCAN HEALTH PLAN, *Plaintiff*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants.*	Case No. 1:23-cv-3910-CJN

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR EXPEDITED SUMMARY JUDGMENT

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INTRODUCTION

Defendants fail to rebut Plaintiff SCAN's showing that CMS ignored its governing regulations in determining SCAN's overall 2024 Star Rating. Far from refuting SCAN's arguments, Defendants' briefing reaffirms that CMS departed from its own regulations for determining Star Ratings in two different respects, either one of which was independently sufficient to unlawfully knock down SCAN's Star Rating from 4 to 3.5 stars.

First, CMS disregarded its binding regulations governing how SCAN's Star Rating must be determined. SCAN and Defendants agree that a Medicare Advantage plan's measure-specific Star Ratings is calculated on a "curve," using "cut points" as the dividing lines between each of the star levels, and that CMS applies a "guardrail" of "5 percentage points" to restrict how far each "cut point" can change "from 1 year to the next." 42 C.F.R. § 422.166(a)(2)(i); *id.* § 423.186(a)(2)(i). Defendants concede (at 18) that CMS did *not* determine SCAN's 2024 measure-specific Star Ratings using cut points that had been restricted by the 5 percentage point guardrail relative to the *actual* cut points from the 2023 Star Ratings. In doing so, CMS violated its own regulations. Defendants' contrary arguments all fail.

Defendants argue (at 22-25, 27-35) that CMS's later-in-time Federal Register *preambles* are themselves binding rules that override the earlier guardrail regulations in the Code of Federal Regulations and authorize CMS to set the 2024 Star Rating cut points with guardrails applied relative to a *simulation* of the 2023 Star Rating cut points, rather than relative to the *actual* 2023 Star Rating cut points, as provided in CMS's regulations. But the binding law of the Circuit is that "where, as here, there is a discrepancy between the preamble and the Code, it is the codified provisions that control." *AT&T Corp. v. FCC*, 970 F.3d 344, 350-51 (D.C. Cir. 2020). For all of their hand-wringing and knot-tying, Defendants cannot escape the simple fact that CMS chose

to adopt a non-binding "simulation" policy in CMS's preambles that squarely contradicts its binding regulations, which do not allow for any "simulation," but rather set CMS's guardrails based on the prior year's *actual* cut-points.

SCAN has also explained that there is an additional, independently dispositive defect: Even if CMS *could* rely on its "simulation" preambles as a valid basis to "simulate" the 2023 Star Rating cut points in violation of CMS's codified regulation, CMS's preambles provided no notice whatsoever, much less opportunity for comment, that CMS would simulate the 2023 Star Rating cut points with "no guardrails" relative to the 2022 Star Rating cut points, as CMS did here. On the contrary, CMS's regulations expressly required CMS to calculate the 2023 Star Rating cut points *with guardrails* relative to the 2022 Star Rating cut points. 42 C.F.R. § 422.166(a)(2); *id.* § 423.186(a)(2). CMS's decision to disregard its binding regulations and instead apply "no guardrails" in its simulation relative to the 2022 Star Rating cut points resulted in CMS's simulated 2023 Star Rating cut points ballooning upward by 30%, 40%, or more in a single year, dropping SCAN's Star Rating down to 3.5 stars. That was clear error.

Defendants spend much of their briefing arguing (at 9, 28, 32-34) that SCAN did not file comments in 2020 objecting to CMS's simulation ("rerun") proposal. But setting aside that under the law of the Circuit such a comment is not required for SCAN's as-applied challenge to the determination of its 2024 Star Rating, Defendants' argument highlights yet another dispositive defect in their case. SCAN and other commenters *praised* CMS's proposal to simulate ("rerun") the 2023 Star Ratings *with guardrails* because CMS told commenters ***five times*** that its "rerun" would be calculated *with guardrails*, which CMS variously described as running its simulation with "the implementation of guardrails," "on top of guardrails," with "a 5 percent guardrail," and that "guardrails would be applied." *Infra* at 16-17. Given CMS's representations *ad nauseum*

that it would "rerun" the 2023 Star Ratings *with* the 5 percentage point guardrail, as mandated by its regulations, CMS could not reverse itself by applying "no guardrails" to dramatically balloon the Star Rating cut points in a single year. For all of these reasons, CMS violated its regulation when it failed to apply the required 5 percentage point guardrail, and CMS's determination of SCAN's overall Star Rating must be set aside.

Second, CMS made another key error, which was likewise independently sufficient to knock SCAN's Star Rating down from 4 stars to 3.5 stars. CMS concluded that, on a secret shopper call placed on February 9, 2023, SCAN failed to meet CMS's standard to make an interpreter "available" to the caller within 8 minutes of reaching a customer service agent. But CMS evaluated the challenged secret shopper call contrary to its own regulation, which requires that "interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative . . . ." 42 C.F.R. § 422.111(h)(1)(iii). That is, an interpreter needs to be on the phone line, in dialogue with the caller, within 8 minutes. SCAN met that standard, and Defendants' contrary arguments fail.

Defendants argue (at 37-40) that CMS's regulation at § 422.111(h)(1)(iii) is "inapposite" because it does "not even mention Star Ratings" and is not a "regulation 'governing' Star Ratings," and thus the "text of Section 422.111(h) is irrelevant to the calculation of Measure C30," the "Interpreter Availability" measure. That is a curious position for Defendants' counsel to take, because Defendants have asserted time and time again, across their multiple decisions here, their rulemakings, and their public-facing guidance, that 42 C.F.R. § 422.111(h)(iii) *does* provide the governing standard for Star Rating measure C30, "Interpreter Availability." Indeed, CMS's Reconsideration Decision concerning SCAN's appeal of the February 9, 2023 call stated that CMS determines measure C30 "to ensure compliance with regulatory requirements, found

at 42 C.F.R. §§ 422.111(h) . . . for providing timely and accurate information." A.R.450. And in the Informal Hearing of SCAN's appeal, CMS's Hearing Officer concluded that "42 C.F.R. §[] 422.111(h) establishes the 8-minute measure for interpreter availability." A.R.6.[1] It is too late for Defendants' counsel to offer a post-hoc explanation for the alleged "irrelevance" of 42 C.F.R. § 422.111(h)(1)(iii) to CMS's measure C30, contrary to CMS's decisions. CMS expressly defines interpreter "availability" to mean a call "must be *connected* to an interpreter within . . . 8 minutes." 86 Fed. Reg. 5,864, 6,008 (Jan. 19, 2021) (emphasis added). That standard was met here.

And, even assuming (contrary to the governing regulation) that CMS may consider more than just the time it takes to connect a call to the interpreter, here, the secret shopper botched the February 9, 2023 call, repeatedly stumbling over her question, and speaking in slow, non-standard language that she had to repeat and clarify to be understood. These errors resulted in it taking over 8 minutes to answer her question. In its decisions below, CMS did not dispute that these extrinsic factors caused the test call to fail, instead finding that it was *appropriate* to count any delays caused by the secret shopper against SCAN's Star Rating, because "any differences in the way they [the questions] were stated is down to the individual caller, just like a non-test call would be, which is what CMS is testing." A.R.455. CMS's Hearing Officer affirmed this reasoning, noting that: "How prospective members ask a question will differ from call to call." A.R.6.

But Defendants do not actually attempt to defend this rationale for CMS's decision. Instead, Defendants now switch to a new post-hoc explanation: That the third-party interpreter

[1] The Hearing Officer also concluded that CMS's non-binding guidance provides an additional interpretative gloss on the meaning of § 422.111(h)(iii), but held that "42 C.F.R. §[] 422.111(h) establishes the 8-minute measure for interpreter availability." *Id.*

"failed to take notes" on the call, and that *this* is the reason the test call exceeded CMS's 8-minute benchmark. But the problem with that newfound theory is that it is based on a secret, self-serving call transcript that—on top of just translating the call incorrectly—CMS did not timely disclose to SCAN in the administrative appeal process. Unsurprisingly, neither CMS's Reconsideration Decision nor the subsequent Informal Hearing Decision relied upon CMS's secret transcript, or CMS's blame-the-interpreter theory. Defendants' post-hoc rationalization for CMS's decision is non-cognizable. *See SEC v. Chenery Corp*., 318 U.S. 80, 95 (1943) (holding that "an administrative order cannot be upheld unless the grounds upon which the agency acted . . . were those upon which its action can be sustained").

Either CMS's "guardrail" error *or* its "secret shopper" error was each independently sufficient to cause SCAN's Star Rating to drop from 4 stars to 3.5 stars. CMS's determination of SCAN's Star Rating should therefore be set aside on either or both of these two grounds.

Relief is urgently needed from this Court before June 3, 2024: All health plans must submit bids to CMS by June 3, 2024 to participate in the 2025 Medicare Advantage program, and SCAN's 2024 Star Rating determines *how* SCAN must bid under the law. In lieu of preliminary injunction proceedings, the parties therefore stipulated to a schedule for expedited summary judgment in advance of that June 3 deadline, Dkt. 19, which the Court has entered (Mar. 5, 2024 Minute Order).

The Court should grant summary judgment to SCAN and set aside CMS's determination of SCAN's 3.5-star Star Rating. As SCAN explained in its Motion, the Court should enjoin the Defendants from using CMS's unlawful 3.5-star Star Rating in determining SCAN's eligibility for quality bonus payments. And the Court should order the Defendants, prior to June 3, 2024, to recalculate SCAN's Star Rating in compliance with governing law by (i) applying the required

5 percentage point guardrail in determining SCAN's 2024 Star Rating, and (ii) excluding the February 9, 2023 secret-shopper call from CMS's determination of SCAN's Star Rating (or, alternatively, determining that SCAN "passed" ("completed") the challenged call), and to utilize that recalculated Star Rating for purposes of determining SCAN's eligibility for quality bonus payments. Defendants do not dispute that if SCAN prevails on the merits, it is entitled to all of its requested relief, and Defendants have therefore forfeited their ability to contest that issue.

For all of these reasons, SCAN's Motion for expedited summary judgment should be granted, and Defendants' Cross Motion for expedited summary judgment should be denied.

ARGUMENT

I. CMS Violated Its Regulations In Determining SCAN's 2024 Star Rating Without Applying The Required Regulatory Guardrails

CMS improperly determined SCAN's 2024 Star Rating by using cut points that CMS determined based on *simulated* 2023 Star Rating measure-specific cut points, rather than the *actual* 2023 Star Rating cut points, as CMS's regulations required. And even if CMS were allowed to run a simulation of the 2023 Star Rating cut points, CMS did not apply *any guardrail* at all to limit changes in the simulated 2023 Star Rating cut points relative to the 2022 Star Rating cut points—again, contrary to its binding regulation. Either one (or both) of these two errors erroneously reduced SCAN's Star Rating from 4 stars to 3.5 stars. And Defendants' procedural arguments, that SCAN somehow forfeited the "simulation" issue, or that CMS's errors were harmless, are baseless.

A. *CMS Violated Its Regulation By Determining SCAN's 2024 Star Rating Using A Simulation Of The 2023 Star Rating Cut Points Premised On A Non-Binding And Contradictory Federal Register Preamble*

CMS's regulations in 42 C.F.R. § 422.166(a)(1)-(2) and § 423.186(a)(1)-(2) required CMS to calculate SCAN's 2024 Star Rating by applying a 5 percentage point guardrail to limit

changes in the 2024 Star Rating measure-specific cut points relative to the *actual* cut points that CMS determined in calculating the 2023 Star Ratings a year earlier. SCAN Br. 21-28. Instead, CMS erroneously determined SCAN's 2024 Star Rating using cut points that CMS calculated by applying a 5 percentage point guardrail relative to *simulated* 2023 Star Rating cut points that CMS generated by applying the Tukey outlier deletion method a full year before CMS's regulations permitted CMS to do so. *Id.*

In response, Defendants argue (at 22-25, 27-35) that CMS's Federal Register *preambles* are themselves binding legislative rules that override earlier-promulgated, binding provisions of the Code of Federal Regulations, and that the preambles authorized CMS to set the 2024 Star Rating cut points based on a *simulation* of the 2023 Star Rating cut points. To be sure, those preambles provide that, to implement Tukey outlier deletion for the 2024 Star Ratings, "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. 33,833, 33,835 (June 2, 2020); 85 Fed. Reg. 9,002, 9,044 (Feb. 18, 2020). Defendants, however, claim that these preambles authorized CMS to apply guardrails on changes in the 2024 Star Rating cut points relative to *simulated* 2023 Star Rating cut points that CMS generated by applying the new Tukey outlier deletion methodology a year before CMS's regulations allowed. Defendants take that position notwithstanding that CMS's regulations provide that "[e]ffective for the [2023] Star Ratings issued in October 2022 . . . CMS will add a [5 percentage point] guardrail" based on the prior year's actual "measure-threshold-specific cut points," and that "[e]ffective for the [2024] Star Ratings issued in October 2023 . . . Tukey outer fence outliers are removed." 42 C.F.R. § 422.166(a)(1)-(2) and § 423.186(a)(1)-(2).

Defendants are wrong. CMS's determination of SCAN's 2024 Star Rating was erroneous

because CMS failed to "'comply with its own regulations.'" *Nat'l Env't Dev. Ass'ns Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) (citation omitted). The D.C. Circuit has expressly rejected CMS's assertions (at 22-27) that an agency's "explanatory statements, published in the Federal Register, should be treated as part of the binding regulation." *AT&T Corp. v. FCC*, 970 F.3d 344, 350 (D.C. Cir. 2020). The D.C. Circuit so-held because "the 'real dividing point' between the portions of a final rule with and without legal force is designation for 'publication in the Code of Federal Regulations.'" *Id*. (citation omitted). So, "if a preamble purports to establish the regulatory treatment of [an issue] but the regulations as published in the Code do not, then the preamble statement is a nullity." *Id.* at 351. As then-Judge Scalia explained, "[p]ublication in the Federal Register does not suggest that the matter published was meant to be a regulation, since the APA requires general statements of policy to be published as well." *Brock v. Cathedral Bluffs Shale Oil Co*., 796 F.2d 533, 539 (D.C. Cir. 1986) (Scalia, J.) (citing 5 U.S.C. § 552(a)(1)(D)). This is not a technicality: Americans are entitled to know their own, and agencies', binding obligations. *See id.*

Since all agencies must "publish in the Federal Register" *non-binding* "statements of general policy or interpretations," the fact that CMS's "simulation" pronouncements appeared in Federal Register preambles does not render them binding legislative rules that could override CMS's codified regulations. 5 U.S.C. § 552(a)(1)(D). But that is *doubly* true for CMS, because CMS extraordinarily—and unlike practically any other agency—*also* must subject its *non-binding* interpretative rules and policy statements to notice and comment (not just publication in the Federal Register). *Compare* 5 U.S.C. § 553(b)(4)(A) (other agencies need not offer notice-and-comment on non-binding "interpretative rules" and "general statements of policy"), *with* 42 U.S.C. § 1395hh(a)(1)-(2), (b)(1) (CMS must promulgate a "rule, requirement, *or other statement*

of policy" by providing "notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment."). The Supreme Court has explained this unusual requirement, that CMS must provide "notice and a chance to comment on" *non-binding* "Medicare interpretive rules" and "policies." *Azar v. Allina Health Servs*., 139 S. Ct. 1804, 1816 (2019); *see also* Defs. Br. 15, 20 (discussing the notice-and-comment requirements of 42 U.S.C. § 1395hh(b)(1)). The upshot of this requirement is that the Federal Register is chock-full of CMS requests for comment on its *non-binding* policies and interpretative rules. *See id.* 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.

To be sure, the D.C. Circuit has reserved the narrow "possibility that statements in a preamble 'may in some unique cases constitute binding, final agency action susceptible to judicial review.'" *AT&T*, 970 F.3d at 350 (citation omitted). But such "unique cases" are "not the norm" because agency statements "having general applicability and legal effect are to be published in the Code of Federal Regulations." *Id*. at 350-51. That is because the Code of Federal Regulations provides the "*complete* codifications of the documents of each agency of the Government having general applicability and legal effect." 44 U.S.C. § 1510(a) (emphasis added). That is, the "Code of Federal Regulations" "contain[s] each Federal regulation of general applicability," not just a selection. 1 C.F.R. § 8.1; *Brock*, 796 F.2d at 539. CMS cannot simply amend the plain text of its regulations by relying on preambles in the Federal Register. That black-letter law dooms CMS's argument here.

And the D.C. Circuit has specifically ruled out its narrow "unique cases" safety valve in the circumstances of this case: "[W]here, as here, there is a *discrepancy* between the preamble

and the Code, *it is the codified provisions that control*." *AT&T*, 970 F.3d at 350-51 (emphases added). Indeed, all parties seem to accept that if there is a discrepancy between CMS's Federal Register preambles and the Code of Federal Regulations, the Code of Federal Regulations necessarily controls. *See* Defs. Br. 25 n.4. SCAN has already detailed these discrepancies at length: Following its Federal Register preamble, (i) CMS applied a guardrail to restrict changes in the 2024 Star Rating cut points relative to *simulated* 2023 Star Rating cut points, not the *actual* 2023 Star Rating cut points required by the regulation; (ii) CMS removed Tukey outliers from the simulated 2023 Star Rating measure data a full year before CMS's regulations permitted it to; and (iii) in its simulation, CMS applied "no guardrails" relative to the 2022 Star Rating cut points, contrary to CMS's regulation. *Supra* at 1-3, 6; SCAN Br. 21-28.

CMS's regulations unambiguously foreclosed CMS from applying guardrails on the 2024 Star Rating cut points relative to a *simulation* of the 2023 Star Rating cut points. The plain text of the regulations requires CMS to ensure that the *same* variable, the "measure-threshold-specific cut points," cannot change more than 5 percentage points "from 1 year to the next." 42 C.F.R. § 422.166(a)(1)-(2) and § 423.186(a)(1)-(2); *cf. Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 523 (D.C. Cir. 2009) (noting that "from 'one year to the next'" refers to the same variable in two years). No simulation is allowed to alter the prior year's "measure-threshold-specific cut points."

Nor do CMS's other Star Rating regulations leave room for any ambiguity, read together as a whole and in context. *See, e.g.*, *United States v. Bronstein*, 849 F.3d 1101, 1109 (D.C. Cir. 2017) ("Challenged terms must be read in context of the regulation as a whole."). CMS expressly defined its "guardrail" as a "cap" or "absolute percentage cap," 42 C.F.R. § 422.166(a)(2), § 423.186(a)(2), with the "absolute percentage cap" in turn defined as "a cap applied to non–CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's

measure-threshold-specific cut point to no more than the stated percentage as *compared to the prior year's cut point*." *Id.* § 422.162(a) (emphasis added); *see also id.* § 423.182(a) (same). And CMS defined a "guardrail" as "a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to *the prior year's measure-threshold-specific cut point*." *Id.* § 422.162(a) (emphasis added); *id.* § 423.182(a) (same). CMS further defined this "cap" or "cut point cap" as "a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the *prior year's measure-threshold-specific cut point*." *Id.* The text of these provisions plainly contradicts CMS's preambles providing for a "rerun" or "simulation"—they literally specify that the object to be "compared to" is the "*prior year's . . . cut point*."

Given the clear "discrepanc[ies]" between CMS's unambiguous regulations and its preambles, "it is the codified provisions that control." *AT&T*, 970 F.3d at 351; *id.* at 350 ("[B]ecause the regulation itself is clear, [the Court] need not evaluate' . . . the regulatory 'preamble.'" (citation omitted)). Far from rebutting SCAN's position, Defendants' cited cases affirmatively support it. Defendants place principal reliance on *St. Helena Clear Lake Hospital v. Becerra*, No. 19-cv-00141 (CJN), 2021 WL 1226713, at *6-7 (D.D.C. Mar. 31, 2021), *aff'd*, 30 F.4th 301 (D.C. Cir. 2022). There, the regulation and statute did not foreclose the agency's "interpretation," and so this Court deferred to it. That is far afield from any sort of holding that a Federal Register preamble is a binding legislative rule. The D.C. Circuit's decision in that same case confirms exactly that. *St. Helena Clear Lake Hosp. v. Becerra*, 30 F.4th 301, 304 (D.C. Cir. 2022). There, the D.C. Circuit expressly refused to defer to CMS's interpretation promulgated in its Federal Register "preamble." *Id.* Instead, the Court reaffirmed the holding of *AT&T*: "[W]e have held that the preamble of a regulation does not have quasi-legislative bite, in other

words it is not part of the legal requirement of the regulation." *Id.* So too here.[2]

Defendants protest (at 22) that CMS "clearly intended [the preambles] to be binding." But under *AT&T*, that is beside the point: When CMS seeks to countermand the Code of Federal Regulations, even for one year, it must do so through a regulation in the Code of Federal Regulations, not through a preamble, *even a preamble that CMS "intends" to be binding.* 970 F.3d at 350-51 ("[W]here, as here, there is a discrepancy between the preamble and the Code, it is the codified provisions that control."). That explains *why*, when CMS has chosen to make one-year *ad hoc* adjustments to its rules for determining Star Ratings, it has consistently published those one-year adjustments in the Code of Federal Regulations. SCAN Br. 29-30.

CMS's claims about its "intentions" are not just irrelevant, they are also wrong. In 2020, Defendants' Office of the General Counsel issued an Advisory Opinion about the "Appropriate Use of Preamble Text for Rulemaking" in light of *Allina* (2019) and *AT&T* (2020).[3] Defendants *correctly* stated that preambles will rarely "constitute binding . . . agency action." *Id.* Defendants therefore stated that CMS must be crystal clear in purporting to bind itself to preamble text:

> [W]hen HHS engages in notice-and-comment rulemaking through preamble language only, the Department ***must be sufficiently clear to separate binding legal obligations from the rest of the preamble text*** that contains nonbinding interpretive statements. . . . ***HHS will make clear its intent to engage in rulemaking through preambles by either***: 1) ***specifically speaking to the Department's intent*** in both the proposed and final rule preamble text, such as by using the phrase "***HHS***

[2] CMS's other cited decision, *Chemical Waste Management, Inc. v. EPA*, is even further afield. 869 F.2d 1526, 1534 (D.C. Cir. 1989). There, the D.C. Circuit opined that the rule at issue was a non-binding "interpretative rule" that could be "sustained" even absent any prior "notice and opportunity for comment." *Id.* The D.C. Circuit then explained that EPA *had* in all events subjected its "interpretative rule" to "notice and opportunity for comment," and so the petitioner could not argue that they had been deprived of the opportunity to comment. *Id*. That is far from finding that Federal Register preambles are binding regulations, contrary to *AT&T.*

[3] U.S. Dep't of Health and Human Services ("HHS"), Advisory Opinion 20-05 on Implementing *Allina* at 3 (Dec. 3, 2020), 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.

> ***intends to bind itself***" to the rule, or 2) stating that HHS would engage in notice-and-comment rulemaking in order to change the stated preamble policy.

Dep't of HHS Advisory Op. at 3 (emphasis added). CMS did none of that here: It simply noted, *in a half-sentence* buried in a 250 page document, that "[i]n the first year that [Tukey outlier deletion] would be implemented, the prior year's thresholds *would be rerun*." 85 Fed. Reg. at 9,044; *see also* 85 Fed. Reg. at 33,835 ("not[ing]" that "for the first year (2024 Star Ratings), we *will rerun* the prior year's thresholds" (emphasis added)). "Noting" such forward-looking intentions of what CMS "would" or "will" do is not mandatory or binding. *Compare Am. Petroleum Inst. v. E.P.A.*, 684 F.3d 1342, 1354 (D.C. Cir. 2012) ("the statement that applicants 'will initially be required' is predictive of the agency's future actions, not one from which 'legal consequences w[ould] flow'"), *and Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 69 (2004) (the verb "will" is not "binding"), *with Defs. of Wildlife v. Zinke*, 849 F.3d 1077, 1085 (D.C. Cir. 2017) (finding that government's mandatory language that Wyoming "will*, and must*, maintain a buffer" to "meet" its legal obligations manifested "clear intent by the Service to bind Wyoming" (emphasis in original)).

This alone should be sufficient to resolve this case: CMS was required to determine its guardrail for the permissible change in the 2024 Star Rating cut points based on a 5 percentage point change compared to the *actual* 2023 Star Rating cut points, as provided in its earlier regulations, not a *simulation* provided in later, contradictory preambles. Had CMS done so, SCAN's Star Rating would not have fallen to 3.5 stars; rather, it would have been 4 stars.

B. *CMS's Uncodified Federal Register Preambles Cannot Vary CMS's Codified Regulations For Two Additional Reasons Specific To This Case*

On top of these settled legal principles, CMS's reliance (at 22-33) on uncodified Federal Register preambles is also unavailing for two, more specific reasons particular to this case. First, CMS's preambles provided no notice whatsoever, much less opportunity for comment, that CMS

would simulate the 2023 Star Rating cut points with "no guardrails" relative to the 2022 Star Ratings, as it did here. Second, CMS revoked its "simulation" preamble in 2022, when CMS revoked the regulation that this preamble purported to interpret, and CMS never revived that preamble.

1. *CMS unlawfully departed from its Federal Register preambles by running its simulation of the 2023 Star Rating cut points with "no guardrails"*

When CMS calculated the simulated 2023 Star Rating cut points, it did so with "no guardrails" relative to the 2022 Star Rating cut points. CMS's Federal Register preambles provided no notice, much less opportunity for comment, that CMS would disregard its guardrails regulations with respect to the simulated 2023 Star Ratings. A.R.668 (2024 Star Rating Technical Notes) ("the 2023 Star Ratings cut points were rerun including . . . no guardrails").

The wild swings in CMS's simulated 2023 Star Rating cut points by 30%, 40%, or more caused by the deletion of Tukey outliers could have been limited if CMS had simply applied in its 2023 Star Ratings simulation its 5 percentage point guardrail relative to the 2022 Star Rating cut points, as required by its regulation: "Effective for the [2023] Star Ratings issued in October 2022 . . . CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next." 42 C.F.R. §§ 422.166(a)(2)(i), 423.186(a)(2)(i); SCAN Br. 25. Instead, CMS admits that it *entirely disregarded* the guardrails that were supposed to restrict how far the simulated 2023 Star Rating cut points could change, relative to the 2022 Star Rating cut points. A.R.668 ("For the purposes of calculating the guardrails for the 2024 Star Ratings, the 2023 Star Ratings cut points were rerun including . . . *no guardrails*."). That was clear error.

Defendants claim (at 28) that nowhere in CMS's preambles did CMS "say anything about using [a guardrail based on] data from two years prior." But if CMS was going to try to disregard

its binding guardrail regulations in running its simulation, CMS had to do so through a new regulation promulgated through notice-and-comment rulemaking. *See, e.g.*, *Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 83-84 (D.C. Cir. 2020) (modifying "pre-existing legal obligations" requires "notice-and-comment"); *AT&T*, 970 F.3d at 350. And far from leaving the issue unaddressed in its preambles, as CMS claims it did, 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. Both of CMS's preambles proposing and adopting a "rerun" (simulation) literally stated that "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 33,833 (emphasis added); *see also* 85 Fed. Reg. at 9,044 (same). No commenter would reasonably read "guardrails would be applied" in the "rerun" to actually mean "no guardrails apply." *See id.*

CMS understood its proposal to "rerun" its simulation of the 2023 Star Ratings *with* guardrails the same way. In the Federal Register notice where CMS announced that it would "rerun" (simulate) the prior year's cut points, CMS modeled for the public the financial impact of that change on Medicare Advantage plans. 85 Fed. Reg. at 9,044. Since CMS did not yet have data from the 2023 Star Ratings, to illustrate the effects of phasing in Tukey outlier deletion through a "rerun," CMS utilized a then-available data set, the 2018 Star Ratings data. *Id.* CMS modeled its proposed "rerun" through a "simulation of the impact of Tukey outlier deletion," namely, that "Tukey outer fence outlier deletion ***and a 5 percent guardrail*** had been implemented for the 2018 Star Ratings." *Id.* (emphasis added). CMS misled the public: It was telling them that a "5 percent guardrail" would apply relative to the prior year's actual measure-specific cut points, because *CMS itself* simulated its "rerun" proposal exactly that way. *Id.*

CMS repeated this same claim when it finalized its "rerun" proposal: "CMS ***simulations*** were conducted ***assuming the implementation of guardrails*** which limits the fluctuation in cut points." *Id.* at 33,892-93 (emphasis added). CMS reassured commenters that applying guardrails would prevent sudden, unpredicted revenue losses (by lowering plans' Star Ratings), because as CMS phased in its "rerun" (simulation), "***we are implementing these changes on top of guardrails***, which will already ***limit significant movements of cut points from year-to-year.*** *Id.* at 33,892 (emphasis added). CMS did *not* inform the public that it would apply "no guardrails" and allow cut points to balloon 30%, 40%, or more in a single year. *Id.* So on top of its binding guardrail regulations, by subjecting its "*with* guardrails" "rerun" proposal to comment, CMS established a policy to carry out its simulation of the 2023 Star Ratings *with* guardrails, then arbitrarily departed from it without required notice and comment, *Allina*, 139 S. Ct. at 1816, and explanation of the "good reasons for the new policy." *FCC v. Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009).

Not only were CMS's representations misleading, but the public was in fact misled. That is *why*, as CMS touts (at 28), no one came forth with comments *against* CMS's plan to "rerun" the 2023 Star Ratings *with* guardrails. For example, Gateway Health commented:

> Cut Point Guard Rails - Gateway understands that ***CMS intends to implement a 5% guardrail on cut point movement. Due to outlier removal***, it appears that cut point movement will likely be significantly higher than in previous years, and resultantly, plans could potentially be ***expected to make 5% improvements*** in multiple measures ***year over year until cut points stabilize***. Given this potentiality, Gateway requests that CMS consider setting the guardrails closer to measure level targets to earn quality improvement (typically 2-3%).

R.R.736 (emphases added).[4] Gateway and SCAN understood that when CMS phased in Tukey "outlier removal," CMS would impose a "guardrail" to ensure a *gradual* phase-in limiting changes

[4] "R.R." refers to the Rulemaking Record.

to "5% improvements" "***year over year*** until cut points stabilize," not a change of 30%, 40%, or more in a single year. *Id.* (emphasis added). SCAN likewise commented that it "appreciate[d] CMS' proposal to include outlier removal ***and guardrails*** in the threshold calculation," arguing that the gradual phase-in of Tukey outlier deletion with "guardrails" "will likely ***improve stability***." R.R.382 (emphasis added). Indeed, in support of its comment, SCAN expressly relied on CMS's simulation in the Federal Register of the "CY2018 Star rating[s]," *id.*, in which CMS simulated that "Tukey outer fence outlier deletion ***and a 5 percent guardrail*** had been implemented for the 2018 Star Ratings." 85 Fed. Reg. at 33,833 (emphasis added). And the Wakely Consulting Group issued a Report—cited by CMS—which modeled the financial impact of CMS's new "Tukey outlier" "rerun" proposal: In that Report, "***guardrails were applied*** to limit the change between 2019 and 2020 [the first year in which Tukey was modeled]." R.R.557 (emphasis added); *see also, e.g.*, R.R.510, 601, 639 (citing Wakely); 85 Fed. Reg. at 33,892 (CMS citing Wakely). CMS never disputed commenters' belief that guardrails *would* apply.

Defendants should not be heard to tout (at 34-35) that commenters failed to oppose CMS's "rerun" proposal, when CMS successfully hoodwinked the Medicare Advantage industry by proposing its "rerun" *with* the application of "guardrails" to limit dramatic cut point movements. Instead, commenters' praise for CMS's "with guardrails" proposal for ensuring year-over-year stability is a clear sign that CMS did *not* provide effective notice that it would apply "no guardrails" to balloon cut points and massively defund plans in one year. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (finding notice inadequate where agency proposed an "interpretation that was favorable to the [regulated entities]," explaining that if agency had given notice of the possibility of an adverse change, it would have triggered an "avalanche of comments" in opposition); *CSX Transp., Inc. v. Surface Transp. Bd.,* 584 F.3d

1076, 1080 (D.C. Cir. 2009) (commenters need not "divine [the agency's] unspoken thoughts").

CMS's unexplained reversal from "with guardrails" to "no guardrails" is impermissible under *AT&T*, *Allina* and *Fox*. And this "no guardrails" error ***is independently sufficient to grant SCAN relief, even if the Court were to conclude that CMS's Federal Register preamble controls over its regulation.*** CMS deprived commenters of their right to comment on CMS's *actual* rerun proposal. Had CMS proposed its "no guardrails" methodology for comment, that would have triggered an "avalanche of comments" in opposition, including from SCAN, urging CMS to abandon its "rerun" plan and apply guardrails relative to the *actual* 2023 Star Ratings. *Allina*, 746 F.3d at 1108. This is a global defect that renders invalid the application to SCAN of both of (i) CMS's policy to run its 2023 Star Rating simulation with "no guardrails" relative to the 2022 Star Rating cut points (which is alone enough to resolve the case in SCAN's favor, *see* SCAN Br. 30-31), and also (ii) CMS's "rerun" policy in its preambles in its totality. *See id.*

2. *CMS unlawfully determined SCAN Health's 2024 Star Ratings based on the 2020 Federal Register "simulation" preamble that CMS revoked in 2022*

As SCAN has already briefed in detail (SCAN Br. 31-33), CMS's appeal to its 2020 "simulation" preambles as grounds to "rerun" the 2023 Star Rating cut points is also unavailing because CMS revoked those preambles in 2022, and never attempted to revive them.

In response, CMS argues (at 29-33) that CMS's revocation and deletion of its Tukey outlier deletion regulation from the Code of Federal Regulations in May 2022 was ineffective, because repealing a rule requires notice and comment. But Defendants' argument misapprehends the posture of this case. SCAN is not *objecting* to CMS's *revocation* of its Tukey outlier deletion regulation and "simulation" preamble for failure to follow notice and comment procedures (the typical posture in which this issue arises). Instead, SCAN is seeking to hold CMS accountable not to *enforce* against SCAN a preamble that was *in fact* revoked and never revived.

Defendants' cases (at 29-33) arise in the *opposite* posture, where private parties successfully argue that the *revocation* of (their preferred) rule was *ineffective*. But agencies do not get to enforce revoked rules against citizens by arguing the agency's own revocation was procedurally defective. *Cf. Aerolineas Argentinas v. United States*, 77 F.3d 1564, 1575, 1578 (Fed. Cir. 1996) (finding that once regulations were repealed, agency's imposition of monetary obligations on private parties was an "illegal exaction of moneys to meet an obligation of the government").[5] If, for example, an agency invalidly revokes a rule providing a civil penalty, the agency obviously cannot penalize a citizen under that revoked rule, on the theory that the revocation was invalid.

CMS's 2020 preamble allegedly providing for a simulation of the 2023 cut points had no further force and effect once CMS vacated the very regulation that formed the entire basis for that preamble. *See Nat. Res. Def. Council*, 955 F.3d at 83 (an "interpretive rule" "derive[s] a proposition from an existing document" like a "regulation," rather than the interpretive rule "creating legal effects"). CMS in no way proposed to revive any of the Federal Register preamble from 2020 regarding its proposed "rerun," much less solicited public comment on the "rerun" issue—as CMS rightly concedes (at 33), these issues were not "reopen[ed]" for public comment. CMS did not revive its 2020 preamble after it was revoked.

C. *Defendants' Procedural Objections Fail*

Defendants argue (at 34-37) that SCAN has no *procedural* right to challenge CMS's

[5] CMS's lengthy discussion of *Select Specialty Hospital-Akron, LLC v. Sebelius* is far afield. That case merely confirms that, once a legislative rule (*i.e.*, an addition to the Code of Federal Regulations) goes through notice and comment, CMS may then conform the Code of Federal Regulations to the final legislative rule, even if there was initially a technical error in drafting the Code of Federal Regulations. 820 F. Supp. 2d 13 (D.D.C. 2011). It was not a case, as here, where CMS first adopted, and then deleted regulatory text from the Code of Federal Regulations, and then claimed that the text had never been validly deleted at all. *See id.*

unlawful determination of SCAN's 2024 Star Rating. These arguments all fail.

1. *Defendants' "waiver" arguments are wrong*

Defendants claim (at 34-35) that because SCAN did not comment on CMS's "proposal to rerun the prior year's cut points," SCAN has "waived any challenge to that re-run." Not so.

As detailed above, SCAN did comment directly on CMS's "rerun" proposal *with* the inclusion of guardrails. *Supra* at 17. But it is also beside the point. No statute requires issue exhaustion here, and so Defendants can only appeal to the doctrine of *prudential* issue exhaustion, under which a court may in its discretion find a waiver of an issue not raised before the agency. *See Koretoff v. Vilsack*, 707 F.3d 394, 399 (D.C. Cir. 2013) (Williams, J., concurring) (distinguishing prudential and mandatory exhaustion).

Discretionary issue exhaustion does not apply in the posture of SCAN's challenge. Defendants are gaslighting the Court by pretending that this case is a *pre-enforcement, facial* challenge to an agency's *final rule*. In reality, SCAN brings an *as-applied* challenge to CMS's *determination of SCAN's Star Rating* as 3.5 Stars, rather than 4.0 Stars, by *applying* CMS's unlawful and invalid preambles in a manner that is contrary to the governing regulations. SCAN Br. 28. When a plaintiff attacks a final agency action that applies an unlawful policy, interpretative rule, or regulation against the plaintiff, courts do not ask whether the plaintiff raised that unlawfulness in the underlying notice-and-comment proceeding—often years earlier. That would mean that once an agency promulgates an unlawful regulation, the agency is immunized to apply it against anyone except an opposing commenter. That is not the law.

In Defendants' case *Koretoff*, for example, the D.C. Circuit affirmed judgment against an interest group's *pre-enforcement, facial* challenge to a regulation, as "waived . . . by failing to raise [the issues] during notice and comment." 707 F.3d at 397. But the Court "emphasize[d] that nothing in this opinion affects the [plaintiffs'] ability to raise their [waived] arguments if and

when the Secretary applies the rule." *Id*. at 399. That is because a party may raise new issues not raised in notice-and-comment rulemaking "when a rule is brought before this court for review of further agency action applying it." *Id.* (quoting *Murphy Exploration & Prod. Co. v. U.S. Dep't of Interior*, 270 F.3d 957, 958 (D.C. Cir. 2001)). Thus, "a party that has objected in the rulemaking can raise its claim in a facial challenge in court, and a party attacking the rule in the agency's own *application* proceedings can *similarly* ***extend*** *the attack on appeal from the agency*." *Id.* at 400 (Williams, J., concurring) (emphasis added). As the D.C. Circuit long ago explained, this must be the rule in order to avoid "effectively deny[ing] many parties ultimately affected by a rule an opportunity to question its validity." *Murphy*, 270 F.3d at 959 (citation omitted).

Applying *Koretoff* and *Murphy*, this Court has held in case after case that "a party may challenge the very validity of a regulation when that regulation is applied without waiving arguments that were not raised before the agency in the underlying rulemaking proceedings." *Banner Health v. Burwell*, 126 F. Supp. 3d 28, 68 (D.D.C. 2015) (collecting cases), *aff'd, Banner Health v. Price*, 867 F.3d 1323 (D.C. Cir. 2017); *see also E. Tex. Med. Center-Athens v. Azar*, 337 F. Supp. 3d 1, 13 (D.D.C. 2018) (same). *Koretoff* and *Murphy* also comport with the broader rule that in non-adversarial administrative proceedings—like CMS's non-adversarial determination of SCAN's 2024 Star Rating—prudential issue exhaustion does not apply *at all*. *See Sandoz Inc. v. Becerra*, 57 F.4th 272, 279 (D.C. Cir. 2023).

While the preceding defects are dispositive of Defendants' "waiver" theory, there are more besides. While Defendants complain (at 34-35) that SCAN did not oppose CMS's "rerun" proposal, regulated parties do not, of course, "waive" any challenge to a rule or regulation that was *not even proposed* for exposure to comment (here, "no guardrails"), or, where the agency

affirmatively misleads regulated parties on the fundamental elements of its proposal (*i.e.*, the details of CMS's "rerun"). *See, e.g.*, *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (party could bring challenge based on issue it did *not* raise in rulemaking because "the notice published by the EPA did not provide interested parties with an adequate opportunity to comment"). For all of these reasons, SCAN's challenge to CMS's determination of its Star Rating is not waived.

2. *Defendants' "harmless error" arguments are also wrong*

Defendants argue (at 35-37) that even if CMS *did* determine SCAN's 2024 Star Rating in a manner contrary to CMS's own binding regulations, that error was "harmless" because "Plaintiff was in no way harmed by the fact that the [simulation] proposal and final decision were not codified in the Code of Federal Regulations."

Again, Defendants misconceive the posture of this case. This is not a facial, pre-enforcement challenge. If SCAN prevails on its as-applied challenge to CMS's determination of SCAN's 2024 Star Rating, SCAN will receive the quality bonus payments to which it is legally entitled, plus benefits to its plan benefit design, as well as its reputation and membership, which have already been harmed by CMS's erroneous 3.5-star Star Rating. SCAN Br. 19-20, 43-45. That is not "harmless." Instead, a harmless error is one that has "no bearing on the procedure used or the substance of decision reached." *IBEW, Loc. Union No. 474 v. NLRB*, 814 F.2d 697, 715 (D.C. Cir. 1987); *see also Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1121 (D.C. Cir. 2010) (a harmless error does not "affect the outcome" of the agency action).

Showing harmful error is "not . . . a particularly onerous requirement," and is easily met here. *Jicarilla*, 613 F.3d at 1121. The "procedure used" by CMS was harmful, as it calculated SCAN's Star Rating using the wrong procedural steps, drawn from the wrong source of law. *See IBEW*, 814 F.2d at 715 ("an order may not stand if the agency has misconceived the [source of]

law"); *see also Genus Lifesciences, Inc. v. Azar*, No. 20-cv-00211, 2021 WL 270409, at *3 (D.D.C. Jan. 27, 2021) (a "mistaken interpretation of the governing . . . regulations" that leads to a "mistaken analysis" "crosses the border into arbitrary and capricious territory"). And CMS's errors also harmed the "substance of decision reached," as CMS determined SCAN's 2024 Star Rating as 3.5 stars, rather than 4 stars, reducing payments to SCAN by $250 million. *IBEW*, 814 F.2d at 715; *see also Genus*, 2021 WL 270409, at *3 (harmless error is one where the "outcome" is identical with or without the error). Defendants' contrary position is absurd: "[P]rejudice is obvious" where an agency uses the wrong "methodology" to determine the "revenue" owing to a plaintiff. *Jicarilla*, 613 F.3d at 1121. That is true here: A $250 million error is not "harmless."

Unsurprisingly, Defendants do not cite a single case in which any court has ever held that an agency's violation of its binding regulations by *applying* a *counter-regulatory* interpretation to determine the rights of a regulated party was "harmless." Instead, an agency's action must be set aside where an agency determines a party's rights without "comply[ing] with its own regulations," as "[an] agency is not free to ignore or violate its regulations while they remain in effect." *Nat'l Env't Dev. Ass'ns*, 752 F.3d at 1009 (citations omitted); *see also AT&T*, 970 F.3d at 350.

Moreover, had CMS accurately proposed in 2020 its procedure to apply "no guardrails" to balloon Star Rating cut points in one year, SCAN and others would have objected, and urged CMS to apply the guardrails mandated by CMS's regulations based on the *actual* 2023 Star Ratings—exactly what SCAN did when CMS announced SCAN's 2024 Star Rating. Ex. 1 at 2-8. By "evad[ing] altogether the notice and comment requirements" for CMS's "no guardrails" simulation (*i.e.*, the core features of CMS's "rerun" proposal), CMS committed one of the "most egregious" breaches of notice-and-comment obligations. *Allina*, 746 F.3d at 1109. Since CMS

"wholly failed to provide petitioners . . . the opportunity to comment" on CMS's *actual* "rerun" (simulation) proposal, the error "cannot be considered harmless." *Id.*; *see also NRDC*, 955 F.3d at 85 (same).

In sum, CMS's determination of SCAN's overall 2024 Star Rating using a *simulation* of the 2023 Star Rating cut points, not the *actual* 2023 Star Rating cut points, and without applying *any guardrail* relative to the 2022 Star Rating cut points, was arbitrary and capricious and contrary to law for all the reasons identified above, and should be set aside.

II. CMS Improperly Determined That A Single Flawed Secret Shopper Call Should Lower SCAN's Star Rating From 4 Stars to 3.5 Stars

SCAN's second claim likewise provides a complete and independent basis for relief: CMS improperly determined that SCAN had failed the "C30" "Call Center—Foreign Language Interpreter and TTY Availability" measure on a February 9, 2023 secret shopper call. CMS so-found in two decisions: Initially, CMS issued its first reasoned decision on February 22, 2024, known as the Reconsideration Decision. A.R.445. Then, after SCAN appealed the Reconsideration Decision, CMS issued a Hearing Officer's Decision on March 25, 2024, affirming the reasoning of the Reconsideration Decision. A.R.5.

Both of these decisions erred on the same grounds. First, CMS flouted its regulation, which requires only that an interpreter be "available" within 8 minutes, *i.e.*, connected to the call. Here, the secret shopper was indisputably connected to the interpreter within 6 minutes 35 seconds. Second, CMS arbitrarily and capriciously found that it was proper for CMS to count against SCAN the extensive delay caused by CMS's own secret shopper—a delay unlike other calls SCAN received—in determining that this call failed measure C30.

Excluding the February 9, 2023 secret shopper call from measure C30 (or correcting the call from a "fail" to a "pass") would result in measure C30 increasing from 4 stars to 5 stars, and

raise SCAN's overall Star Rating to 4 stars. CMS should be required to do just that here.

A. *CMS's Determination That No Interpreter Was Available Within 8 Minutes On The February 9, 2023 Test Call Was Inconsistent With CMS's Own Regulation*

CMS violated its own regulation when it found that no interpreter was available within 8 minutes of reaching a customer service agent on the February 9, 2023 secret shopper call. CMS's governing regulation, 42 C.F.R. § 422.111(h)(1)(iii), requires that "interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative . . . ." But here, CMS improperly required not only that the interpreter be available—which occurred at 6 minutes and 35 seconds—but also that CMS's caller had her question posed, repeated, and answered within the 8-minute timeframe.

Defendants argue (at 37-39) that CMS's regulation at § 422.111(h)(1)(iii) is "inapposite" because it does "not even mention Star Ratings" and thus the "text of Section 422.111(h) is irrelevant to the calculation of Measure C30." That is a curious position for Defendants' counsel to take now, because CMS asserted in its two decisions below, consistent with CMS's prior guidance, that 42 C.F.R. § 422.111(h)(iii) *does* provide the governing standard for Star Rating measure C30, "Interpreter Availability."

First, CMS's Reconsideration Decision found that CMS's determination of measure C30 on the February 9, 2023 secret shopper call was proper, explaining that "CMS monitors plan sponsors' Part C and Part D call centers" through its call-monitoring studies, including measure C30, "to ***ensure compliance with regulatory requirements, found at 42 C.F.R. §§ 422.111(h)*** and § 423.128(d), for providing timely and accurate information." A.R.450 (emphasis added). Specifically, CMS explained, "[t]here are two call center measures included in the Part C and D Star Ratings program – one measure [C30] focuses on Part C and the other [D01] on Part D. The measures capture . . . Accessibility of Foreign Language Interpretation[2] ***42 C.F.R.***

§§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii)." *Id.* (underlined language in footnotes).

The Hearing Officer Decision then doubled down, expressly concluding that "***42 C.F.R. §§ 422.111(h) establishes the 8-minute measure for interpreter availability***." A.R.6 (emphasis added). (The Hearing Officer also concluded that CMS's guidance provides an additional gloss on the meaning of § 422.111(h)(iii), but conceded that "42 C.F.R. §§ 422.111(h) establishes the 8-minute measure.") It is too late now for Defendants' counsel to offer a different, post-hoc explanation for the alleged "irrelevance" of 42 C.F.R. § 422.111(h)(1)(iii) to the determination of measure C30, contrary to CMS's decisions below. *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943) (holding that "an administrative order cannot be upheld unless the grounds upon which the agency acted . . . were those upon which its action can be sustained").

The decisions below make sense: CMS's prior guidance says the same thing. When CMS "proposed to amend § 422.111(h)(1)(iii)" to require that "interpreters be available within 8 minutes of reaching the customer service representative," CMS explained that "***performance is measured against this standard in our current monitoring*** and oversight activities," *i.e.* the call monitoring measure C30. 86 Fed. Reg. 5,864, 6,006 (Jan. 19, 2021) (emphasis added); *see also* 85 Fed. Reg. at 9,116 (2020) (proposed rule). Indeed, CMS clearly referenced measure C30, explaining that "data from our ***call center monitoring*** indicates that 95% of plans already meet ***this standard***," *i.e.*, the standard in "§ 422.111(h)(1)(iii)." *Id.* (emphases added). It's not as if CMS has two *different* 8-minute standards, or a different data collection concerning the 8-minute standard, besides C30. CMS explained that, under § 422.111(h)(1)(iii), "80 percent of calls requiring an interpreter ***must be connected to an interpreter within the proposed 8 minutes***." *Id.* at 6,007-08 (emphasis added) (requiring "80 percent of calls being ***connected*** to an interpreter within 8 minutes"). *That* is the requirement that CMS exposed to the notice-and-comment

required by *Allina* and *AT&T*. And *that* is the requirement to fulfill Star Rating measure C30: "[M]any [Star Rating] ***measures*** are based on ***compliance with Medicare rules*** and requirements (for example, ***call center measures*** and appeals measures) and reflect ***compliance with Medicare program requirements***." 85 Fed. Reg. 33,796, 33,834 (June 2, 2020) (emphasis added).

CMS's other guidance that Defendants rely upon, issued without the notice-and-comment required by *Allina*, says the same thing. In CMS's "Call Center Monitoring Accuracy and Accessibility Study Technical Notes" that purport to further define the Interpreter Availability measure C30, CMS explained that its call monitoring "studies are for the purpose of ***monitoring*** the performance of plan sponsors' call centers ***with respect to the standards adopted to implement 42 C.F.R. §422.111(h)(1)***." A.R.481 (emphasis added). CMS explained that measure C30 concerning "Interpreter Availability was tested to determine if the services ***were compliant with 42 C.F.R. §§ 422.111(h)(1)(iii)*** . . . which require interpreters to be available for 80 percent of incoming calls requiring an interpreter within 8 minutes." A.R.509 (emphasis added). CMS has explained that it uses contractors to "monitor the ***performance of plan sponsors' call centers with respect to the standards at 42 C.F.R. § 422.111(h)(1)***," through the "Accuracy & Accessibility Study" that measures "availability of interpreters for individuals," *i.e.*, via measure C30. A.R.457 (emphasis added).

Defendants' desire to evade these prior statements is understandable: § 422.111(h)(1)(iii) unambiguously provides only that "interpreters must be available . . . within 8 minutes of reaching the customer service representative," *i.e.*, the caller "connected to an interpreter" in 8 minutes. 86 Fed. Reg. at 6,007. CMS does not dispute (at 39-40) that SCAN's contracted interpreter was "available" in this plain language sense of being connected to the February 9, 2023 secret shopper and "present or ready for immediate use" at 6 minutes and 35 seconds: He

was already providing interpretation services at that point. Available, Merriam-Webster Dictionary (2024); *see also United States v. Soybel*, 13 F.4th 584, 595 (7th Cir. 2021) ("available" means "present or ready for immediate use"); SCAN Br. 35-37.

Defendants next argue (at 39-40) that, even if § 422.111(h)(1)(iii) does govern the determination of measure C30, they still prevail under that regulation because having an interpreter "available" means that the interpreter must have *completed* answering one full question. Namely, Defendants invent (at 40) their own definition of "available" as "requir[ing] that an interpreter demonstrate that he or she can provide [the] relevant service—here, helping the beneficiary receive answers from a customer service representative." But in its notice-and-comment preamble adopting § 422.111(h)(1)(iii), CMS asserted "available" has its plain meaning: The time it takes to be "connected to an interpreter," not to complete some freewheeling dialogue test. 86 Fed. Reg. at 6,007.

Defendants are of course correct (at 18-19, 40-42) that CMS has unilaterally issued other guidance, without notice and comment, that purports to deem measure C30 "completed" only when *three* conditions are met: upon (i) "establishing contact with an interpreter," (ii) "answering the introductory question," and (iii) "then beginning the first of three general Medicare or plan-specific accuracy questions (phase 4) within eight minutes of reaching a CSR." A.R.488. But under *Allina* and *AT&T*, CMS's unilateral guidance, issued without required notice and comment, contradicts both its binding regulation in § 422.111(h)(1)(iii) and interpretation set forth in CMS's notice-and-comment preamble adopting that regulation, and is thus irrelevant.

Moreover, even if Defendants were correct in their claim that (i) Star Rating measure C30 and (ii) § 422.111(h)(1)(iii) prescribe two entirely different 8-minute standards for interpreter availability—a fantastical coincidence, and contrary to the Reconsideration Decision and

Hearing Officer Decision—that would create more problems for CMS than it solves. CMS has never articulated any rationale for measuring under C30 a different and far stricter standard than its own compliance regulation. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) (holding that agency action is invalid where it "fail[s] to consider an important aspect of the problem"). And CMS has certainly never subjected that more-stringent standard to the notice-and-comment required by *Allina*.

To the extent Defendants are right (at 39-40) that CMS has an interest in measuring not just interpreter availability, but also speed and quality in *delivering* these services, CMS could easily propose a new regulation imposing such a standard, through notice-and-comment rulemaking. For example, CMS could codify its "Interpreter *Accuracy*" test, which measures interpreter competency in answering three substantive questions. *See* A.R.489. It is hard to imagine CMS doing so, since it previously *eliminated* that "Interpreter Accuracy" Star Rating measure, finding it was "not particularly helpful." A.R.500. But regardless, what CMS cannot do under *Allina*, *AT&T*, and *Fox*, is propose through notice and comment a standard of the interpreter being "available," *i.e.* "connected," but use unilateral sub-regulatory guidance, without comment, to impose a far stricter standard.[6]

CMS therefore violated its own regulation in determining that SCAN's interpreter was

[6] Defendants argue (at 39 n.8) that SCAN is seeking "special treatment," because SCAN is seeking correction of only a single call, and Defendants speculate that other calls might have also been impacted by CMS's unlawful departure from its regulation. But, as CMS has emphasized, no other Medicare Advantage plan appealed any call on this specific issue, so it is simply speculation that anyone else was so-impacted. A.R.455. In any event, this is simply how an as-applied (non-facial) challenge to a discrete final agency action—the determination of SCAN's 2024 Star Rating—works. There is no requirement that SCAN *also* launch a facial challenge to CMS's guidance, seeking nationwide vacaturs and injunctions (and, in some judges view, such an approach would in fact be disfavored, *see, e.g.*, *Trump v. Hawaii*, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) (questioning the origins and validity of "nationwide injunctions")).

unavailable within 8 minutes on the February 9, 2023 secret shopper call.

B. *CMS's Determination That No Interpreter Was Available Within 8 Minutes On The February 9, 2023 Test Call Was Also Arbitrary And Capricious*

CMS's determination of measure C30 for the challenged call was also arbitrary and capricious, even under CMS's interpretation of what C30 measures. SCAN's receipt of $250 million in funding from quality bonus payments—and the breadth of benefits that SCAN's over 280,000 members will receive from SCAN's nonprofit health plan in plan year 2025—hinged solely on one failed call and the happenstance of how clearly, quickly, and effectively a CMS *third-party contractor* was able to state her question and clarify herself. CMS's decisions below did not dispute that these extrinsic factors caused the test call to fail, instead finding that it was *appropriate* to count any delays caused by the secret shopper against SCAN, because "any differences in the way they [the questions] were stated is down to the individual caller, just like a non-test call would be, which is what CMS is testing." A.R.455. CMS's Hearing Officer affirmed this reasoning: "How prospective members ask a question will differ from call to call." A.R.6.

That's exactly the point, and demonstrates why CMS's invalid reinterpretation of what C30 requires is arbitrary and capricious. CMS's reasoning violates its own guidance for the Star Ratings program, which requires CMS to evaluate Medicare Advantage plans "fairly and equally" based only on matters that are "under the control of the health or drug plan" to provide a "a true reflection of the plan's quality." 83 Fed. Reg. 16,520-21, 16,584 (Apr. 16, 2018). Rather than defend the actual reasoning of the Reconsideration Decision and Informal Hearing Decision, Defendants offer another post-hoc rationalization. Defendants now argue that any delay was actually the interpreter's fault because, rather than failing to *understand* the secret shopper's malformed, stumbling question, the interpreter actually said he "failed to take notes," *i.e.*, failed

to write down the caller's question. Defs. Br. 40-42 ("CMS, on the other hand, translated 'I missed that' as 'I failed to take notes.'"). But in neither of CMS's decisions below did CMS so much as mention any fault by the interpreter in taking notes, or CMS's supposed "I failed to take notes" transcript. A.R.449-56 (Reconsideration Decision); A.R.5-7 (Informal Hearing Decision). CMS's post-hoc "blame the interpreter" theory cannot be considered now. *Chenery*, 318 U.S. at 95.

There is good reason that CMS's newfound theory was not part of its decisions below: CMS is relying on a secret, self-serving transcript. And the belatedly produced administrative record, *see* Dkt. 22, lays bare what happened: On January 30, 2024—well after SCAN filed its internal administrative appeal, and after it filed its Complaint in this case—CMS requested that its call-center contractor create a transcript of the call, which they did. A.R.1034-35. Dissatisfied with the results of that transcript, CMS responded with "comments" instructing the contractor to edit the transcript. A.R.1034. CMS told its contractor that "if the interpreter admitted to not taking notes and that is why they didn't catch the full question, ***it is very important, and we need that in the transcript***." *Id*. (emphasis added). CMS's contractor complied and added that text into the transcript, stating, the "updated translation is attached." *Id.* CMS did *not* rely on this transcript in its February 22, 2024 Reconsideration Decision, and CMS thus did not send the secret transcript to SCAN as part of the record of that Decision. A.R.445-723. SCAN requested an Informal Hearing on February 29, 2024, without access to CMS's secret transcript. A.R.422-431. Only after SCAN submitted its opening brief to the Hearing Officer did CMS respond in its *opposition* brief in that internal appeal, filed March 12, 2024, finally disclosing its secret transcript, arguing for the first time that the interpreter "failed to take notes." A.R.15, 321. (Under CMS's regulation, SCAN had no right to reply to this new evidence. 42 C.F.R.

§ 422.260(c)). Unsurprisingly, since this argument and the secret transcript were *not* presented or adopted in the underlying Reconsideration Decision being reviewed by the Hearing Officer or provided to SCAN earlier, the Hearing Officer refused to rely on them. A.R.5-6.

Counsel's post-hoc rationalizations and secret evidence are not bases to uphold agency action. *See State Farm*, 463 U.S. at 50; *Chenery*, 318 U.S. at 95. But even if Defendants' argument and evidence were not barred, they fail on their own terms. The only *certified* translation in the record (without CMS's self-serving line-edits) shows that the interpreter could not understand the caller's malformed question about the "medical benefits of uh… Village Health HMO . . . -POS . . .C . . . -SNP." A.R.105 (Interpreter: "Excuse me, ma'am. I missed that. The medical benefits of this village. Can you repeat it, please?"). The caller had to clarify herself, that she was trying to recite "the name of the plan." *Id.* The call recording speaks for itself. Ex. 4 to Plumb Decl. at 17; *see also* A.R.105 (certified transcript).

And even if Defendants were right to "blame the interpreter" for any delay (they are not), that compounds CMS's problems, rather than cures them. CMS has no justification for why SCAN should be penalized hundreds of millions of dollars based on whether a third-party interpreter "takes notes" when actively providing interpretation services well within the 8 minute time frame for "availability." It is CMS that mandated that Medicare Advantage plans must make interpreter services available for all of the "150 to 180 languages" offered by the "largest commercial interpretation service providers in the U.S.," as "these organizations" are the "experts in assessing the languages for which interpretation services are needed." 76 Fed. Reg. 21,432, 21,502, 21,547 (Apr. 15, 2011) (finding that third-party interpreters will cost only "$1.00 per minute" or "$9,933 per year"). It might be one thing if SCAN never hired any interpretation service, or did not have them available during all business hours; but CMS has never explained

how any faults by the "largest commercial interpretation service providers in the U.S." (*id.* at 21,502) in *taking notes* are something "under the control of the health or drug plan," provide a "a true reflection of the plan's quality," or are a non-arbitrary basis to penalize SCAN. 83 Fed. Reg. at 16,520-21. CMS disregarded these "important aspect[s] of the problem." *State Farm*, 463 U.S. at 43.

This is not the way that a well-functioning regulatory regime operates: In 2016, CMS's staff provided the public with the commonsense guidance that if an interpreter's deficient performance "successfully interpreting" undermined a plan's ability to respond to questions, CMS would *not* "count [that] against you" even on the measure of interpreter *accuracy*—a separate measure that is supposed to measure quality of interpretation services. A.R.325. According to CMS's staff, they would "listen" to the "recorded conversation," and if the failure "is due to the failure strictly of the interpreter, I wouldn't hold that against you." *Id.* Subsequently, CMS purported to "clarify" that CMS "would not hold the performance of the interpreter against the plan, generally speaking, so long as the response to the accuracy question is accurate." *Id.* CMS's staff had it right: CMS's call center monitoring measures must account for only matters "under the control of the health or drug plan." 83 Fed. Reg. at 16,521, 16,555. CMS has never justified—and cannot now justify—its contrary decision here.

Here is the key problem: CMS's claim (at 42) that, in essence, "rules are rules" and "CMS implemented them [the rules] exactly as it said it would" ignores that CMS is referring to non-binding guidance documents defining measure C30 that were not promulgated with the required notice-and-comment consistent with the mandates of *Allina.* And under any form of guidance—valid or not—in an informal adjudication, CMS must still treat "like cases alike," *Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007), consider the "important

aspect[s] of the problem," *State Farm*, 463 U.S. at 43, and consider obvious "alternative[s]" "within the ambit of the existing [policy]," *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (citation omitted). Once CMS committed itself only to measure matters under the "control of the health or drug plan" in order to provide "a true reflection of the plan's quality," 83 Fed. Reg. at 16,520-21, 16,560, CMS could not turn around and apply an arbitrary standard to knock down SCAN's Star Rating due to issues outside its control. And CMS needed to consider the fact that SCAN clearly *can* answer the exact same question, *correctly posed*, within the 1 minute 25 seconds left on the call, as shown by the March 24, 2023 secret shopper call. SCAN Br. 38.

For all the foregoing reasons, CMS's determination that no interpreter was available within 8 minutes of the secret shopper reaching a customer service agent on February 9, 2023 was both contrary to law and arbitrary and capricious. CMS's determination should be set aside, and CMS should disregard the February 9, 2023 call in its 2024 Star Rating determination (or, alternatively, measure C30 should be corrected to reflect that SCAN passed this call).

III. It Is Undisputed That If SCAN Prevails On Either Of Its Two Merits Claims, CMS's 2024 Star Rating Determination Should Be Set Aside, And, In Turn, Be Re-Determined In Accordance With Governing Law

In its Opening Brief, SCAN argued (at 5, 43) that because CMS's determination of SCAN's 3.5-star Star Rating was arbitrary and capricious and contrary to law, it must be set aside. 5 U.S.C. § 706(2)(A). SCAN further argued (at 43-45) that the Court should enjoin Defendants from using CMS's unlawful 3.5-star Star Rating in determining SCAN's eligibility for quality bonus payments. SCAN also argued (at 5-6) that the Court should order the Defendants, before June 3, 2024, to recalculate SCAN's Star Rating in compliance with 42 C.F.R. §§ 422.111(h), 422.166(a), 423.186(a), by (i) applying the 5 percentage point guardrail required by CMS's regulation, and (ii) excluding the February 9, 2023 secret-shopper call from CMS's

determination of SCAN's Star Rating (or coding that call as a "pass"). Defendants did not dispute that, if SCAN prevails on the merits, the foregoing relief is proper. Nor did Defendants dispute that all equitable favor the issuance of equitable relief. SCAN Br. 43-45. Defendants have waived any right to dispute these issues. *See, e.g.*, *Witte v. General Nutrition Corp.*, 104 F. Supp. 3d 1, 4 (D.D.C. 2015) (finding that an issue not addressed in defendants' "opposition brief" is "waived").

CONCLUSION

For the foregoing reasons, SCAN is entitled to expedited summary judgment and Defendants' cross-motion should be denied. The Court should enjoin Defendants from using CMS's unlawful 3.5-star Star Rating in determining SCAN's eligibility for quality bonus payments. And the Court should order Defendants, prior to June 3, 2024, to recalculate SCAN's Star Rating in compliance with governing law by (i) applying the required 5 percentage point guardrail in determining SCAN's 2024 Star Rating, and (ii) excluding the February 9, 2023 secret-shopper call from CMS's determination of SCAN's Star Rating (or, alternatively, determining that SCAN "passed" ("completed") the challenged call), and to utilize that recalculated Star Rating for purposes of determining SCAN's eligibility for quality bonus payments.

Dated: April 8, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have electronically filed the foregoing with the Clerk of the Court using CM/ECF system which will send notification of such filing on all counsel of record on April 8, 2024.

Dated: April 8, 2024

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SCAN HEALTH PLAN, *Plaintiff*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants.*	Case No. 1:23-cv-3910-CJN

[PROPOSED] ORDER

UPON CONSIDERATION of Plaintiff SCAN Health Plan's Motion for Expedited Summary Judgment, Defendants Department of Health and Human Services, the Centers for Medicare and Medicaid Services ("CMS"), Xavier Becerra, and Chiquita Brooks-LaSure's ("Defendants'") Cross-Motion for Expedited Summary Judgment, the parties' submissions on these motions, and the entire record, it is **HEREBY ORDERED** that:

1. Plaintiffs' Motion For Expedited Summary Judgment is **GRANTED**;
2. Defendants' Cross-Motion For Summary Judgment is **DENIED**;
3. CMS's calculation of SCAN Health Plan's 3.5-star 2024 Star Rating is **SET ASIDE** and **VACATED**;
4. Defendants are **ORDERED** not to utilize SCAN Health Plan's vacated 3.5-star 2024 Star Rating in connection with any quality bonus payment eligibility decisions;

5. Defendants are **ORDERED** to recalculate, prior to June 3, 2024, SCAN Health Plan's 2024 Star Rating consistent with the Court's Memorandum Opinion On Plaintiff's Motion For Expedited Summary Judgment, namely:
    a. Defendants shall apply the required 5 percentage point regulatory guardrail relative to prior-year actual measure-specific cut points in determining SCAN Health Plan's 2024 Star Rating, and
    b. Defendants shall exclude the February 9, 2023 secret-shopper call from Defendants' determination of SCAN Health Plan's Star Rating (or, alternatively, shall deem that call "completed"); and
6. Defendants are **ORDERED** to utilize SCAN Health Plan's recalculated 2024 Star Rating for purposes of determining SCAN Health Plan's eligibility for quality bonus payments for the 2025 Medicare Advantage plan year; and
7. This matter is **REMANDED** to CMS for further proceedings consistent with the Court's Opinion.

This is a final appealable Order.

IT IS SO ORDERED.

SO ORDERED this ____ day of _____, 2024.

HONORABLE CARL J. NICHOLS
United States District Judge