UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELEVANCE HEALTH, INC., et al. Plaintiffs, v. **XAVIER BECERRA**, in his official capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services and **CHIQUITA BROOKS-LASURE**, in her official capacity as Administrator, Centers for Medicare and Medicaid Services Defendants.	Case No. 1:23-cv-03902-RDM

REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Plaintiffs Elevance Health, Inc. f/k/a Anthem Inc. ("Elevance"), along with its affiliated entities AMH Health, LLC; Anthem Healthchoice HMO, Inc.; Anthem Health Plans, Inc.; Anthem Insurance Companies, Inc.; Blue Cross Blue Shield Healthcare Plan of Georgia, Inc.; Community Care Health Plan of Louisiana, Inc.; Freedom Health, Inc; Healthkeepers, Inc. (the "Health Plan Plaintiffs," and collectively with Elevance, "Plaintiffs"), through their undersigned counsel, hereby submit this Reply in support of Plaintiffs' Motion for Summary Judgment and Opposition to Defendants' Cross-Motion for Summary Judgment.

INTRODUCTION

Plaintiffs bring this case to challenge CMS's failure to comply with the plain regulatory requirement set forth in 42 C.F.R. § 422.166(a)(2)(i) to apply guardrails to calculate Medicare Advantage Star rating cut points (the "Guardrail Requirement"). The Guardrail Requirement states: "Effective for the Star Ratings issued in October 2022 and subsequent years, 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). That regulation further defines the cap as "equal to 5 percentage points . . . or 5 percent" depending on the measure's type of scale. *See id.* For 2024 Star Ratings, there is no dispute that CMS applied guardrails in a way that caused cut points to move more than 5 percent from 1 year [i.e., 2023] to the next [i.e., 2024]" in violation of the Guardrail Requirement. Specifically, CMS violated the regulation by retroactively applying the Tukey statistical methodology to create simulated 2023 cut points, and then used those simulated 2023 cut points instead of actual 2023 cut points when applying guardrails. As result of using those simulated cut points, the majority of the cut points increased by more than 5 percent from 2023 to 2024. This is without question a violation of the plain text of the Guardrail Requirement.

Instead of addressing Plaintiffs' core arguments, CMS's opposition and cross-motion ("CMS Opposition") attempts to obfuscate the issues by making two fundamentally flawed arguments. First, CMS fatally mischaracterizes the nature of this dispute as a challenge to the rule-making process to implement the Tukey statistical methodology (the "Tukey Methodology") starting in 2024. It is not a facial challenge the Tukey Methodology rulemaking. The Tukey Methodology was inserted as a sentence into 42 C.F.R. § 422.166(a)(2)(i) in a final rule dated June 2, 2020 (notably after the Guardrail Requirement was added by a final rule dated April 16, 2019). The regulatory language implementing the Tukey Methodology language states that "[e]ffective for the Star Ratings issued in October 2023 [i.e., for 2024 Star Ratings] 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).[1] While CMS had missteps in the rulemaking process to insert that language into 42 C.F.R. § 422.166(a)(2)(i), those missteps are not the basis for Plaintiffs' challenge, as CMS contends. Rather, Plaintiffs bring an as-applied challenge based upon the undisputed fact that CMS violated the Guardrail Requirement in calculating Plaintiffs' 2024 Star Ratings when it used guardrails that allowed cut points to move more than 5 percent from the prior year. Therefore, CMS's lengthy arguments going to the rule-making process are fundamentally misplaced.

Second, after attempting to mischaracterize the dispute, CMS then argues that certain statements made during rulemaking to implement the Tukey Methodology should be given the effect of law and enforced over the plain language of the Guardrail Requirement. CMS argues that these preamble statements have the effect of law. However, CMS's argument violates a

[1] Each year, Star ratings are released to the public in October for the next year. *See* 85 Fed. Reg. 33796, 33797 (June 2, 2020) (A.R. 001026). Therefore, Star ratings released in October 2023 are for 2024 Star ratings.

fundamental tenet of rulemaking, which is that language in a preamble does not create law and certainly does not override regulatory text. Equally unavailing are CMS's attempts to excuse its conduct by arguing that Plaintiffs should have been aware of its intention to violate the Guardrail Requirement based on information published in so-called "simulations" posted to its website, as it is black letter law that agencies cannot override the law through issuance of sub-regulatory guidance. As such, CMS's arguments relating to the preamble text and sub-regulatory guidance fail.

In the end, this case is straight-forward: CMS violated the Guardrail Requirement set forth in 42 C.F.R. § 422.166(a)(2)(i) when setting 2024 Star rating cut points because the cut points undisputedly moved more than 5 percent from 2023 cut points. CMS's illegal actions were caused when it applied the Tukey Methodology to create simulated 2023 cut points, a year earlier than allowed under law, to which it applied the 5 percent guardrail instead of applying the guardrail to the actual 2023 cut points. As a result, CMS has violated the law and acted arbitrarily and capriciously.

ARGUMENT

I. CMS VIOLATED THE GUARDRAIL REQUIREMENT WHEN CALCULATING 2024 STAR RATINGS.

A. CMS Improperly Characterizes This Case As A Challenge To The Rule-Making Process to Implement the Tukey Methodology and Not an As-Applied Challenge to CMS's Violation of the Guardrail Requirement.

Plaintiffs' core point is simple: CMS violated the plain language of the Guardrail Requirement set forth in 42 C.F.R. § 422.266(a)(1)(i). Tellingly, CMS largely ignores that argument and instead attempts to contort Plaintiffs' claims into a rule-making challenge to the Tukey Methodology. But Plaintiffs do not challenge the rulemaking process. Rather, Plaintiffs challenge CMS's final agency action in calculating 2024 Star Ratings in a way that run afoul of

the Guardrail Requirement at 42 C.F.R. § 422.166(a)(2)(i). And it is because CMS violated its own regulation that Plaintiffs seek relief from this Court to set aside CMS's unlawful final agency action. *See* 5 U.S.C. § 706(2)(A); *Scott & White Health Plan v. Becerra*, No. 22-cv-3202 (CRC), 2023 WL 6121904, at *6 (D.D.C. Sept. 19, 2023) (setting aside agency action as contrary to law and holding that the agency's "decision must be set aside because it is clearly contrary to [the operative regulation's] plain language") (citation omitted), *appeal dismissed*, No. 23-5264 (D.C. Cir. Jan. 9, 2024); *Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("[A]n agency action may be set aside as arbitrary and capricious if the agency fails to comply with its own regulations.") (citation omitted) (internal quotation marks omitted).

Thus, to prevail, Plaintiffs need only show that CMS violated its own regulation. As set forth in greater detail in its opening brief, CMS clearly did so. The Guardrail Requirement of 42 C.F.R. § 422.166(a)(2)(i) is clear and unambiguous. Indeed, CMS *does not contend otherwise*. The regulation states, in pertinent part:

> . . . Effective for the Star Ratings issued in October 2022 **and subsequent years, 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. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap).** New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

42 C.F.R. § 422.166(a)(2)(i) (2024) (emphasis added). Critically, there is no dispute that CMS in fact set cut points for 2024 Star Ratings that increased by more than 5 percentage points relative to the cut points used for 2023 Star Ratings. The only dispute is whether the emphasized text permits CMS to apply guardrails using *simulated* 2023 Star Rating cut points that were never used in 2023. Nothing in the plain language permits CMS to use simulated cut points.

First, as Plaintiffs explained in their opening brief, the text of the Guardrail Requirement requires a "guardrail" to be applied to ensure that cut points "do not increase or decrease more than the value of the cap from 1 year to the next." Dkt. 17[2] at 27 (quoting 42 C.F.R. § 422.166(a)(2)(i)) (emphasis added). This language contemplates a year-by-year comparison of the cut points used. CMS accuses Plaintiffs of "wish[ing] to read additional words into the regulatory text[,]" pointing out that the regulation does not say "*actual, unadjusted* cut points." *Id.* at 28. While the regulation does not expressly use the term "*actual* cut points" (it says "cut points"), the only natural reading of that phrase is the actual cut points used. Lest there be any doubt, "guardrail" is defined by regulation 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." 42 C.F.R. § 422.162(a) (emphasis added). The language that the "prior year's measure-threshold-specific cut point" is to be used clearly and unequivocally contemplates the actual prior year cut points and not some simulated or hypothetical cut points. To apply any other reading would be wholly inconsistent with the purpose of guardrails, which are designed to prevent fluctuation by more than 5 percentage points *"from 1 year to the next." See* 84 Fed. Reg. 15680, 15754 (Apr. 16, 2019); *see also* 87 Fed. Reg. 27704, 27813-14 (May 9, 2022) ("To increase the predictability of the cut points used for measure-level ratings, in the April 2019 final rule (84 FR 15761), we adopted a rule that, starting with the 2022 Star Ratings, guardrails would be implemented for measures that have been in the program for more than 3 years. As specified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), the guardrails ensure that the

[2] Defendants filed a combined cross-motion for summary judgment and opposition brief at both Dockets 17 and 18. Because these docket entries at 17 and 18 are identical, Plaintiffs cite to Docket 17 only throughout.

measure threshold-specific cut points for non-CAHPS measures do not increase or decrease more than 5 percentage points from 1 year to the next.").

Indeed, CMS proposed to *eliminate* guardrails in 2022 expressly because the guardrails act as a hard cap on cut point movement from one year to the next. *See* 87 Fed. Reg. 79452, 79625-26 (A.R. 001314-15) ("A cap on upward movement can inflate the measure-level Star Ratings if true improvements in performance cannot be fully incorporated in the current year's ratings. If overall industry performance shifts upward on a measure, the Star Ratings cut points affected by a cap for that measure may not fully take into account this upward shift in industry performance . . . . [W]e now have evidence from the 2022 and 2023 Star Ratings that shows that unintended consequence of the policy. For example, for the 2023 Star Ratings for Part C Osteoporosis Management in Women who had a Fracture, the four star threshold without the cap was greater than or equal to 60 percent, but this threshold was reduced to greater than or equal to 55 percent when guardrails were applied. In effect, the cap makes it easier for contracts to receive four stars than it would have been if there was no cap."). However, CMS ultimately declined to amend § 422.166(a)(2)(i) and left the Guardrails Regulation intact. 88 Fed. Reg. 22120, 22121 (Apr. 12, 2023) (A.R. 002480). Thus, there is not *any* question that the guardrails are intended to act as a cap on cut point movement from one year to the next based upon actual cut points.

Second, CMS itself interpreted and historically applied the Guardrail Requirement consistent with Plaintiffs' position. Indeed, when CMS applied the 5 percent Guardrail Requirement in October 2022 (for 2023 Star Ratings), CMS applied a 5 percent guardrail based on the *actual* cut points from the 2022 Star Ratings. *See* CMS, *Medicare 2023 Part C & D Star Ratings Technical Notes*, 17 (Jan. 19, 2023), https://www.cms.gov/files/document/2023-star-ratings-technical-notes.pdf ("[E]ach 1 to 5 star level cut points is compared to the prior year's

value and capped at an increase or decrease of at most 5 percentage points . . . ."); *id.* at 147 (applying "5 percentage point" guardrail to the "prior year's cut point"). CMS furthermore reduced cut points when they exceed the 5 percent cap. *See* 87 Fed. Reg. at 79625-26 (A.R. 001314-15). In other words, CMS's interpretation of the very same regulation just over a year ago aligned with Plaintiffs' reading today. CMS adhered to the unambiguous language of the Guardrail Requirement for 2023 Star Ratings, but then conducted an about-face for 2024 Star Ratings.

Third, CMS ignores Plaintiffs' argument that the agency also violated the plain language of the Guardrail Requirement by applying the Tukey Methodology a year earlier than permitted by law. As Plaintiffs explained in their opening brief, the Tukey Methodology was included in 42 C.F.R. § 422.166(a)(2)(i) effective for 2024 Star Ratings and states: "*Effective for the Star Ratings issued in October 2023* [*i.e.*, for 2024 Star Ratings] and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed." (emphasis added). In other words, CMS's regulatory authority to implement Tukey commenced "[e]ffective for the Star Ratings issued in October 2023" and only applied for "subsequent years." *Id.* But by applying the Tukey Methodology to create simulated cut points for 2023 Star Ratings and then using those simulated cut points for purposes of applying guardrails, CMS unequivocally applied the Tukey Methodology a year earlier than permitted by law. The plain regulatory text does not permit CMS to apply the Tukey Methodology prior to 2024 Star Ratings, and CMS violated that language by retroactively applying the Tukey Methodology to simulate cut points for 2023 Star Ratings (*i.e.*, those that were issued in October 2022). Yet, CMS's brief is conspicuously silent on this clear violation of law.

Thus, CMS acted contrary to law and its actions must be set aside. *See Scott & White*, 2023 WL 6121904, at *6 (holding that CMS's decision "must be set aside because it is clearly contrary to [the relevant regulation's] plain language") (citation omitted).

B. CMS Largely Ignores the Plain Language of the Guardrail Requirement and Omits the Rulemaking First Implementing that Regulation.

After attempting to contort this case into a rule-making challenge, CMS spends just three paragraphs of its 37-page brief arguing that the "better reading" of the Guardrail Requirement is that *simulated* cut points should be used. *See* Dkt. 17 at 27–28. Specifically, CMS argues that if the Guardrail Requirement is meant to mean actual cut points, that "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." *Id.* at 28. CMS continues that the "better reading is that Tukey is consistently applied in both years." *Id.*

CMS's explanation that it seeks an "apples to apples" comparison is not a valid justification to violate the plain language of the Guardrail Requirement or the regulatory language implementing the Tukey Methodology. Nothing about the plain and unambiguous language of the regulation, nor its purpose, gives CMS license to throw out cut points *actually* used in 2023 and replace them with simulated cut points that were never used. Nor does the plain language permit CMS to retroactively apply the Tukey Methodology.

Moreover, CMS's interpretation actually would result in inconsistent application. To be sure, CMS argues that for 2024 Star Ratings, it should apply the mandated guardrail to simulated 2023 cut points after applying the Tukey Methodology. However, as set forth above, in calculating 2023 Star Ratings, CMS used 2022 *actual* cut points. And undoubtedly, when calculating 2025 Star Ratings, CMS will apply a guardrail using 2024 *actual* cut points. Then again, in calculating 2026 Star Ratings, CMS will apply a guardrail using 2025 *actual* cut points, and so on. Thus,

CMS's interpretation would create an anomaly where *only* 2024 Star Ratings are calculated using *simulated* cut points for the prior year, whereas every other year will use *actual* cut points for the period year—a plainly inconsistent approach. On the other hand, Plaintiffs' interpretation sensibly would result in CMS using *actual* cut points each year—a clearly *consistent* approach.

In addition to the fact that CMS barely addresses the plain regulatory language for the Guardrail Requirement, the Federal Register in which the Guardrail Requirement was originally promulgated is conspicuously absent from the Administrative Record CMS filed in this case. *See* 84 Fed. Reg. 15680 (Apr. 16, 2019); *see also* Dkt. 16 (Notice of Filing Certified List of the Contents of the Record). This final rule, published in the Federal Register and codified in the Code of Federal Regulations defines what a guardrail is and adds guardrails into the regulatory scheme for determining cut points for the first time. The original version of the rule is also important because it shows how guardrails were originally intended to be applied before the Tukey Methodology was ever proposed. *Compare* 84 Fed. Reg. 15680, 15830 (Apr. 16, 2019) (finalizing the Guardrail Requirement in 42 C.F.R. § 422.166(a)(1)(i) in 2019) *with* 85 Fed. Reg. 9002, 9009 (Feb. 18, 2020) (A.R. 00008) (proposing the Tukey Methodology for the first time).

In finalizing the Guardrail Requirement, CMS explained that "[t]o increase the predictability of the cut points we also proposed a second enhancement to the clustering algorithm: A guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. We proposed a guardrail of 5 percent to be a bi-directional cap that restricts movement both above and below the prior year's cut points." 84 Fed. Reg. at 15754. At that time, outlier deletion methods were being considered, but no method, including the Tukey Methodology, had been proposed—let alone finalized. *Id*. at 15756 ("CMS will continue to evaluate [outlier removal methods] and . . . will consider proposing outlier deletion in future rulemaking."). The Guardrail

Requirement stood on its own as a method of increasing predictability of cut points from year to year.

Under the APA, the Administrative Record is intended to include the entire record considered by the agency. *See* 5 U.S.C. § 706 (instructing that the court "shall review the whole record[.]"); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971) (finding "review is to be based on the full administrative record that was before the Secretary at the time he made his decision"). Absence of the Guardrail Requirement from the Administrative Record signals that CMS did not consider this independent obligation and the important regulatory history around it, including the definition or original intent of guardrails, despite leaving the guardrail definition and regulation unchanged in subsequent rulemaking. This lack of consideration is, on its own, arbitrary and capricious. By ignoring these important codified provisions, CMS violated the previously existing, independent obligation imposed by the Guardrail Requirement, to apply a 5 percent bi-directional cap that restricts movement both above and below the prior year's cut points.

C. CMS Cannot Override The Plain Language of the Guardrail Requirement With Preamble Language.

1. CMS's Codified Regulations Control Over Statements In Federal Register Preambles That Lack The Force And Effect Of Law.

Perhaps recognizing that its interpretation is not supported by the plain regulatory text, CMS improperly argues that scattered statements from rulemaking preambles should be given the force of law to contravene the plain regulatory text. *See* Dkt. 17 at 24-27. Specifically, CMS showcases a single seven-word quote from one such preamble, in which CMS stated: "we *will* rerun the prior year's thresholds." Dkt. 17 at 26 (citing 85 Fed. Reg. at 33835 (A.R. 001064)) (emphasis in original). According to CMS, "[t]here 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 [a] Memorandum explicitly stating just that." Dkt. 17 at 26. The preamble language CMS cites—and the "simulations" CMS published on its website—lack the force and effect of law and cannot override the plain regulatory text.[3]

This Circuit and courts across the country have held—time and again—that preamble language does not have the force and effect of law and cannot be used to contradict plain regulatory text. That is because "a preamble does not create law; that is what a regulation's text is for." *Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 237 (D.D.C. 2014). As the D.C. Circuit has recognized, 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.'" *AT&T Corp. v. FCC*, 449 U.S. App. D.C. 106, 112 (D.C. Cir. 2020) (quoting *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 539 (D.C. Cir. 1986)); *see also United Steel, Paper & Forestry, Rubber, Mfg., Energy, Allied Indus. & Serv. Workers Int'l Union v. MSHA*, 925 F.3d 1279, 1283-84, 1284 n.2 (D.C. Cir. 2019) (rejecting the agency's argument that the preamble to a rule expressed the agency's intention in a way that contradicted the plain language of the codified regulation, explaining that the preamble "lacks the force and effect of law."); *Blanco v. Samuel*, 91 F.4th 1061, 1076 (11th Cir. 2024) ("[W]e are unaware of any authority suggesting that the language an agency uses in a preamble should be awarded the same weight as if the agency chose to formally use the language in the regulation itself.") (footnote omitted); *Peabody Twentymile Mining, LLC v. Sec'y of Labor*, 931 F.3d 992, 998 (10th Cir. 2019) ("[W]hile the preamble can inform the interpretation of a regulation, it is not binding and cannot be read to conflict with the language of the regulation itself.") (citations omitted).

[3] CMS admits that "[t]he meaning and intent of section 422.166(a)(2)(i) are clear[.]" Dkt. 17 at 29. Therefore, by CMS's own admission, the court need not evaluate the preamble, which is not law.

Indeed, in *AT&T Corp.*, the D.C. Circuit rejected the agency's view that "its explanatory statements, published in the Federal Register, should be treated as part of the binding regulation." *Id*. at 112. There, the D.C. Circuit explained that "where . . . there is a discrepancy between the preamble and the Code, it is the codified provisions that control." *Id*. at 113. "For example, 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.* That is because a "preamble cannot . . . be used to contradict the text of the . . . rule at issue." *Tex. Children's Hosp. v. Azar*, 315 F. Supp. 3d 322, 334 (D.D.C. 2018) (citation omitted); *see also Eco Tour Adventures, Inc. v. Zinke*, 249 F. Supp. 3d 360, 372 (D.D.C. 2017) ("An agency interpretation that conflicts with an unambiguous regulation is substantively invalid[.]") (citations omitted) (internal quotation marks omitted). Accordingly, where an agency's "regulation itself is clear, [a court] need not evaluate . . . the preamble, which itself lacks the force and effect of law." *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018) (citations omitted).

As a result, CMS's attempt to rely upon preamble provisions to contradict the plain regulatory language is improper. It is worth noting that CMS does not assert that the Guardrail Requirement is ambiguous and, therefore, reference to the preamble is required to interpret the Guardrail Requirement. To the contrary, CMS unequivocally states that the regulation is clear and unambiguous. Dkt. 17 at 29. Nor does CMS dispute that it interpreted that regulation in lockstep with Plaintiffs just a year ago. But having departed from the plain language of the regulation, CMS now seeks refuge in statements across multiple preambles that appear nowhere in the operative regulation and cannot be given the force of law.[4]

[4] CMS even reaches beyond statements from preambles and makes much of the fact that it displayed on its website "simulations" of the 2023 Star Rating cut points with the Tukey Methodology applied. Whether or not CMS published simulations on its website has absolutely

After arguing that the preamble has the effect of law, CMS then argues that the cases Plaintiffs cited for the proposition that the text of a regulation controls over that of a preamble "involve situations where the Code of Federal Regulations text directly contradicts the preamble." Dkt. 17 at 27, n.4 (citing Dkt. 15 at 29). CMS then states that "nothing in the regulation contradicts the preamble." *Id*. However, as set forth above, the text of the Guardrail Requirement refers to measure-specific cut points and requires implementation of guardrails to ensure that cut points "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). The only plausible reading is that this means the actual cut points each year, whereas CMS's actions when implementing the Tukey Methodology to use *simulated* cut points for one year contradicts the plain language of the Guardrail Requirement.

Likewise, the preamble contradicts the regulatory definition of "guardrail," which is defined 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*." 42 C.F.R. § 422.162 (emphasis added). Nothing about this definition sanctions CMS to "rerun the prior year's thresholds" and replace the prior year's cut point with "simulated" or "rerun" (whichever modifier CMS elects to use) cut points. Doing so not only contradicts the plain meaning of "cut points" but guts the purpose of the regulatory requirement that cut points do not fluctuate by more than 5 percentage points "from 1 year to the next."

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no impact on this case. Nothing about a "simulation" posted on CMS's website has any bearing on whether CMS violated its own regulation when calculating 2024 Star Ratings. Nor can CMS make or amend law by publishing "simulations" on its website. *See, e.g., Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808, 1817 (2019) (holding that the government's website announcement, which changed a substantive legal standard, violated the Medicare Act). This is a red herring.

CMS's interpretation even contradicts the plain language of the Tukey Methodology regulation, which states that Tukey will be used "[e]ffective for the Star Ratings issued in *October 2023 and subsequent years*"—i.e., for 2024 Star Ratings. 42 C.F.R. § 422.166(a)(1)(i) (emphasis added). It did not permit CMS to "rerun the prior year's thresholds" (as the preamble statement reads), as doing so has the effect of implementing Tukey retroactively to the Star Ratings issued in October 2022 (those used for 2023 Star Ratings). Accordingly, CMS's actions are contrary to the plain regulatory text of both the guardrail and the Tukey Methodology regulatory language.

2. CMS's Belated Assertion That It Did Not Want To "Unnecessarily Complicate The Regulation" By Codifying The Preamble Statements It Now Relies Upon Is Unavailing.

In support of its attempt to elevate the preamble language to the full force and effect of law, CMS argues that it did not include the preamble language in the final codified regulation because it did not want to "unnecessarily complicate the regulation[.]" *See* Dkt. 17 at 15 ("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."); *id.* at 27 ("CMS sometimes promulgates rules or large portions of rule [sic] without codifying regulations at all so as not to overly complicate the already voluminous Code of Federal Regulations.") (footnote omitted). That defense in unavailing.

First, it is a post-hoc rationale that appears for the first time in CMS's brief. Indeed, CMS cites no evidence in the Administrative Record or otherwise to support the argument that it elected not to carry over into the regulation the preamble statements it now relies upon out of concern for overcomplicating the regulation. It is a litigation position, nothing more.

Second, it strains credulity that CMS would have held out of the regulation a material change to the process for calculating Star Ratings out of concern for overcomplicating the Code of Federal Regulations, especially since including it would amount to a single sentence (and

perhaps even a clarifying phrase). As just an example of how easy it would have been, CMS could have simply stated in the codified regulation: "In the first year of implementation of Tukey for the Star Ratings issued in October 2023, the prior year's cut points will be simulated with Tukey applied for purposes of calculating the guardrail." Indeed, even a cursory review of 42 C.F.R. § 422.166 (Calculation of Star Ratings) demonstrates that the process for calculating Star Ratings is complex, to say the least. For instance, the subsection of the regulation within which the Guardrail Requirement sits, 42 C.F.R. § 422.166(a)(2) ("Clustering algorithm for all measures except CAHPS measures"), itself contains numerous sub-provisions with nuanced and step-by-step instructions befitting of an *algorithm* which carries significant consequences. CMS could have added a clarifying sentence that would have blended in seamlessly, but it did not.

Finally, the fact that CMS's decision to rerun the prior year's cut points "applied only to calculations for one year," Dkt. 17 at 15, is not a valid reason to stop short of amending the regulation and instead attempt to do so through the backdoor by later invoking statements from preambles. Nor is it consistent with CMS's past practice. That is, when CMS has chosen to make one-year *ad hoc* adjustments to the methodology by which it calculates Star Ratings, CMS has consistently published those one-year adjustments in the Code of Federal Regulations. *See, e.g.*, 42 C.F.R. § 422.166(f)(1)(i) (stating rules to apply "[f]or the 2022 Star Ratings only"); *id.* § 422.166(i)(11) (providing "[s]pecial rules for the 2022 Star Ratings only"); *id.* § 422.166(i)(12) (providing "[s]pecial rules for the 2023 Star Ratings only"); *id*. § 422.166(j) (stating "Special rules for 2021 and 2022 Star Ratings only"). This too is the case for the Guardrail Requirement specifically. *See* 42 C.F.R. § 422.166(a)(2)(i) ("Effective for the Star Ratings issued in October 2023 and subsequent years . . . ."); *id.* ("Effective for the Star Rating issued in October 2022 and subsequent years . . . ." CMS's post hoc defense that it did not want to "unnecessarily complicate

the Regulation" by codifying the preamble statements it now relies upon cannot bear its own weight.

3. The Case Law CMS Cites In Support Of Its "Preamble Defense" Is Inapposite.

CMS cites to cases in which the courts generally found the preamble language at issue to be a valid agency interpretation of the regulation promulgated in the notice and comment rulemaking in which the preamble language was found. That is unlike the situation here, where the preamble language CMS is straining to give the force of law would abrogate an entirely independent regulatory obligation that was promulgated through a separate notice and comment rulemaking almost a year before the Tukey rule was ever even proposed. *See* 84 Fed. Reg. at 15830 (promulgating the Guardrail Requirement); *see also* 85 Fed. Reg. at 9009, 9043 (A.R. 000008, 000042) (proposing the Tukey Methodology without proposing any change to the Guardrail Requirement earlier promulgated).

In particular, CMS relies on *St. Helena Clear Lake Hosp. v. Becerra*, to support its position that the preamble in the instant case may be relied on as though it were the regulation itself. *See* Dkt. 17 at 25-26 (citing *St. Helena Clear Lake Hosp. v. Becerra*, No. 1:19-cv-00141 (CJN), 2021 WL 1226713 (D.D.C. 2021), *aff'd*, 30 F.4th 301 (D.C. Cir. 2022)). The preamble language in *St. Helena*, however, was not published to change an earlier and separate regulatory requirement promulgated through notice and comment rulemaking. *See St. Helena*, 2021 WL 1226713, at *2-3. Instead, the *St. Helena* preamble language, which the *St. Helena* court referred to as an interpretation of the regulation at issue, *see id*. at *6-7, explained CMS's policy regarding prohibiting Critical Access Hospital reimbursement for the cost of compensating any physicians who are not present in the facility but are on call, and was included in the first series of regulations governing Critical Access Hospital reimbursement in 1998. *Id*. at *2. The policy described in the

preamble language was so entrenched that a Congressional directive was later required to force CMS to enact a regulation providing reimbursement for emergency room physicians who are not present in the facility but are on call. *Id*. at *3. St. Helena challenged the CMS policy on arbitrary and capricious and procedural grounds, seeking reimbursement for specialty on-call physicians other than emergency room physicians. *Id*. at *5-7. The court found that "St. Helena has failed to demonstrate that the Board's interpretation was 'plainly erroneous or inconsistent'" with the regulation at issue, that "[t]he Secretary is not required to address every conceivable reasonable cost policy through notice and comment rulemaking," and even if it were, the policy had appeared in published rulemaking since 1998 and had not changed since, except for the narrow exception promulgated in 2001, allowing reimbursement for the cost of compensating emergency room physicians who are on call but not present in the facility. *Id*. at *7; *see also St. Helena Clear Lake Hosp. v. Becerra*, 30 F.4th 301, 304-305 (D.C. Cir. 2022) (affirming the district court and finding the policy described in the preamble to the "*critical* key regulation" was reasonable in light of that regulation) (emphasis in original). Nowhere in these decisions does a court grant preamble language the power to change an independent, validly promulgated regulation, as CMS would have this court do now.

The other cases relied upon by CMS similarly miss the mark. *See e.g., Beaumont Hosp.-Wayne v. Azar*, No. 18-12352, 2019 WL 5455415, at *7, *9-10 (E.D. Mich. Oct. 24, 2019) (noting that the relevant preamble language appeared in the same notice of rulemaking that codified the regulation the preamble language was meant to interpret, finding that "interpretive guides are entitled to some weight" and finding that the Administrator's decision "was not contrary to law."); *Defs. of Wildlife v. Zinke*, 849 F.3d 1077, 1080-1087 (D.C. Cir. 2017) (finding that a preamble analyzing the gray wolf population in Wyoming, and requiring Wyoming to adhere to its own State

conservation laws, was consistent with the relevant regulation and statutes, which would remove the gray wolf from the endangered list in Wyoming); *Chem. Waste Mgmt., Inc. v. EPA*, 869 F.2d 1526, 1534-35 (D.C. Cir. 1989) (evaluating the Plaintiffs' challenge that the agency failed to engage in adequate notice and comment rulemaking, and whether those rules operated retroactively); *United States v. Acquest Transit LLC*, No. 09CV55S, 2020 WL 3042673, at *21-24 (W.D.N.Y. June 4, 2020) (evaluating a preamble that did not conflict with a regulatory requirement).

None of these cases has facts analogous to the facts of this case. Not one of these courts allowed an agency to change a prior, valid and independent, notice and comment regulation through the use of a later preamble statement. Nor is CMS's argument that the preamble language is merely an aid in interpreting the Guardrail Requirement. To the contrary, CMS's position is that the preamble language itself allows CMS to create simulated cut points for purposes of applying guardrails in calculating 2024 Star Ratings. CMS's attempt to abrogate its own guardrails regulations is a clear violation of law that is not permitted by the APA.

D. CMS's Error Was Not "Harmless"

CMS argues that any error on its part was "harmless." This argument rests upon CMS's fundamental misconstruction of this case. According to CMS, the preamble to which it cites provided sufficient notice of its intent to rerun the 2023 cut points and its "removal of the Tukey sentence from the Code of Federal Regulations text in 2022" was "inadvertent." *See* Dkt. 17 at 38. Therefore, according to CMS, any error on the part of CMS was "harmless." *Id*. at 39.

CMS's argument completely misses the point.[5] Plaintiffs are not challenging the rulemaking process to implement the Tukey Methodology, including when CMS "inadvertently"

[5] CMS spends approximately four and a half pages of its brief arguing the validity of the rulemaking surrounding the inadvertent removal and then reinsertion of the Tukey outlier deletion

removed the Tukey Methodology language from the Code of Federal Regulations. As explained above, Plaintiffs' calculation of 2024 Star Ratings violated the Guardrail Requirement in several respects, including by replacing the actual 2023 cut points with simulated cut points, applying guardrails to those simulated cut points, and applying Tukey retroactively to Star Ratings issued in 2022 (for 2023 Star Ratings) a year earlier than permitted by law. CMS's actions were contrary to law and arbitrary and capricious. Its violation of the Guardrail Requirement exposes Plaintiffs to hundreds of millions of dollars in capricious loss. That error is far from "harmless."

E. CMS Is Not Entitled Deference

CMS contends—in a single sentence—that although "[t]he meaning and intent of section 422.166(a)(2)(i) are clear . . . even if there were any ambiguity, the Court should find that CMS's reading is reasonable and entitled to deference." Dkt. 17 at 24. At issue is whether CMS violated the plain language of its own regulations. Although CMS has failed to articulate the basis for its claimed deference, it presumably contends that its interpretation of its own regulations are entitled to deference under *Auer v. Robbins*, 519 U.S. 452 (1997) ("*Auer*"). CMS is not entitled to any deference, whether under *Auer* or otherwise.

As the Supreme Court has emphasized, "*Auer* deference is not the answer to every question of interpreting an agency's rules. *Far from it*." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019) (emphasis added). Indeed, *Auer* deference is only appropriate "if the regulation in question is 'genuinely ambiguous' and if the agency's reading is reasonable." *See Doe v. SEC*, 28 F.4th 1306, 1311 (D.C. Cir. 2022) (quoting *Kisor*, 139 S. Ct. at 2415-16). None of the prerequisites for *Auer* deference exist here.

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methodology from the text of the regulation. Dkt. 17 at 31-35. However, this too misses the point as Plaintiffs have not challenged the validity of the rulemaking; instead Plaintiffs challenge CMS's application of simulated cut points to their 2024 Star Ratings as described *supra*.

First, the Guardrail Requirement of 42 C.F.R. § 422.166(a)(2)(i) is clear and unambiguous. As such, "[t]he regulation . . . means what it means—and the court must give it effect, as the court would any law." *Kisor*, 139 S. Ct. at 2415. Because the regulation is not "genuinely ambiguous," deference to the agency is neither warranted nor appropriate. As the Supreme Court of United States has explained:

> *[T]he possibility of deference can arise only if a regulation is genuinely ambiguous*. And when we use that term, we mean it—genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation.
> . . . .
>
> But if the law gives an answer—if there is only one reasonable construction of a regulation—then a court has no business deferring to any other reading, no matter how much the agency insists it would make more sense. *Deference in that circumstance would "permit the agency, under the guise of interpreting a regulation, to create* de facto *a new regulation*."

Id. at 2414-15 (quoting *Christensen v. Harris County*, 529 U.S. 576, 588 (2000)) (emphasis added). "[B]efore concluding that a regulation is 'genuinely ambiguous,' a court must exhaust all the 'traditional tools' of construction." *Id.* at 1215 (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843, n.9 (1984)).

Here, CMS concedes that the "meaning and intent of section 422.166(a)(2)(i) are clear." Dkt. 17 at 29. Plaintiffs agree the Guardrail Requirement is clear and unambiguous for the reasons set forth in their opening brief and herein. Specifically, it requires CMS to apply guardrails such that actual cut points for 2023 are used and not simulated cut points. Given the clear meaning of this regulation, CMS is entitled to no deference in their attempts to violate it.

Second, even if genuine ambiguity existed in the Guardrail Regulation (it does not), CMS's position on the meaning of the regulation still must be "reasonable." *Kisor*, 139 S. Ct. at 2415 (citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 515 (1994)). In other words, "genuine

ambiguity" is "necessary but not sufficient" for deference. *See Nat'l Lifeline Ass'n v. FCC*, 983 F.3d 498, 507 (D.D.C. 2020). An agency's interpretation of an ambiguous regulation must "come within the zone of ambiguity the court has identified after employing all its interpretive tools." *Kisor*, 139 S. Ct. at 2416. And as to that zone of ambiguity, the "agency's reading must fall 'within the bounds of reasonable interpretation.'" *Id*. (quoting *Arlington v. FCC*, 569 U.S. 290, 296 (2013). As the Supreme Court has cautioned: "[L]et there be no mistake: That is a requirement an agency can fail." *Kisor*, 139 S. Ct. at 2416. It does here.

CMS does not purport to fill any zone of ambiguity in the regulation. It simply draws upon statements from uncodified preambles to change the meaning of the regulation for 2024 Star Ratings only. Its construction also rests upon several flawed textual premises. For starters, it would require the term "measure-specific cut points," as used in the regulation, to carry a radically different meaning for one year only. In addition, CMS's argument ignores how CMS, itself, interpreted the term historically. Moreover, CMS's interpretation does not align with the text of the regulation. As written, the regulation tests whether cut points changed by more than 5 percentage points from "1 year to the next." But CMS's novel position on the Guardrail Requirement would test (for one year only) an altogether different question: whether the cut points "[*would have*] increase[d] or decrease[d] more than the value of the cap from 1 year to the next [*if CMS had implemented the Tukey outlier deletion methodology the previous year*]."

Because CMS's position changes the meaning of the guardrail for one year only without any change to the text of the regulation, even if the Guardrail Requirement were considered "genuinely ambiguous," CMS's interpretation should not be considered reasonable.

II. PLAINTIFFS HAVE NOT WAIVED ANY OF THEIR ARGUMENTS

CMS argues that the doctrine of administrative waiver forecloses Plaintiffs from challenging CMS's decision to rerun 2023 cut points because they did not timely challenge the

issue in the appropriate rulemaking. That argument is unavailing because it rests upon a fundamental mischaracterization of this case.

Despite CMS's effort to reframe this lawsuit to excuse their violation of the Guardrail Requirement, this is not a rulemaking challenge. Rather, it is an as-applied challenge to CMS's violation of law in calculating Plaintiffs' 2024 Star Ratings. CMS marshals case after case that rest upon the agency's misconstruction of this action. The cases CMS cites in support of waiver generally all involve facial challenges to rules. *See e.g., Transp. Div. of the Int'l Ass'n of Sheet Metal v. FRA*, 40 F.4th 646, 653 (D.C. Cir. 2022) ("In 2020, the Federal Railroad Administration . . . issued a broad-ranging rule revising the regulations governing freight railroad safety. Two unions representing employees of freight railroads . . . have petitioned for review.") (internal citation omitted); *Koretoff v. Vilsack*, 707 F.3d 394, 397-99 (D.C. Cir. 2013) (per curiam); *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1261-62 (D.C. Cir. 2004) (per curiam). In contrast, Plaintiffs have not made a *facial challenge* to any rules, but instead have challenged CMS's improper calculating of Plaintiffs' 2024 Star Ratings by applying the Tukey Methodology via the improper application of simulated cut points (among other errors) to determine Plaintiffs' 2024 Star Ratings. That conduct was arbitrary and capricious, and contrary to law.

This district has a history of distinguishing between facial rule challenges and challenges involving the application of a rule when determining whether a plaintiff has waived an argument not raised during the rulemaking process. This court has explained that "a series of cases from the D.C. Circuit Court of Appeals indicate 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, 68-69 (D.D.C. 2015) (citing *Weaver v. Fed. Motor Carrier Safety Admin*., 744 F.3d 142, 145 (D.C. Cir.

2014); *Nat. Res. Def. Council v. EPA*, 513 F.3d 257, 260 (D.C. Cir. 2008)) , *aff'd in part and rev'd in part on different grounds*, 867 F.3d 1223 (D.C. Cir. 2017) (not discussing administrative waiver); *see also Murphy Expl. & Prod. Co. v. United States DOI*, 270 F.3d 957, 958-59 (D.C. Cir. 2001) ("As we opined in *Functional Music*, because 'administrative rules and regulations are capable of continuing application,' were we to limit review to the adoption of the rule without further judicial relief at the time of its application, we 'would effectively deny many parties ultimately affected by a rule an opportunity to question its validity'") (quoting *Functional Music, Inc. v. FCC*, 274 F.2d 543, 546 (D.C. Cir. 1958)). Notably, one of the cases cited by defendants squarely acknowledges this distinction. *Koretoff*, 707 F.3d at 397-99 (finding waiver as to a facial challenge but "emphasiz[ing] that nothing in this opinion affects the producers' ability to raise their statutory arguments if and when the Secretary ***applies the rule***") (citation omitted) (emphasis added).

Here, Plaintiffs have challenged CMS's calculation of 2024 Star Ratings as being contrary to the unambiguous language of 42 C.F.R. § 422.166(a)(2)(i).[6] Whether or not Plaintiffs commented on the preamble statements CMS now relies upon is irrelevant to Plaintiffs' ability to assert this action. Plaintiffs have not waived their ability to assert this action.

Moreover, even if this Court were to construe this lawsuit as a facial rulemaking challenge, Plaintiffs (through Elevance (f/k/a Anthem Inc.) as the ultimate parent) provided more than sufficient comments in April 2020 in response to the proposed Tukey Methodology. Specifically, Plaintiffs stated they:

> CMS is proposing to remove outlier values via the Tukey outer fence methodology. While Anthem appreciates CMS' focus on

[6] As addressed *supra*, the preamble statements CMS attempts to frame as rules cannot violate the plain language of the text of the regulation. Thus, the preamble statements cited by CMS are not proper rules and do not have the force and effect of law.

> providing more stability to the cut points from year-to-year, we believe the best approach to achieve that goal is to return to the previous CMS policy of predetermined thresholds.
>
> . . . .
>
> If CMS chooses not to reinstate the predetermined 4-Star thresholds, we have concerns with CMS' proposed outlier approach. Removing outliers is a statistical approach that is typically employed where there is reason to believe that the outlier values are somehow invalid—for example data entry errors, sampling problems, or measurement issues. Our understanding is that current integrity monitoring should account for these types of issues, so that outliers in the existing star ratings reflect natural variation. We are concerned the approach could further cluster cut points, inaccurately pulling cut points down.

A.R. 000582. Plaintiffs further voiced opposition to the Tukey Methodology in February 2023 in response to CMS adding it back into the regulation after CMS had inadvertently deleted it from the text of the regulation:

> [W]e support the removal of the Tukey outlier deletion, which undermines the predictability of cut points. We have concerns with the implementation of the Tukey outlier deletion process, and its impact on the calculation of cut points for Star Ratings as the process is executed after the measurement year has ended and all performance indicators have been reported.

A.R. 002257-58. Elevance's comments challenged the whole of CMS's adoption of the Tukey Methodology and thus subsume the simulated cut points issue, which is a byproduct of the way in which CMS implemented the Tukey Methodology. Further, CMS pointed out that at least one other commenter specifically challenged the use of simulated cut points and that "CMS responded to these comments in detail." Dkt. 17 at 21 (citing A.R. 001937). Case law instructs "that, even in the facial challenge posture, 'the waiver rule would not bar a facial challenge if the agency has actually addressed the issue, either sua sponte or at the behest of another party.'" *Banner Health*, 126 F. Supp. 3d at 68, n.24 (citations omitted). Therefore, the application of administrative waiver has no bearing on this dispute.

III. CMS'S ATTEMPT AT DEFENDING ITS (MIS)CALCULATIONS FOR MEASURE C25 IS UNAVAILING.

CMS attempts to rebut Plaintiffs' C25 argument by providing a post-hoc rationalization of its calculations, accompanied by zero citations or evidentiary support, that identifies for the first time an arithmetic error that when added to the correct year's data would in fact result in the exact same value that Plaintiffs' expert was able to replicate with the current year's data. *See* Dkt. 17 at 39-42.

This argument does not meet the threshold for any showing in a summary judgment proceeding. The administrative record is devoid of any support for CMS's argument on this point. Moreover, CMS has attached no support to its briefing for their statements describing the arithmetic that CMS purportedly conducted. Indeed, this follows a pattern, as CMS has published nothing previously in any of its plan previews, sub-regulatory publications or otherwise, that would show its work under C25. In other words, CMS's calculation of C25 cut points is shrouded in mystery. As such, this post-hoc rationalization by CMS remains completely devoid of support and would render this argument arbitrary and capricious as a matter of law. "An agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence." *FiberTower Spectrum Holdings, LLC v. FCC*, 782 F.3d 692, 700 (D.C. Cir. 2015) (quoting *Ctr. For Auto Safety v. Fed. Highway Admin.*, 956 F.2d 309, 314 (D.C. Cir. 1992)). Given CMS's new (and unsupported) position on this measure, it is impossible for Plaintiffs to fully analyze its impact. While the limitations of data to support CMS's arguments prevent Plaintiffs from fully responding to this issue, it remains clear that CMS's calculations of C25 are yet another example of its fatally flawed implementation of Tukey and what happens when the agency chooses to contradict its own regulations.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' motion for summary judgment, set aside CMS's unlawful actions as "not in accordance with law" and "arbitrary" and "capricious," 5 U.S.C. § 706(2)(A), and order Defendants to recalculate Plaintiffs' 2024 Star Ratings by not applying the Tukey Methodology and using actual 2023 Star Rating cut points.

Dated: April 8, 2024

Respectfully submitted,

ELEVANCE HEALTH, INC. and the HEALTH PLAN PLAINTIFFS

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CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2024, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of this filing to the attorneys of record and all registered participants.

/s/ Lesley C. Reynolds
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