

**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

ORAL HEARING REQUESTED

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 7(h), 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, the “Plaintiffs”), respectfully request that this Court enter summary judgment in their favor.

Plaintiffs bring this case under the Administrative Procedure Act, 5 U.S.C. §§ 500 *et. seq.*, to rectify the unlawful and arbitrary and capricious methodology used by the Centers for Medicare & Medicaid Services (“CMS”) to calculate Plaintiffs’ 2024 Medicare Advantage Star Ratings. Star

Ratings have significant financial and operational ramifications depending on the Star awarded to the plan because they directly impact: (1) member enrollment; (2) the amount of payment that CMS makes to the plan; and (3) the premiums and benefits that the plan is able to offer to Medicare beneficiaries. Specifically, in order to enter into contracts with CMS, plans must prepare and submit financial bids every year to CMS on the first Monday in June. The bids must include the plans' own expected costs for traditional Medicare benefits for the coming year. Because the Star Ratings system influences the revenue a plan expects to receive, knowing the correct Star Rating directly impacts the bids and services that a plan can ultimately afford to provide. The Court's decision on Plaintiffs' motion will directly impact Plaintiffs' Star Ratings, thereby affecting Plaintiffs' forthcoming financial bids to CMS.

For the reasons set forth more fully in the accompanying Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment, which is incorporated herein by reference, this Court should grant Plaintiffs' motion for summary judgment.¹

Pursuant to Local Rule 7(f), Plaintiffs respectfully request an oral hearing. However, as indicated in the parties' Joint Motion for Briefing Schedule, Plaintiffs' Medicare Advantage bids are due on June 3, 2024 and the outcome of the Court's decision may impact those bids. *See* Dkt. 9 at 1-2 (¶¶ 2-3). Accordingly, Plaintiffs respectfully requested in the joint motion that the Court render a decision before June 3, 2024, so as to provide sufficient time to allow Plaintiffs the opportunity to adjust their financial bids to CMS, if needed (e.g., by mid-to-late May). *Id.* As a

¹ Plaintiffs note that SCAN Health Plan has filed a separate lawsuit against the Department of Health and Human Services, et al., also raising a challenge to SCAN Health Plan's 2024 Star Ratings (the "SCAN Health Lawsuit"). *See* Complaint, No. 23-3910 (D.D.C. Dec. 29, 2023), Dkt. 1. The SCAN Health Lawsuit share some overlapping legal issues relating to Defendants' violation of the guardrail regulation. SCAN Health Plan also challenges other legal issues based upon facts that do not arise in this case. *See id.* Given that there are differing legal issues based upon separate sets of facts and administrative records, Plaintiffs do not believe these matters are related within the meaning of Local Rule 40.5, but Plaintiffs raise this for awareness of the Court.

result, if this Court notifies Plaintiffs that an oral hearing would not be materially helpful and holding a hearing would unnecessarily delay the Court's decision, Plaintiffs are willing to withdraw their request for an oral hearing.

Pursuant to Local Rule 12(m), Plaintiffs' counsel notified counsel for Defendants of their intention to file this motion. Defendants have indicated that they oppose the relief requested in this motion.

Dated: March 8, 2024

Respectfully submitted,

**ELEVANCE HEALTH, INC. and the
HEALTH PLAN PLAINTIFFS**

By: /s/ Lesley C. Reynolds

Lesley C. Reynolds (D.C. Bar No. 487580)
Lara E. Parkin (D.C. Bar No. 475974)
David A. Bender (D.C. Bar No. 1030503)
REED SMITH LLP
1301 K Street, N.W.
Suite 1000 – East Tower
Washington, D.C. 20005
(202) 414-9200
lreynolds@reedsmith.com
lparkin@reedsmith.com
dbender@reedsmith.com

Martin J. Bishop (*pro hac vice granted*)
Steven D. Hamilton (*pro hac vice granted*)
REED SMITH LLP
10 South Wacker Drive
40th Floor
Chicago, IL 60606
(312) 207-1000
mbishop@reedsmith.com
shamilton@reedsmith.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on March 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
Lesley C. Reynolds

**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

**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

TABLE OF CONTENTS

	Page
INTRODUCTION	1
STATEMENT OF FACTS	2
I. The Parties	2
II. Medicare Advantage Program	3
III. Medicare Advantage Star Ratings	4
A. CMS Calculates Star Rating For Medicare Advantage Organizations (“MAOs”) That Profoundly Impact Member Enrollment In Each MAO, CMS’s Payments To The MAOs, And The Premium And Benefits The MAO Provides To Medicare Beneficiaries.	4
B. To Protect MAOs From Arbitrary Fluctuations In The Profoundly Important Star Ratings, CMS Promulgates The Cut Point Guardrails Requirement.....	7
C. In Discussing Whether To Amend The Cut Point Guardrails Requirement, CMS Confirms The Requirement Does Not Permit CMS To Move Cut Points More Than 5 Percent Per Year, And Declines To Amend That Requirement.	8
D. CMS’s Changes the Star Ratings Calculations Methodology by Interjecting the Tukey Statistical Methodology Starting with 2024 Star Ratings.....	9
E. In Its 2024 Star Rating Calculations, CMS Reveals That Its New Tukey Methodology Violates CMS’s Never Amended Cut Points Guardrails Requirement.....	10
STANDARD OF REVIEW	12
ARGUMENT.....	13
I. CMS Acted Contrary to Law When It Violated the Plain Language of 42 C.F.R. § 422.166(a)(2)(i).....	13
A. CMS Implemented Cut Point Guardrails in Violation of the Plain Language of 42 C.F.R. § 422.166(a)(2)(i) When it Calculated Cut Point Guardrails Using Simulated 2023 Cut Points.....	13
B. Under the Guise of Calculating Guardrails for 2024 Star Ratings, CMS Applied the Tukey statistical Methodology a Year Earlier Than Permitted in Violation of the Plain Language of 42 C.F.R. § 422.166(a)(2)(i).....	15
C. CMS Undermined The Core Purpose Of The Guardrail Requirement and Directly Injured Plaintiffs.	16
D. To the Extent CMS Argues that it Stated in Rulemaking It Was Going to Simulate Cut Points for 2023, that is Irrelevant.....	19

II.	CMS Acted Contrary to Law When It Violated the Plain Language of 42 C.F.R. § 422.166(a)(2)(i) By Calculating Cut Points for a Certain Measure (C25) By Using Current Year Data Instead of Prior Year Data.....	20
III.	CMS Acted Arbitrarily And Capriciously In Calculating 2024 Star Ratings.....	21
	CONCLUSION.....	22

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Am. Bioscience, Inc. v. Thompson</i> , 269 F.3d 1077 (D.C. Cir. 2001).....	12
<i>Barrick Goldstrike Mines, Inc. v. Whitman</i> , 260 F. Supp. 2d 28 (D.D.C. 2003).....	19
<i>Ctr. for Biological Diversity v. Regan</i> , No. 21-119 (RDM), 2024 WL 655368 (D.D.C. Feb. 15, 2024).....	12
<i>E. Band of Cherokee Indians v. Dep’t of the Interior</i> , 534 F. Supp. 3d 86 (D.D.C. (2021))	13
<i>Erie Blvd. Hydropower, LP v. FERC</i> , 878 F.3d 258 (D.C. Cir. 2017).....	22
<i>Marshall Cnty. Health Care Auth. v. Shalala</i> , 988 F.2d 1221 (D.C. Cir. 1993).....	12
* <i>Melinta Therapeutics, LLC v. FDA</i> , No. 22-2190 (RC), 2022 WL 6100188, <i>appeal dismissed for lack of jurisdiction</i> by No. 22-5288, 2022 WL 10723218 (D.C. Cir. Dec. 1, 2022).....	21, 22
<i>Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983).....	21
<i>Nat’l Envtl. Dev. Assoc.’s Clean Air Project v. EPA</i> , 752 F.3d 999 (D.C. Cir. 2014).....	21
<i>Nat’l Wildlife Fed’n v. EPA</i> , 286 F.3d 554 (D.C. Cir. 2002).....	19
<i>Ovintiv USA, Inc. v. Haaland</i> , 665 F. Supp. 3d 59 (D.D.C. 2023).....	13
<i>Rempfer v. Sharfstein</i> , 583 F.3d 860 (D.C. Cir. 2009).....	12
<i>Richards v. INS</i> , 554 F.2d 1173 (D.C. Cir. 1977).....	12
* <i>Scott & White Health Plan v. Becerra</i> , No. 22-cv-3202 (CRC), 2023 WL 6121904 (D.D.C. Sept. 19, 2023), <i>appeal filed</i> No. 23-5264 (D.C. Cir. Nov. 21, 2023).....	14, 16, 22

Sierra Club v. Mainella,
459 F. Supp. 2d 76 (D.D.C. 2006)12

Tex. Children’s Hosp. v. Azar,
315 F. Supp. 3d 322 (D.D.C. 2018)19

Statutes

5 U.S.C. § 706(2)(A).....13, 21, 22

42 U.S.C. 1395w-24(a)(6)(A).....3

42 U.S.C. 1395w-24(a)(6)(A)(ii)-(iii).....3

42 U.S.C. §§ 1395 et seq.....3

42 U.S.C. §§ 1395c to 1395i-63

42 U.S.C. § 1395hh(a)(2).....19

42 U.S.C. §§ 1395j to 1395w-63

42 U.S.C. § 1395w-23(a)4

42 U.S.C. § 1395w-23(o).....4, 6

Administrative Procedure Act, 5 U.S.C. §§ 500 *et. seq.*.....1

Other Authorities

42 C.F.R. Part 422(d).....4

42 C.F.R. § 422.162(a).....20

42 C.F.R. § 422.1662

42 C.F.R. § 422.166(a)(2).....14

42 C.F.R. § 422.166(a)(2)(i) *passim*

42 C.F.R. § 422.166(h)5

42 C.F.R. § 422.254(f)4

84 Fed. Reg. 156807

84 Fed. Reg. 157547, 8

84 Fed. Reg. 1575717

84 Fed. Reg. 157618

84 Fed. Reg. 158307

84 Fed. Reg. 265787

85 Fed. Reg. 90029

85 Fed. Reg. 90099

85 Fed. Reg. 90449

85 Fed. Reg. 192307

85 Fed. Reg. 192757

85 Fed. Reg. 337969

85 Fed. Reg. 33833-36.....9

85 Fed. Reg. 339079, 10

87 Fed. Reg. 277048

87 Fed. Reg. 27813-14.....8

87 Fed. Reg. 2789510

87 Fed. Reg. 794528, 10

87 Fed. Reg. 7962517

87 Fed. Reg. 79625-26.....8, 9, 22

87 Fed. Reg. 79634-35.....10

88 Fed. Reg. 221209

88 Fed. Reg. 221219

88 Fed. Reg. 2229510

88 Fed. Reg. 2233210

*Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4589 (42
C.F.R. Parts 417, 422)*.....3

Federal Rules of Civil Procedure Rule 5612

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 Memorandum of Law in support of their Motion for Summary Judgment.

INTRODUCTION

Plaintiffs bring this case under the Administrative Procedure Act, 5 U.S.C. §§ 500 *et. seq.*, to rectify the unlawful and arbitrary and capricious methodology that the Centers for Medicare & Medicaid Services (“CMS”) used to calculate Plaintiffs’ 2024 Medicare Advantage Star Ratings. As explained below, a federal regulation expressly establishes an unambiguous limitation on fluctuations in these ratings for the very purpose of protecting health plans like Plaintiffs from the exact kind of arbitrary fluctuation in CMS’s ratings calculations that Plaintiffs have suffered and that exposes them to hundreds of millions of dollars in capricious loss.

CMS implemented the Medicare Advantage Star Ratings as a process to purportedly rate the overall quality of Medicare Advantage organizations (“MAOs”) on a scale of 1 to 5 “Stars.” CMS calculates Star Ratings by examining data and information relating to approximately 42 individual measures that are intended to assess the overall quality of the plan in several broad categories. A plan’s overall Star Rating is a weighted assessment of the individual measures. CMS then publishes these Star Ratings to the public so that current and prospective Medicare beneficiaries can compare plans through a tool known as “Plan Finder.” Moreover, Star Ratings have significant financial and operational ramifications depending on the Star awarded to the plan. For instance, if a Medicare Advantage organization receives a 4-Star rating or higher, that

organization is entitled to Quality Bonus Payments that can amount to millions of dollars or more and which are used to directly benefit Medicare beneficiaries.

The crux of this case lies in Defendants’ unlawful calculation of the Star Rating “cut points,” which are effectively the grading rubric that Defendants use to calculate Star Ratings. Defendants calculate “cut points” for certain individual measures to determine whether a plan receives a 1, 2, 3, 4, or 5 Star for that specific measure.

In calculating the cut points, 42 C.F.R. § 422.166 establishes a “guardrail” such that the cut point from one year to the next cannot increase or decrease more than 5 percentage points. Despite that unambiguous and clear regulatory obligation, CMS implemented a new methodology to calculate cut points starting in 2024—called the Tukey statistical methodology—and then leveraged that new methodology to set cut points for 2024 Star Ratings that exceed the 5 percent guardrail. CMS’s actions not only violated the law, they caused a downward shift in Star Ratings across the industry and with respect to Plaintiffs specifically. Defendants’ action is directly contrary to the law, arbitrary and capricious and harmful to Plaintiffs.

STATEMENT OF FACTS

I. THE PARTIES

Elevance, through its affiliated entities such as the Health Plan Plaintiffs, provide medical and prescription drug coverage to approximately 2.9 million Medicare beneficiaries under Medicare Parts C and D by operating numerous health plans in 22 states and Puerto Rico. *See* Dkt. 13 at 6 (Am. Compl. ¶ 11). The Health Plan Plaintiffs are Elevance’s direct or indirect subsidiaries and enter into contracts with CMS to provide coverage to Medicare beneficiaries under Medicare Parts C and/or D. *Id.*

Defendant Xavier Becerra (“Becerra”), in his official capacity as Secretary of Health and Human Services (“HHS”), is responsible for overseeing CMS. *See* Dkt. 13 at 7 (Am. Compl. ¶

12). Defendant Chiquita Brooks-LaSure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services (“CMS”) (collectively with Becerra, the “Defendants”) is responsible for the administration of the Medicare health program, including Medicare Parts C and D. *See* Dkt. 13 at 8 (Am. Compl. ¶ 13).

II. MEDICARE ADVANTAGE PROGRAM

The Medicare program provides various healthcare benefits for people age 65 and older or with certain disabilities or diseases. *See* 42 U.S.C. §§ 1395 et seq. Generally, eligible individuals can receive Medicare benefits directly from the federal government under Medicare Parts A and B. *See* 42 U.S.C. §§ 1395c to 1395i-6 (Part A); 42 U.S.C. §§ 1395j to 1395w-6 (Part B). Alternatively, under Medicare Part C (known as “Medicare Advantage”) CMS contracts with private organizations—i.e., MAOs—that offer health plans to Medicare-eligible individuals and are responsible for providing Medicare benefits to enrollees.¹ *See* Medicare Program, *Establishment of the Medicare Advantage Program*, 70 Fed. Reg. 4588, 4589 (Jan. 28, 2005) (codified at 42 C.F.R. Parts 417, 422).

In order to enter into contracts with CMS, MAOs must prepare and submit financial bids every year to CMS. The bids and its supporting documentation are a complex submission because, in addition to the bid amount itself, MAOs must submit (1) a detailed package to CMS stating the specific benefits and cost sharing amounts their plans will cover, for both Medicare Advantage medical coverage and Part D prescription drug coverage, 42 U.S.C. § 1395w-24(a)(6)(A); and (2) a detailed financial breakdown of how the plan arrived at its bid amount, with the actuarial basis and support for those calculations, 42 U.S.C. § 1395w- 24(a)(6)(A)(ii)-(iii). Each separate benefit

¹ MAOs generally receive a per member, per month payment from CMS in return for providing coverage to their enrollees for traditional Medicare services.

plan offering submitted by a Medicare Advantage plan requires its own bid and supporting documentation. *See* 42 C.F.R. § 422.254(f).

III. MEDICARE ADVANTAGE STAR RATINGS

A. CMS Calculates Star Rating For MAOs That Profoundly Impact Member Enrollment In Each MAO, CMS's Payments To The MAOs, And The Premium And Benefits The MAO Provides To Medicare Beneficiaries.

In an effort to measure the quality of health and drug services received by consumers enrolled in MAOs and PDPs, CMS publishes annual Star Ratings for MAOs (“Star Ratings”) based upon certain data sets that rate each MAO on a scale of 1 to 5 Stars. *See* 42 U.S.C. § 1395w-23(o); *see also* 42 C.F.R. Part 422, Subpart D; *see also* CMS, *Fact Sheet - 2024 Medicare Advantage and Part D Star Ratings* (Oct. 13, 2023), <https://www.cms.gov/files/document/101323-fact-sheet-2024-medicare-advantage-and-part-d-ratings.pdf> (hereinafter “2024 Star Ratings Fact Sheet”). The Star Rating that CMS assigns to a particular MAO is critically important because it directly impacts: (1) member enrollment; (2) the amount of payment that CMS makes to the MAO; and (3) the premiums and benefits that the MAO is able to offer to Medicare beneficiaries.² Dkt. 13 at 12 (Am. Compl. ¶ 27). Indeed, as CMS explained in its most recent Star Rating Technical Notes, “CMS created the Part C & D Star Ratings to provide quality and performance information to Medicare beneficiaries to assist them in choosing their health and drug services during the annual fall open enrollment period.” CMS, *Medicare 2024 Part C & D Star Ratings Technical Notes*, 10 (Dec. 13, 2023), <https://www.cms.gov/files/document/2024technotes20230929.pdf> (hereinafter “CMS Star Rating Technical Notes”).

² Specifically, under the Congressionally-mandated “Quality Bonus Payment” program, if an MAO’s contract receives an overall Star Rating of 4 Stars or higher, the federal benchmark is raised 5% for those plans, which results in higher payments to the plans. *See* 42 U.S.C. § 1395w-23(a), (o). In addition, the rebate amount that plans receive if their bid is below the benchmark is impacted by Star Ratings. *Id.*

Star Ratings influence the attractiveness of a particular MAO's plan to a Medicare beneficiary because they can identify plans that are purportedly of higher quality relative to other choices. Dkt. 13 at 10-11, 21 (Am. Compl. ¶¶ 23, 58). CMS facilitates the plan selection process by maintaining a website known as the Medicare "Plan Finder," which is an online tool that displays information about available plans, including Star Ratings, to assist beneficiaries in choosing the coverage that is right for them. *See* 42 C.F.R. § 422.166(h). Further, MAOs that receive a 5-Star Rating may be afforded the opportunity to enroll members throughout the year, whereas lower rated plans generally cannot. Dkt. 13 at 21 (Am. Compl. ¶ 58).

An MAO receives a Star Rating for each contract held by the MAO. CMS calculates the rating by assessing certain individual measures that CMS identifies in any given year. *See* 2024 Star Ratings Fact Sheet at 6-8 (for a full listing of the measures used to determine an MA-PD plan's 2024 Star Rating). In 2024, there were a total of 42 Parts C and D measures (Part C measures were designated as C01 to C30 and Part D measures were designated as D01 to D12) that fall into the following five broad categories: (1) outcomes; (2) intermediate outcomes; (3) patient experience; (4) access to care; and (5) process for maintaining, monitoring or improving beneficiaries' health status. *See* CMS Star Rating Technical Notes at 9. Examples of Part C and Part D individual measures include:

- C01 – Breast Cancer Screening: This measures "[t]he percentage of women MA enrollees 50 to 74 years of age (denominator) as of December 31 of the measurement year who had a mammogram to screen for breast cancer in the past two years (numerator)."
- C02 – Colorectal Cancer Screening: This measures "[t]he percentage of MA enrollees aged 50 to 75 (denominator) as of December 31 of the measurement year who had appropriate screenings for colorectal cancer (numerator)."
- C25 – Complaints about the Health Plan: This measures the rate of complaints about the health plan per 1,000 members using a formula stated in the CMS Star Rating Technical Notes.

- D01 – Call Center – Foreign Language Interpreter and TTY³ Availability: This is a calculation of the number of completed contacts with the health plan’s call center interpreter and TTY divided by the number of attempted contacts.

CMS Star Rating Technical Notes at 37-41, 76-77, 86-87.

To assess how each MAO performed for each of these 42 measures, CMS relies upon various data sources such as Healthcare Effectiveness Data and Information Set (“HEDIS”) and Consumer Assessment of Healthcare Providers and Systems (“CAHPS”) survey data. *Id.* at 15-18. For each measure, CMS establishes a set of “cut points” or thresholds that MAOs need to meet to receive a 1, 2, 3, 4, or 5 star rating for that individual measure. *Id.* at 18-19. To determine cut points for each measure, CMS uses one of two methods: clustering or relative distribution and significance testing. *Id.* Under clustering, which is applied to the majority of the Star Ratings measures, “the Star Rating for each measure is determined by applying a clustering algorithm to the measure’s numeric value scores from all contracts.” *Id.* at 18. “[T]he clustering algorithm identifies the “gaps” among the scores and creates four cut points resulting in the creation of five levels (one for each Star Rating).” *Id.* “The scores in the same Star Rating level are as similar as possible; the scores in different Star Rating levels are as different as possible. Star Rating levels 1 through 5 are assigned with 1 being the worst and 5 being the best.” *Id.*⁴

³ TTY is “[a] teletypewriter[,] . . . an electronic device for text communication via a telephone line, used when one or more of the parties has hearing or speech difficulties.” CMS Star Rating Technical Notes at 194.

⁴ Relative distribution and significance testing “is applied to determine valid star cut points for CAHPS measures.” CMS Star Rating Technical Notes at 19. “In order to account for the reliability of scores produced from the CAHPS survey, the method combines evaluating the relative percentile distribution with significance testing” to establish cut points. *Id.* “For example, to obtain 5 stars, a contract’s CAHPS measure score needs to be ranked at least at the 80th percentile and be statistically significantly higher than the national average CAHPS measure score, as well as either have not low reliability or have a measure score more than one standard error above the 80th percentile.” *Id.*

B. To Protect MAOs From Arbitrary Fluctuations In The Profoundly Important Star Ratings, CMS Promulgates The Cut Point Guardrails Requirement.

In April 2019, CMS introduced the concept of a “guardrail” to Star Rating cut points. Specifically, CMS amended 42 C.F.R. § 422.166(a)(2)(i) to require the use of “guardrails” to cap the amount of any increases or decreases to no more than 5 percent in measure cut point values from one year to the next for non-CAPHS based measures. *See* 42 C.F.R. § 422.166(a)(2)(i) (2020); *see also* 84 Fed. Reg. 15680, 15830 (Apr. 16, 2019) (corrections to final rule published in 84 Fed. Reg. 26578 (June 7, 2019)). Thereafter, due to the pandemic, CMS delayed the implementation of the guardrails such that they began with the 2023 Star Ratings that CMS identified in October 2022. *See* 85 Fed. Reg. 19230, 19275 (Apr. 6, 2020).

In implementing guardrails, CMS explained that it added them “[t]o increase the predictability of the cut points” and fully appreciated that the guardrails would act as a regulator on the movement of cut points from one year to the next. *See* 84 Fed. Reg. at 15754. As CMS explained:

To 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. A 5 percent cap restricts the movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability. *The trade-off for the predictability provided by bi-directional caps is the inability to fully keep pace with changes in performance across the industry.* While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, *changes in overall performance that are greater than the cap would not be reflected in the new cut points.* A cap on upward movement may inflate the measure-level Star Ratings if true gains in performance improvements cannot be fully incorporated in the current year’s ratings. Conversely, a cap on downward movement may decrease the measure-level Star Ratings since the ratings would not be adjusted fully for downward shifts in performance.

Id. (emphasis added). CMS subsequently reiterated the fact that guardrails increase predictability with the trade-off being that they would limit the movement of cut-points both upwards and downwards. *See* 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 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.”)

C. In Discussing Whether To Amend The Cut Point Guardrails Requirement, CMS Confirms The Requirement Does Not Permit CMS To Move Cut Points More Than 5 Percent Per Year, And Declines To Amend That Requirement.

Notably, after recognizing that the guardrails limited the movement of measure cut points and in conjunction with the proposal to implement the Tukey statistical methodology (as explained more below), in December 2022, CMS solicited comments on a proposal to eliminate the guardrails for the 2026 Star Ratings or beyond. 87 Fed. Reg. 79452, 79625-26. As CMS explained at the time:

Based on recent experience with calculating Star Ratings . . . we are proposing to modify the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points.

When we initially proposed guardrails so that the cut points for non-CAHPS measures do not increase or decrease more than the cap from one year to the next, we recognized that with guardrails there may be an inability for thresholds to fully keep pace with changes in performance across the industry. 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. While we recognized the possibility at the time we finalized the guardrails policy, we 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.

Id. at 79625. Thus, as CMS recognized, the guardrails acted as a hard cap on shifting measure cut points and CMS proposed to eliminate the guardrail to make cut points (especially for higher star ratings) more difficult to obtain. *Id.* However, CMS ultimately declined to amend § 422.166(a)(2)(i) and left the guardrails untouched. 88 Fed. Reg. 22120, 22121 (Apr. 12, 2023) (“The remaining Star Ratings provisions of the proposed rule are not being finalized in this rule and instead will be addressed in a later final rule. Those provisions include . . . removing guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure’s cut points for the current year’s measure-level Star Ratings compared to the prior year’s measure-threshold specific cut points) when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures[.]”). Accordingly, the guardrails are still required by law and are applicable to the 2024 Star Ratings.

D. CMS’s Changes the Star Ratings Calculations Methodology by Interjecting the Tukey Statistical Methodology Staring with 2024 Star Ratings.

In 2020 rulemaking, CMS introduced the idea that for the 2024 Star Ratings it would implement the Tukey statistical methodology (the “Tukey Methodology”) into a hierarchical clustering methodology, in a purported attempt to stabilize cut points. In doing so, CMS referred to this as the “Tukey outlier deletion.” 85 Fed. Reg. 9002, 9009, 9044 (Feb. 18, 2020) (proposed); *see also* 85 Fed. Reg. 33796, 33833-36, 33907 (June 2, 2020). Generally, using the Tukey

Methodology, CMS would identify and delete outlier contracts—*i.e.*, contracts with data points that differ greatly (much smaller or larger) from the other values in the data set—before applying the already-applicable mean resampling and hierarchical clustering processes for all non-CAHPS measures. CMS Star Rating Technical Notes at 18-19.

Although CMS introduced the Tukey Methodology in 2020 (to be effective in 2024), CMS flubbed the rulemaking process. Specifically, although CMS initially included the Tukey Methodology language in the regulatory text to amend 42 C.F.R. § 422.166(a)(2)(i), in subsequent rulemaking CMS actually deleted the applicable language regarding the Tukey Methodology from the regulatory text. *Compare* 85 Fed. Reg. at 33907 *with* 87 Fed. Reg. at 27895. Thus, the actual regulatory text did not contain any language regarding the Tukey Methodology. In December 2022, CMS identified the error and proposed rules adding the Tukey Methodology language back into the regulatory text (*see* 87 Fed. Reg. 79452, 79634-35 (Dec. 27, 2022)) and finalized that correction in April 2023, indicating that the relevant sentence “was inadvertently removed from the codified regulation text.” 88 Fed. Reg. at 22295, 22332.

E. In Its 2024 Star Rating Calculations, CMS Reveals That Its New Tukey Methodology Violates CMS’s Never Amended Cut Points Guardrails Requirement.

In October 2023, CMS announced the 2024 Star Rating for MAOs. In calculating its 2024 Star Ratings, CMS applied the Tukey Methodology for the first time. Specifically, CMS evaluated the MA plans on the 42 measures used to score Part C & D plans. CMS then utilized the Tukey Methodology to identify contracts that were outliers from each measure, and then excluded the scores for those contracts on that specific measure to calculate the cut points for that measure. Once these cut points were identified, to account for the regulatory guardrail component, CMS then took those 2024 Star Ratings cut points and had to compare them to the cut points from 2023. Instead, of using the actual cut points that were used for the 2023 Star Ratings, however, CMS

simulated the 2023 Star Rating cut points to act as though it had applied Tukey, and then applied the guardrails to those *simulated* cut points instead of the *actual* 2023 cut points. *See* CMS Star Rating Technical Notes at 158. When applying guardrails to those *simulated* 2023 cut points, the cut points for 2024 Star Ratings increased for some measures by “more than the value of the [5-percentage point] cap from 1 year to the next,” in contradiction to the plain regulatory language of 42 C.F.R. § 422.166(a)(2)(i). *See* Ex. A, Declaration of J. Mark Abernathy (“Abernathy Decl.”) at 8-11 (¶¶ 20-26).

CMS’s application of the Tukey Methodology and the simulation of 2023 cut points had a direct and negative impact on the calculation of Plaintiffs’ 2024 Star Ratings. *See* Dkt. 13 at 22 (Am. Compl. ¶¶ 61-62). Specifically, as set forth below, Plaintiffs held several contracts that, based upon the flawed methodology employed by CMS, had depressed 2024 Star Ratings. If CMS had calculated the 2024 Star Ratings without the improper application of guardrails to the simulated 2023 cut points, these contracts would have obtained higher Star Ratings as indicated in the following table:

Contract	Assigned 2024 Star Ratings	2024 Star Ratings Without Improper Application of Guardrails
H1947	3.5	4.0
H2836	3.0	3.5
H3447	3.5	4.0
H4909	3.0	3.5
H5422	3.0	3.5
H5427	4.5	5.0
H5854	4.0	4.5
H9065	3.5	4.0

See Ex. A, Abernathy Decl. at 14-15 (¶ 37, Table 3).

An additional contract, H8432, may also change under an updated MA Stars calculation. CMS does not provide all information necessary to replicate its cut points, as CMS acknowledges in its Star Rating Technical Notes. *See Medicare 2024 Part C & D Star Ratings Technical Notes.* Contract H8432 may move from 3.0 to 3.5 Stars; however, due to CMS's failure to provide all necessary information to replicate its cut point calculations, Plaintiffs cannot predict with absolute certainty the contract movement if CMS had not incorrectly calculated cut points. *See Ex. A, Abernathy Decl. at 15 (¶ 38).* CMS does not provide MAOs with sufficient information to allow full replication and confirmation of CMS's cut point calculations, which necessarily complicates Plaintiffs' ability to successfully appeal its Star ratings and is itself arbitrary and capricious.

STANDARD OF REVIEW

“[W]hen a party seeks review of agency action under the APA. . . , the district judge sits as an appellate tribunal.” *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). “The general standard for summary judgment set forth in Rule 56 of the Federal Rules of Civil Procedure does not apply to a review of agency action.” *Ctr. for Biological Diversity v. Regan*, No. 21-119 (RDM), 2024 WL 655368, at *16 (D.D.C. Feb. 15, 2024). Instead, summary judgment “serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review. *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citing *Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)). In other words, “[t]he entire case on review is a question of law[.]” *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).

ARGUMENT

This Court should set aside CMS’s calculation of 2024 Star Ratings for three reasons: (1) CMS acted contrary to law when it violated the guardrail requirements of 42 C.F.R. § 422.166(a)(2)(i) by setting 2024 Star Rating cut points when it considered simulated cut points that resulted in changes of more than 5 percentage points from those of the prior year; (2) CMS acted contrary to law and in an arbitrary and capricious manner by using the wrong year’s data when (mis)calculating cut points for measure C25; and (3) CMS’s implementation of the Tukey statistical deletion methodology was arbitrary and capricious because it caused CMS to violate its own laws and precipitated cut-point *instability*. Accordingly, this Court should grant Plaintiffs’ motion for summary judgment, set aside CMS’s unlawful actions 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 using the Tukey statistical methodology, using actual 2023 Star Rating actual cut points, and using the correct data year for measure C25, as required by law.

I. CMS ACTED CONTRARY TO LAW WHEN IT VIOLATED THE PLAIN LANGUAGE OF 42 C.F.R. § 422.166(A)(2)(I).

A. CMS Implemented Cut Point Guardrails in Violation of the Plain Language of 42 C.F.R. § 422.166(a)(2)(i) When it Calculated Cut Point Guardrails Using Simulated 2023 Cut Points.

CMS’s novel approach to setting cut points for 2024 Star Ratings resulted in cut points that increased by “more than the value of the [5-percentage point] cap from 1 year to the next,” in direct violation of 42 C.F.R. § 422.166(a)(2)(i). Under the APA, the reviewing court must “hold unlawful and set aside agency action, findings, and conclusions” that are “not in accordance with law.” 5 U.S.C. § 706(2)(A). “[A]n agency action is ‘not in accordance with law’ if it violates some extant federal statute or regulation.” *Ovintiv USA, Inc. v. Haaland*, 665 F. Supp. 3d 59, 72 (D.D.C. 2023) (quoting *E. Band of Cherokee Indians v. Dep’t of the Interior*, 534 F. Supp. 3d 86, 97 (D.D.C.

(2021)). Thus, a government agency cannot violate regulations; if it does, then the agency action must be set aside as contrary to law. *See 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 filed* No. 23-5264 (D.C. Cir. Nov. 21, 2023).

In this case, the guardrail requirement of 42 C.F.R. § 422.166(a)(2)(i) is clear and unambiguous. Specifically, the regulatory language 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). As is evident, this regulation plainly requires CMS to apply a 5-percentage point (or 5 percent) guardrail (referred to as a cap) to certain measure cut points so that those cut points “do not increase or decrease by more than the value of the cap from 1 year to the next.” However, CMS violated this clear and unambiguous language.

Specifically, CMS set cut points for 2024 Star Ratings that changed by more than 5 percentage points (or 5 percent) from 2023. Specifically, in 2024, CMS applied the Tukey statistical methodology for the first time pursuant to 42 C.F.R. § 422.166(a)(2)(i). In doing so, however, CMS hypothetically applied the Tukey statistical methodology to create *simulated* 2023 Star Rating cut points. *See* CMS Star Rating Technical Notes at 158. CMS then applied the guardrails for 2024 Star Ratings to those *simulated* cut points instead of the *actual* 2023 cut points.

Id. As a result, CMS set cut points for 2024 that increased more than 5 percentage (or 5 percent) points from the 2023 cut points. *See* Ex. A, Abernathy Decl. at 8-11 (¶¶ 20-26).

By applying Tukey a year earlier than permitted to create *simulated* 2023 cut points (which were themselves uncapped by guardrails) as opposed to the actual 2023 cut points, several of the cut points for 2024 Star Ratings increased by “more than the value of the [5-percentage point] cap from 1 year to the next” (i.e., from 2023 to 2024) in direct violation of the clear and unambiguous language of 42 C.F.R. § 422.166(a)(2)(i). *See id.* This alone is a clear violation of the plain regulatory requirements set forth in 42 C.F.R. § 422.166(a)(2)(i).

B. Under the Guise of Calculating Guardrails for 2024 Star Ratings, CMS Applied the Tukey statistical Methodology a Year Earlier Than Permitted in Violation of the Plain Language of 42 C.F.R. § 422.166(a)(2)(i).

The point of the guardrail requirement is to protect the MAOs from the instability that results from sudden and large swings in Star Ratings. To achieve that stability goal, the guardrail requirements have multiple aspects that serve the fundamental protective purpose. CMS violated *multiple* aspects of the guardrail requirement.

In addition to using Tukey as an attempted end-run around the guardrail requirement altogether, CMS’s implementation of Tukey violates the plain language of the guardrail requirement in another respect: Specifically, CMS applied Tukey a year earlier than allowed under the regulation. That is, § 422.166(a)(2)(i) provides, in relevant part: “*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.) Thus, CMS’s regulatory authority to implement Tukey clearly commenced “[e]ffective for the Star Ratings issued in October 2023.” *Id.* However, by applying Tukey to the Star Ratings issued in October 2022 (which would be 2023 Star Ratings) to create its simulated cut point comparisons, CMS applied Tukey a year earlier than permitted. Indeed, under the plain language of the

regulation, CMS was without any authority to apply Tukey to Star Ratings issued *prior to 2023*. CMS violated the plain language of its own regulation by retroactively simulating cut points for 2023 Star Ratings (i.e., those that were issued in October 2022) through application of Tukey. The plain language of the regulation did not permit CMS to introduce Tukey for any Star Ratings prior to those issued in October 2023.

CMS then compounded its unlawful conduct because, when it created the *simulated* 2023 cut points, it did not apply the guardrails to those cut points when compared to the 2022 cut points. Indeed, CMS has acknowledged as much in the Technical Notes published by CMS in conjunction with the 2024 Star Ratings, in which CMS stated that:

For the purposes of calculating the guardrails for the 2024 Star Ratings, the *2023 Star Ratings cut points were rerun* including mean resampling, Tukey outlier deletion and *no guardrails*. These *rerun 2023 Star Ratings cut points serve[d] as the basis for applying the guardrails for the 2024 Star Ratings*

CMS Star Rating Technical Notes at 158 (emphasis added). Thus, CMS’s violation of law went even a step further, as CMS not only used simulated 2023 Star Ratings cut points altogether (itself a plain violation of the guardrail requirement), but did so using the Tukey statistical methodology a year earlier than permitted and with *no guardrails*, as CMS itself *admits. Id.*

Because CMS violated the plain language of its own regulation in many respects, 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).

C. CMS Undermined The Core Purpose Of The Guardrail Requirement and Directly Injured Plaintiffs.

By setting cut points for 2024 Star Ratings quality measures that fluctuated by more than 5 percentage points relative to those actually used for 2023 Star Ratings, CMS violated the core

purpose of the guardrail requirement, which was to increase the predictability and stability of cut points from one year to the next, and instead created the exact opposite result: destabilization of cut points from 2023 to 2024.

CMS, itself, has on multiple occasions articulated the purpose of the guardrail requirement. Indeed, in finalizing its approach to cut points in April 2019, CMS stated that “the guardrails [were] a *key component* of how [it] intend[ed] the cut point methodology to *provide stability and predictability from year to year*, in balance with reflecting true performance” and that the guardrails would “lead to *increased stability and predictability of cut points.*” 84 Fed. Reg. at 15757 (emphasis added). Nor was CMS’s April 2019 observation a one-off. CMS doubled down on the “purpose” of guardrails in December 2022 when it again acknowledged that by adding guardrails to its Star Ratings methodology, “[t]he *intent* of th[e] change in methodology was to *increase the predictability and stability of cut points.*” 87 Fed. Reg. at 79625 (emphasis added).

But contrary to the stated purpose of the guardrails requirement, the cut points CMS established for 2024 Star Ratings upended the predictability and stability of cut points that the guardrails were designed to establish. *See* Ex. A, Abernathy Decl. at 8-11 (¶¶ 20-26). Far from achieving either objective, CMS established cut points that shifted well beyond the 5-percentage point cap required under the law. *Id.* Indeed, CMS’s violation of the guardrails requirement had a significant impact on Star Ratings across the industry by causing overall Star Ratings to drop significantly and making it harder for contracts to improve or even maintain their Star Ratings. *Id.*

For proof, the Court need look no further than CMS’s own published data. That is, CMS has reported that only 42% of MA-PD contracts that will be offered in 2024 achieved an overall rating of 4 stars or higher, compared with approximately 51% of contracts in 2023. *See* 2024 Star Ratings Fact Sheet at 2; CMS, *Fact Sheet – 2023 Medicare Advantage and Part D Star Ratings*, 5

(Oct. 6, 2022), <https://www.cms.gov/files/document/2023-medicare-star-ratings-fact-sheet.pdf>. Weighted by enrollment, the average MA-PD Star Rating fell from 4.14 for 2023 to 4.04 for 2024. 2024 Star Ratings Fact Sheet at 3. Likewise, the number of 5-Star plans fell from 57 in 2023 to 31 in 2024, causing enrollment in 5-Star plans to drop precipitously from 2023 to 2024. *See id.* Moreover, by applying guardrails to the *simulated* 2023 cut points instead of the *actual* 2023 cut points, CMS has artificially inflated the cut points this year, and those cut points will be utilized for purposes of applying guardrails in future years—thus compounding the problem on a going forward basis.

These are the very same plans providing largely similar benefits from one year to the next, so one would not expect the value of their offering to fluctuate wildly in just one year. Yet, when CMS arbitrarily changed its methodology, it resulted in the stunning change in ratings noted above across the whole industry. This is exactly the kind of instability and unpredictability that the guardrails requirement—when lawfully followed—prevents.

Unsurprisingly, by ignoring and, in fact, violating the clear and unambiguous language of the guardrail requirement at 42 C.F.R. § 422.166(a)(2)(i), CMS instituted cut points for 2024 quality measures that significantly fluctuated from those used in 2023, thereby causing *destabilization* of cut points from one year to the next (which is exactly what the guardrails were designed to prevent) and directly injuring Plaintiffs. Indeed, had CMS applied the guardrail requirement to the actual 2023 cut points instead of the simulated 2023 cut points, Plaintiffs would have received higher measure-specific Star Ratings for many measures and higher overall Star Ratings for several of its contracts, including at least the contracts identified in Table 1 herein. The net result of CMS's unlawful actions is that it caused Plaintiffs to lose out on tens of millions of dollars in Quality Bonus Payments and rebates. The ripple effects of CMS's action will also flow

to Plaintiffs’ plan beneficiaries whose plan configurations and scope of benefit offerings will necessarily narrow due to Plaintiffs’ artificially lowered 2024 Star Ratings.⁵

D. To the Extent CMS Argues that it Stated in Rulemaking It Was Going to Simulate Cut Points for 2023, that is Irrelevant.

Plaintiffs anticipate that CMS will attempt to defend its plain violations of its own regulations by pointing to language in the preambles of various rulemakings issued in connection with the implementation of the guardrail requirement of 42 C.F.R. § 422.166(a)(2)(i) and the implementation of Tukey for 2024 Star Ratings. Importantly, however, CMS cannot hide behind statements in preambles to rulemakings when their actions run afoul of the operative regulatory text. *See Tex. Children’s Hosp. v. Azar*, 315 F. Supp. 3d 322, 334 (D.D.C. 2018) (“The preamble cannot, however, be used to contradict the text of the . . . rule at issue.”) (citing *Nat’l Wildlife Fed’n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002)); *see also Barrick Goldstrike Mines, Inc. v. Whitman*, 260 F. Supp. 2d 28, 36 (D.D.C. 2003) (when “the preamble to [a] rulemaking is inconsistent with the plain language of the regulation, it is invalid”) (internal citation omitted); *see also* 42 U.S.C. § 1395hh(a)(2) (“No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation . . .”).

⁵ It is worth noting that even if CMS is permitted to apply the Tukey statistical methodology to calculate cut points for the 2024 Star Ratings, CMS still would have violated the guardrail requirement of 42 C.F.R. § 422.166(a)(2)(i) utilizing simulated 2023 cut points to achieve its guardrail analysis. That violation alone would impact at least one of Plaintiff’s contracts—namely, H5422, which should at a minimum move from a 3.0 to 3.5 Stars. *See Ex. A, Abernathy Decl.* at 11-13, 13 n.28 (¶¶ 27-30, 30 n.28).

As these cases reflect, the *law* that CMS must follow is the text of its regulation, not any preamble. While CMS may amend its regulations through lawful notice-and-comment rulemaking, it cannot violate the plain language of its own regulations, or attempt a back-door amendment to their regulations by administrative fiat through scattered statements in preambles to rulemakings. As such, to the extent that CMS argues it identified the use of simulated cut points in preambles, that is legally irrelevant and cannot override the plain language of the regulation.

II. CMS ACTED CONTRARY TO LAW WHEN IT VIOLATED THE PLAIN LANGUAGE OF 42 C.F.R. § 422.166(A)(2)(I) BY CALCULATING CUT POINTS FOR A CERTAIN MEASURE (C25) BY USING CURRENT YEAR DATA INSTEAD OF PRIOR YEAR DATA.

In calculating 2024 Star Ratings, CMS also acted contrary to law and in an arbitrary and capricious manner by miscalculating cut points for measure C25, which measures health plan performance based upon the rate at which members file complaints with Medicare about a health plan. Specifically, CMS misapplied the “restricted range cap,” defined at 42 C.F.R. § 422.162(a), in connection with setting guardrails for quality measures not having a 0 to 100 scale. CMS violated its own regulation and sub-regulatory guidance by calculating the “restricted range cap” with the wrong year’s data—using the current year’s measure score distribution, as opposed to the “*prior year’s* measure score distribution,” as required by law. *See* 42 C.F.R. § 422.162(a) (emphasis added).

Pursuant to the guardrail regulation at 42 C.F.R. § 422.166(a)(2)(i), the guardrail cap shall be 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).” (emphasis added.) Critically, “restricted range cap” is defined as “a cap applied to non-CAHPS measures that restricts movement of the current year’s measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated *using the prior year’s measure score distribution.*” 42 C.F.R. § 422.162(a) (emphasis added). CMS’s sub-

regulatory guidance confirms that the restricted range cap was to be calculated using the *prior year's* measure scores:

- For measures not having a 0 to 100 scale, a restricted range cap of 5 percent of the prior year's score range is applied. Specifically, the restricted range cap is equal to the prior year's (maximum score value – minimum score value) * 0.05.

See CMS Star Rating Technical Notes at 158 (emphasis added).

Despite the regulatory requirement (as affirmed by the guidance), in calculating 2024 Star Ratings, CMS used the *current year's* data, not the *prior year's data*, when calculating the “restricted range cap.” Ex. A, Abernathy Decl. at 12 n.25 (¶ 28 n.25). This too violates the clear and unambiguous language of CMS's own regulation must be set aside as contrary to law and conduct that is arbitrary and capricious. See 5 U.S.C. § 706(2)(A); see also *Melinta Therapeutics, LLC v. FDA*, No. 22-2190 (RC), 2022 WL 6100188, at *4 (“An agency action is arbitrary and capricious if an agency fails to comply with its own regulations.”) (internal quotation marks omitted) (citation omitted), *appeal dismissed for lack of jurisdiction* by No. 22-5288, 2022 WL 10723218 (D.C. Cir. Dec. 1, 2022); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency action is “arbitrary and capricious if the agency has relied on factors which [it was not meant] to consider [or] entirely failed to consider an important aspect of the problem . . .”).

III. CMS ACTED ARBITRARILY AND CAPRICIOUSLY IN CALCULATING 2024 STAR RATINGS.

In addition to the fact that CMS's implementation of the Tukey Methodology to improperly calculate guardrails should be set aside for violating CMS's own regulations, it should be set aside because it is also arbitrary and capricious conduct. As described more fully above, by implementing the Tukey Methodology the way it did, CMS violated the clear and unambiguous language of the guardrail requirement. This is classic arbitrary and capricious conduct. See *Nat'l Env'tl. Dev. Assoc.'s 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); *see also Erie Blvd. Hydropower, LP v. FERC*, 878 F.3d 258, 269 (D.C. Cir. 2017) (similar) (citation omitted); *see also Scott & White*, 2023 WL 6121904, at *5 (“An agency action is arbitrary and capricious if an agency fails to comply with its own regulations.”) (citation omitted) (internal quotation marks omitted); *Melinta*, 2022 WL 6100188, at *4 (same) (citation omitted) (internal quotation marks omitted).

To be sure, CMS’s implementation of Tukey caused *instability* of cut points across the Medicare Advantage industry. *See* Ex. A, Abernathy Decl. at 10-11 (¶¶ 23-26). Notably, this result is inconsistent with CMS’s representation that “the combination of mean resampling and Tukey outlier deletion, with Tukey outlier deletion being finalized after the bi-directional guardrails policy, will provide sufficient predictability and stability of cut points from one year to the next” and that implementation of Tukey “minimizes the need for the guardrails to achieve [the predictability and stability of cut points] and weakens the rationale of the guardrails policy[.]” 87 Fed. Reg. at 79625-26. As it turned out, by implementing Tukey the way that it did, CMS not only gutted the guardrail protections altogether, through its plain violation of the law, but also created cut-point instability. Far from providing “predictability and stability[.]” CMS’s application of Tukey has created uncertainty and volatility. Therefore, in addition to the fact that CMS’s actions are contrary to law, they are also arbitrary and capricious and should be set aside.

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 using actual 2023 Star Rating cut points, as required by law and removing the Tukey outlier deletion.

Dated: March 8, 2024

Respectfully submitted,

**ELEVANCE HEALTH, INC. and the
HEALTH PLAN PLAINTIFFS**

By: /s/ Lesley C. Reynolds

Lesley C. Reynolds (D.C. Bar No. 487580)
Lara E. Parkin (D.C. Bar No. 475974)
David A. Bender (D.C. Bar No. 1030503)
REED SMITH LLP
1301 K Street, N.W.
Suite 1000 – East Tower
Washington, D.C. 20005
(202) 414-9200
lreynolds@reedsmith.com
lparkin@reedsmith.com
dbender@reedsmith.com

Martin J. Bishop (*pro hac vice granted*)
Steven D. Hamilton (*pro hac vice granted*)
REED SMITH LLP
10 South Wacker Drive
40th Floor
Chicago, IL 60606
(312) 207-1000
mbishop@reedsmith.com
shamilton@reedsmith.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2024, I electronically filed the foregoing document and the accompanying exhibits 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
Lesley C. Reynolds

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ELEVANCE HEALTH, INC., et al.

Plaintiffs,

v.

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

Defendants.

Civil Action No. 23-3902 (RDM)

DECLARATION OF J. MARK ABERNATHY

I, J. Mark Abernathy, declare the following to be true and correct:

1. I am over twenty-one years of age, of sound mind, and fully competent to make this declaration.

2. I am a Managing Director with Berkeley Research Group (“BRG”) and was retained by Reed Smith LLP (“Counsel”) on behalf of Elevance Health Inc. (“Elevance Health”) and its affiliated entities (“Elevance Health”) to provide my opinions on certain aspects of the Centers for Medicare and Medicaid Services’ (“CMS”) calculation of the 2024 Medicare Advantage Stars Ratings (“Star Ratings”).

3. BRG is a global consulting firm that helps leading organizations advance in three key areas: disputes and investigations, corporate finance, and performance improvement and advisory. For more than a decade, BRG has been a trusted advisor to clients on operations, compliance, and strategic issues in the Medicare Advantage arena.

4. I am a leading expert in the managed care industry. I am a Certified Public Accountant, Certified in Financial Forensics, a Certified Valuation Analyst, and have held positions in health plans and managed care organizations as CEO, COO, CFO/VP Finance. My work includes financial and operational consulting to managed care regulators and health plans,

as well as litigation support and expert testimony in internal investigations, state and federal investigations, and numerous litigation and arbitration matters. I have been appointed by state and federal judges to provide operational and financial oversight of managed care plans, including both Medicaid and Medicare plans. As state appointed Conservator, I have overseen the collection and reporting of survey and statistical data to state and federal agencies for both Medicare and Medicaid programs. I have also had responsibility for oversight of member call centers, member services, claims adjudication, medical management, and grievances and appeals. I have assisted with developing and provided oversight of correction action plans and reporting to regulators.

5. I have been asked by Counsel to review CMS's calculation of the "cut points" for certain individual measures of the 2024 Star Ratings in light of a change in CMS's methodology to include a Tukey outlier methodology in CMS's process of determining whether a Medicare Advantage Organization ("MAO") receives a 1, 2, 3, 4, or 5 Star for each measure. Each measure's Star Rating factors into the overall Star Rating calculated for each MAO at the contract-level. Specifically, Counsel asked me to opine on the overall impact to the industry resulting from CMS's implementation of the Tukey outlier methodology, in conjunction with its application of regulatorily required "guardrails" in determining the cut points for each Star Rating for the 2024 measures.

6. Counsel also asked me to recalculate the cut points for the 2024 Star Ratings measure C25 / D02 "Complaints about the Health Plan" / "Complaints about the Drug Plan" for Elevance Health's Medicare Advantage contract H5422 using *actual* 2023 cut points rather than *simulated* 2023 cut points resulting from CMS retroactively applying the Tukey outlier methodology to determine the guardrails as required under 42 C.F.R. § 422.166 and opine on any resulting impact on the Star Rating for that measure, as well as the overall Star Rating, for contract H5422.

7. Counsel also asked me to recalculate the cut points for all 2024 Star Ratings measures *without* applying the Tukey outlier methodology in CMS's process of calculating cut

points and assigning Star Ratings to each measure and opine on the impact to the overall 2024 Star Ratings for Elevance Health's Medicare Advantage contracts.

Medicare Star Ratings Program

8. CMS has been publishing Medicare Star Ratings for Medicare Advantage Organizations (“MAOs”) since 2008. The purpose of the Star Ratings program is to “measure the quality of the health and drug services received by consumers enrolled in Medicare Advantage and Prescription Drug Plans” and “to provide Medicare consumers and their caregivers with meaningful information about quality alongside information about benefits and costs to assist them in being informed and active health care consumers.”¹ An MAO's annual Star Rating is calculated for each of its contracts with CMS using the weighted average of its Star Ratings across several quality and performance measures (up to 40 for Medicare Advantage Part C and Prescription Drug Part D plans (“MA-PD”), up to 30 for Part C only plans, and up to 12 for Part D only plans).²

9. Each Star measure is derived from data identified by CMS for that particular measure.³ For measures that are not based on the Consumer Assessment of Healthcare Providers and Systems (“CAHPS”) surveys, CMS calculates cut points to determine an MAO's Star Rating. CMS determines the cut points for each applicable measure using a hierarchical clustering algorithm designed to identify natural gaps that exist within the distribution of the scores from all Medicare contracts. The gaps are used to create four cut points, which result in five levels, one for each Star Rating. The scores in each Star Rating level are intended to be as

¹ CMS, “2024 Medicare Advantage and Part D Star Ratings,” October 13, 2023, available at: <https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-star-ratings>, accessed March 7, 2024.

² A maximum of 30 Part C measures are grouped to calculate a Part C Rating and a maximum of 12 Part D measures are grouped to calculate a Part D Rating. Summary ratings are calculated from the weighted average Star Ratings of the included measures. (CMS, “Medicare Part C & D Star Ratings Technical Notes,” Updated December 13, 2023, available at: <https://www.cms.gov/files/document/2024technotes20230929.pdf>, accessed March 7, 2024.)

³ Data utilized in the Star Ratings measures includes data collected from MAOs, enrollee surveys, CMS contractors, and CMS.

similar as possible, while the scores in different levels are intended to be as different as possible. Star Ratings levels range from 1 to 5, with 1 being the worst and 5 being the best.⁴

10. Effective for Star Ratings published in October 2022 and subsequent years, CMS added a “guardrail” to the cut points for the non-CAHPS measures “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.”⁵ The cap is equal to 5 percentage points for measure 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). Guardrails are not applied to the Part C and Part D improvement measures or new measures that have been in Star Ratings program for three years or less.⁶

11. Once the cut points are calculated and the guardrails are applied, the ratings for individual measures are assigned. These measures are then weighted by type of measure and averaged to arrive at an MAO’s overall Star Rating for a given contract in the given year.⁷ The overall Star Rating assigned to an MAO is critically important to the MAO as it has a direct impact upon the total payments that CMS makes to the MAO, as well as a direct impact on the premiums and benefits that the MAO is able to offer to enrollees, thereby influencing a Medicare beneficiary’s choice to enroll in an MAO plan. Additionally, MAOs that achieve an overall 5-Star Rating are allowed to market to and enroll beneficiaries throughout the year, rather than only during annual Medicare open enrollment periods.⁸

⁴ CMS, “Medicare Part C & D Star Ratings Technical Notes,” Updated December 13, 2023, available at: <https://www.cms.gov/files/document/2024technotes20230929.pdf>, accessed March 7, 2024.

⁵ 42 C.F.R. § 422.166(a)(2).

⁶ CMS, “Medicare Part C & D Star Ratings Technical Notes,” Updated December 13, 2023, available at: <https://www.cms.gov/files/document/2024technotes20230929.pdf>, accessed March 7, 2024.

⁷ For 2024, CMS assigned the highest weights to improvement measures, the next highest to patient experience/complaints and access measures, then by outcome and intermediate outcome measures, and finally by process measures. (CMS, “Medicare Part C & D Star Ratings Technical Notes,” Updated December 13, 2023, available at: <https://www.cms.gov/files/document/2024technotes20230929.pdf>, accessed March 7, 2024.)

⁸ The annual Medicare open enrollment period lasts from October 15th through December 7th each year. Beneficiaries already enrolled in Medicare Advantage also have an open enrollment period from January 1st through March 31st each year. (See <https://www.medicare.gov/basics/get-started-with-medicare/get-more-coverage/joining-a-plan>, accessed March 7, 2024 and <https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf>, accessed March 7, 2024.)

Medicare Star Ratings Impact Payments to MAOs

12. When an MAO contracts with CMS, it does so through an annual financial bidding process. Each MAO's "bid" is based on its annual expected revenues and costs for the package of services it intends to provide. The bid is in the form of a per member per month dollar amount that represents the cost of providing services to a beneficiary with average health. The MAO also submits to CMS a detailed package on the benefits included and beneficiary cost sharing amounts for Part C services, as well as actuarial support and certification for the bid calculation. An MAO must prepare this information annually for every contract that it operates. The package of benefits must include at least all services that beneficiaries are entitled to receive under traditional (Part A and Part B) Medicare except hospice.⁹

13. During the bidding process, CMS also calculates a per member per month "benchmark" for each county in which MAOs operate. CMS calculates county-level benchmarks by determining the average spending in traditional Medicare adjusted for geography and demographics. These benchmarks act as targets against which MAOs bid to provide Part A and Part B coverage to beneficiaries. The per member per month "base rate" that CMS ultimately pays to an MAO is the lower of the MAO's bid or the CMS-set county level benchmark.¹⁰

14. If an MAO's bid is lower than the benchmark, the MAO receives a rebate from CMS equal to a percentage of the difference between the benchmark and the bid. A portion of these rebates are returned to plan enrollees in the form of supplemental benefits or lower premiums. If an MAO's bid is higher than the benchmark, the enrollees in that MAO pay a premium equal to the difference between the MAO's bid rate and the benchmark.¹¹

15. To encourage MAOs to compete for enrollees based on quality, the Affordable Care Act established a Quality Bonus Program that increases CMS's payments to MAOs based

⁹ See MedPac, "Medicare Advantage Program Payment System," Revised October 2023, available at: https://www.medpac.gov/wp-content/uploads/2022/10/MedPAC_Payment_Basics_23_MA_FINAL_SEC.pdf, accessed March 7, 2024.

¹⁰ *Ibid.*

¹¹ *Ibid.*

on the number of Stars it earns under the Medicare Star Ratings program. MAO contracts that receive at least 4 out of 5 Stars qualify for a quality bonus. Quality bonuses are based upon the county-level benchmarks set by CMS during the annual Medicare Advantage bidding process. For most MAOs in bonus status, the benchmark is increased by up to five percentage points. For MAO's in "double bonus" counties, the benchmarks are increased by up to 10 percentage points.¹²

16. For MAOs with bids below the benchmark, the rebates they receive from CMS are also impacted positively by increases to the benchmarks for MAOs that receive at least 3.5 Stars.¹³ These rebates are used by MAOs to enhance benefits or lower premiums for enrollees, which helps MAOs to attract and retain enrollees to remain competitive in their respective markets.

Medicare Star Ratings Influence Enrollment in MAOs

17. As noted above, one of CMS's stated goals of the Star Ratings program is "to help Medicare consumers and their caregivers with meaningful information about quality alongside information about benefits and costs to assist them in being informed and active health care consumers." To help facilitate a beneficiary's plan selection, CMS maintains a "plan compare" online tool on its Medicare.gov website that Medicare beneficiaries can use to help search for Medicare plans. The plan compare tool includes the Star Rating for each plan, which

¹² "Double bonus counties" are defined as urban counties with low traditional Medicare spending and historically high Medicare Advantage enrollment. Additionally, benchmarks are capped and cannot be higher than they would have been prior to the Affordable Care Act, which can result in MAOs that are eligible under the quality bonus program receiving a smaller percentage increase to their benchmark or possibly no increase at all. (Biniek, Jeannie Fugelsten, Damico, Anthony, and Neuman, Tricia. "Spending on Medicare Advantage Quality Bonus Payments Will Reach at Least \$12.8 Billion in 2023," *Kaiser Family Foundation*, August 9, 2023, available at: <https://www.kff.org/medicare/issue-brief/spending-on-medicare-advantage-quality-bonus-payments-will-reach-at-least-12-8-billion-in-2023/>, accessed March 7, 2024.)

¹³ All plans that bid below the benchmark receive a percentage of the difference between the bid and benchmark as a rebate, ranging from 50% to 70% of the difference between the bid and the benchmark. The amount of the rebate paid to the plan is determined by the plan's Star Rating. Plans with < 3.5 Stars get a 50% rebate, plans with 3.5 to 4 Stars get 65%, and plans with 4.5+ Stars get 70%. (CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," February 1, 2023, available at: <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>, accessed March 7, 2024.).

could influence a beneficiary's selection of one MAO over another MAO with similar benefits and cost sharing.¹⁴

18. CMS also allows MAOs that receive a 5-Star Rating the opportunity to enroll beneficiaries throughout the year, rather than only during annual Medicare open enrollment periods. This creates a marketing advantage for 5-Star plans.

19. The influence that the Star Ratings program has on Medicare Advantage enrollment is supported by recent enrollment figures. In 2023, 85% of Medicare Advantage Enrollees were in MAOs that received a Star Rating of 4 or above and qualified for a quality bonus. Further, a systematic literature review conducted in 2023 of PubMed MEDLINE, Embase, and Google attempted to identify articles that quantitatively assessed the impact of Medicare Star Ratings on health plan enrollment. The authors concluded, in part, that, “[i]ncreases in Medicare star ratings led to statistically significant increases in health plan enrollment and decreases in health plan disenrollment.”¹⁵ In other words, an MAO's overall Star Rating for any given year has a direct impact on its enrollment, which demonstrates that MAOs with higher Star Ratings are at a significant advantage in the market to attract and retain enrollees. This is in addition to the impact a Star Rating can have on an MAO's revenue and ability to offer competitive benefits and cost sharing options to its enrollees.

Opinion 1:

CMS's Implementation of Tukey Outlier Methodology and Violation of the Guardrail Requirements Caused Overall Star Ratings to Drop, Made it More Difficult for MAO's to Improve or Maintain Current Ratings, and Caused Instability in the Cut Points Across the Industry.

20. For the 2024 Star Ratings, CMS introduced for the first time a Tukey outlier methodology when performing a hierarchical clustering and mean resampling used to calculate

¹⁴ See <https://www.medicare.gov/plan-compare/#/?year=2024&lang=en>, accessed March 7, 2024.

¹⁵ Borrelli, Eric P et al. “Impact of star ratings on Medicare health plan enrollment: A systematic literature review.” Journal of the American Pharmacists Association: JAPhA vol. 63,4 (2023): 989-997.e3, available at: <https://doi.org/10.1016/j.japh.2023.03.009>, accessed March 7, 2024.

the cut points for all non-CAHPS measures.¹⁶ CMS's stated reason in implementing this methodology was "to improve predictability and stability in the Star Ratings."¹⁷ The Tukey outlier methodology as implemented by CMS involves identifying outlier contracts and then removing those contract scores prior to applying mean resampling within the hierarchical clustering algorithm to determine measure-level cut points.

21. As mentioned above, guardrails required under 42 C.F.R. § 422.166(a)(2) are then applied to the measure-level cut points to "... **cap the amount of increase or decrease in measure cut point values from one year to the next.** Specifically, each 1 to 5 star level cut point is **compared to the prior year's value and capped at an increase or decrease of at most 5 percentage points** for measures having a 0 to 100 scale (absolute percentage cap) **or at most 5 percent of the prior year's restricted score range** for measures not having a 0 to 100 scale (restricted range cap). The final capped cut points after **comparing each 1 through 5 star level cut point to the prior year's values** are used for assigning measure stars."¹⁸ (emphasis added)

22. For 2024, the guardrail requirement requires CMS to apply a 5-percentage point guardrail to non-CAHPS measure-level cut points to ensure "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."¹⁹ CMS states that it did so by simulating the 2023 Star Rating measure-level cut points as if the Tukey outlier methodology was in place for 2023 and then comparing those simulated cut points to the 2024 measure-level cut points, also calculated using the Tukey outlier methodology, to apply the guardrails. In other words, CMS used *simulated*, rather than *actual*, cut points for 2023 when establishing the cut points for 2024, resulting in cut points for 2024 that differed by more than 5 percentage points from the actual cut points in 2023, in violation of the guardrails requirement of 42 C.F.R. § 422.166(a)(2). This also runs

¹⁶ 42 C.F.R. § 422.166(a)(2).

¹⁷ CMS, "2024 Medicare Advantage and Part D Star Ratings," October 13, 2023, available at: <https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-star-ratings>, accessed March 7, 2024.

¹⁸ CMS, "Medicare Part C & D Star Ratings Technical Notes," Updated December 13, 2023, available at: <https://www.cms.gov/files/document/2024technotes20230929.pdf>, accessed March 7, 2024.

¹⁹ 42 C.F.R. § 422.166(a)(2).

counter to CMS's above-stated purpose of the guardrails "to cap the amount of increase or decrease in measure cut point values from one year to the next" and the intent of the implementation of the Tukey outlier methodology to "improve predictability and stability in Star Ratings."²⁰

23. CMS itself acknowledged that its decision on how to implement the Tukey outlier methodology resulted in fewer contracts receiving a Part C Star Rating of 4 or higher and a drop in the overall weighted average Part C Star Rating of nearly 2.5%, from 4.14 to 4.04.²¹

24. Actuaries in the industry have studied the 2024 Star Ratings results and agreed that CMS's change to the Star Ratings measure-level cut point calculations and application of the guardrails significantly impacted the industry by causing overall Star Ratings to drop significantly and making it harder for contracts to improve or even maintain their Star Ratings. According to a white paper by actuaries at Milliman, three key findings included:

- The national average for the 2024 Star Ratings are now at the lowest overall point since 2017 for MA-PDs and since 2014 for Prescription Drug Plans (PDP).
- "While 125 contracts saw at least a 0.5 Star Rating increase, almost twice the number of contracts (244) experienced a decrease in Star Ratings by at least 0.5 Stars."
- "Almost a third of the contracts would have received a 2024 Star Rating at least 0.5 Stars higher than their actual rating, if CMS had applied the 5% guardrails against the actual prior cut points, rather than against simulated values."²²

25. Applying the Tukey outlier methodology (coupled with the violation of the guardrails) also resulted in instability in the cut points throughout the market, contrary to

²⁰ See also 87 Fed. Reg. at 79625, "The intent of this change in methodology was to increase the predictability and stability of cut points."

²¹ CMS, "2024 Medicare Advantage and Part D Star Ratings," October 13, 2023, available at: <https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-star-ratings> accessed on March 7, 2024.

²² Roger, Hayley, Smith, Matthew H., Nelson, Phillip, Yurkovic, Mike. "The future is now: 2024 Star Ratings release, Decoding the Star Rating system evolution," *Milliman*, October 2023, available at: https://www.milliman.com/-/media/milliman/pdfs/2023-articles/10-30-23_the-future-is-now-2024-star-ratings-release_20231027.ashx, accessed March 7, 2024.

CMS's stated intentions of both the Tukey outlier methodology and the guardrails resulting in more stability and predictability. Actuaries at Wakely found that:

- “Far more cut points have increased than decreased, likely indicating the removal of more low Tukey outliers than high Tukey outliers for the majority of Stars measures.
- There is larger variation in 2 and 3 Star cut points.”
- Guardrails are not limiting actual cut point movement in the 2023 to 2024 Star Ratings and show far greater movement than five percent.²³

26. CMS's implementation of the Tukey outlier detection methodology results in guardrails that do not effectively limit actual cut point movement to 5% in the 2023 to 2024 Star Ratings. The 2024 Star Ratings cut points show far greater movement than the guardrails required by 42 C.F.R. § 422.166 when compared to the actual 2023 Star Ratings cut points because the guardrails are applied comparing to the simulated 2023 Tukey outlier methodology cut points. This results in an overall decline in Star Ratings, making it more difficult for MAO's to improve or maintain current ratings, and causes instability in the cut points industry-wide.

Opinion 2:

If CMS Had Used Actual, Rather than Simulated, Cut Points for 2023 in Establishing the Guardrails for the 2024 Cut Points, Elevance Health's Overall Star Rating for Contract H5422 Would Have Been 3.5 Rather than 3.

27. In order to demonstrate the impact of CMS using simulated instead of actual 2023 Star Ratings cut points to apply the guardrails and calculate the 2024 cut points and 2024 Star Ratings, I was asked by Counsel to analyze the cut points for one of the MA-PD measures for contract H5422. Specifically, I was asked to recalculate the cut points for the 2024 Star Ratings measure C25 / D02 “Complaints about the Health Plan” / “Complaints about the Drug Plan” for Elevance Health's Medicare Advantage contract H5422 using *actual* rather than *simulated* 2023 cut points, and then to apply the guardrails as required under 42 C.F.R. §

²³ Tritt, Suzanna-Grace and Winters, Lisa. “Cut to the Point: A Summary of 2024 Star Rating Cut Point Changes,” *Wakely*, available at: <https://www.wakely.com/sites/default/files/files/content/cut-point-summary-2024-star-rating-cut-point-changes.pdf>, accessed March 7, 2024.

422.166 and opine on any resulting impact on the Star Rating for that measure, as well as the overall Star Rating for contract H5422.

28. To do so I followed CMS’s methodology outlined in its “Medicare Part C & D Star Ratings Technical Notes” and started with CMS’s 2024 cut points before it applied any guardrails (column A in Table 1).²⁴ I then calculated the restricted range for the guardrails for this measure using the maximum and minimum values for the 2023 measure year²⁵ and multiplied the difference between the two values of 1.06 by 5% to arrive at a restricted range of 0.05 $((1.06 - 0) * 5\% = .05)$. Then I applied the restricted range of +/- 0.05 to the 2023 actual cut points (reflected in column B in Table 2),²⁶ to calculate what the 2024 cut points (column D in Table 2) should have been by examining the difference between the guardrails and the 2024 actual cut points pre-guardrails. I concluded that the guardrails should have been applied to three of the four cut points (1-2 Stars, 2-3 Stars, and 3-4 Stars) as shown below in Table 2.

Table 1 (CMS)

Category	(A) 2024 CMS Pre-Guardrail Cut Points	(B) 2023 CMS Simulated Cut Points	(C) 2023-2024 CMS Guardrail	(D) 2024 CMS Cut Points with Guardrails
1-2 Star	1.00	0.68	0.07	0.75
2-3 Star	0.60	0.43	0.07	0.50
3-4 Star	0.33	0.25	0.07	0.32
4-5 Star	0.14	0.12	0.07	0.14

²⁴ CMS, “Medicare Part C & D Star Ratings Technical Notes,” Updated December 13, 2023, available at: <https://www.cms.gov/files/document/2024technotes20230929.pdf>, accessed March 7, 2024.

²⁵ In making this calculation, I observed that CMS utilized the minimum and maximum values for the 2024 measure year as opposed to the 2023 measure year values. In other words, CMS used the current year data instead of the prior year data, which is contrary to CMS’s 2024 Technical Notes that specify that the 2023 measure year values should be utilized. (*Ibid.*)

²⁶ CMS, “Medicare 2023 Part C & D Star Ratings Technical Notes, Updated January 19, 2023, available at: <https://www.cms.gov/files/document/2023-star-ratings-technical-notes.pdf>, accessed March 7, 2024.

Table 2 (Abernathy)

Category	(A) 2024 CMS Pre-Guardrail Cut Points	(B) 2023 CMS Actual Cut Points²⁷	C) 2023-2024 CMS Guardrail	(D) 2024 Should Have Been Cut Points with Guardrails
1-2 Star	1.00	1.52	0.05	1.47
2-3 Star	0.60	0.89	0.05	0.84
3-4 Star	0.33	0.50	0.05	0.45
4-5 Star	0.14	0.19	0.05	0.14

29. I then compared Elevance Health’s measure value for C25 / D02 “Complaints about the Health Plan” / “Complaints about the Drug Plan” of 0.37 for contract H5422 to the newly calculated “should have been” cut points and observed that C25 and D02 should have been rated as a 4 Star instead of as a 3 Star as CMS had originally scored.

30. When updating the 2024 C25 and D02 measures to 4 Stars, as well as the D01 measure to 5 Stars for contracts which were impacted by the call challenged by Elevance Health in the CMS reconsideration process, I calculate the overall Star Rating for Elevance Health’s contract H5422 to be 3.5 Stars, as opposed to 3 Stars as CMS had originally scored.²⁸

Opinion 3:

If CMS Had Utilized the 2023 Stars Rating Methodology for 2024 Rather than Implementing the Tukey Outlier Methodology, 8 of Elevance Health’s Contracts Would Have Received Higher Star Ratings, Thereby Impacting the Quality Bonuses from CMS, and One Contract May Have Moved.

31. I was also asked by Counsel to consider an alternative scenario and recalculate the cut points for all 2024 Star Ratings measures without applying the Tukey outlier methodology in the hierarchical clustering and mean resampling process and opine on the

²⁷ CMS indicates a 1-2 Star cut point of 1.52 in its 2023 Technical Notes and 1.53 in the 2023 Star Ratings Data Tables, available at: <https://www.cms.gov/files/zip/2023-star-ratings-data-table.zip>, accessed March 7, 2024.

²⁸ Elevance Health challenged a call in the reconsideration process relating to contracts H2593, H4036, H5431, and R4487 because measure D01 alone changed the contract-level Star Rating for those four contracts. Based upon the reconsideration official’s decision, which found no credible evidence that this call should be held against Elevance Health, measure D01 was recalculated to 5 Stars for that measure. The CMS call log submitted by Elevance Health during the reconsideration process, which I have reviewed, indicates that the challenged call also applies to contract H5422, among other contracts.

impact to the overall 2024 Star Ratings for certain Elevance Health Medicare Advantage contracts.

32. To do so, I again followed the methodology used by CMS to calculate the Part C & D Star Ratings as described in the CMS “Medicare 2024 Part C & D Star Ratings Technical Notes.” This allowed me to establish a baseline for comparison which included the application of the Tukey outlier methodology therein described.

33. Specifically, using the same software, SAS, that CMS used, I applied CMS’s methodology as described in Attachment K to the Star Ratings Technical Notes to the publicly available 2024 Star Ratings Report Card Measure Data. This methodology included the application of the Tukey outlier methodology and hierarchical clustering and mean resampling process.

34. I then applied the same methodology, to the same data, using the same software with the exception that I did not apply the Tukey outlier methodology. I then applied the guardrails from the 2023 actual cut points instead of using the 2023 simulated cut points so that my process mirrored the process utilized for the 2023 Star Ratings.

35. Together, these created two sets of a cut points for all 2024 Star Ratings measures: one with the application of the Tukey outlier methodology and one without it.

36. I then determined the overall Star Rating for each of Elevance Health contracts with respect to each set of cut points, again referencing the methodology set forth in the “Medicare 2024 Part C & D Star Ratings Technical Notes.”

37. In total, as demonstrated in Table 3, the overall Star Rating for 8 Elevance Health contracts increased based solely on the removal of the Tukey outlier methodology. Of those 8 contracts, 5 of them crossed a threshold to 4 Stars or improved from 4 to 4.5 or 4.5 to 5 Stars. Three of the contracts moved from 3 Stars to 3.5 Stars, making them eligible for higher rebates. These changes are material in that they result in Elevance Health being eligible to receive higher quality bonuses and higher percentages of rebates from CMS for 2024 for these contracts.

Table 3

Contract	(A) Current 2024 Star Rating	(B) Updated 2024 Star Rating
H1947	3.5	4.0
H2836	3.0	3.5
H3447	3.5	4.0
H4909	3.0	3.5
H5422	3.0	3.5
H5427	4.5	5.0
H5854	4.0	4.5
H9065	3.5	4.0

38. In addition to the above, one Elevance Health contract (H8432) may move from a 3 to 3.5 Star Rating. CMS does not provide all information necessary to replicate its cut points, as CMS acknowledges in its “Medicare 2024 Part C & D Star Ratings Technical Notes.”²⁹ For H8432, we have not been able to fully validate what CMS’s cut point calculation would be for one measure (C26), as the preordering of the contracts prior to the implementation of the random group assignment seed performed by CMS appears to impact the outcome for this measure (in addition to the specific factors mentioned in the “Medicare 2024 Part C & D Star Ratings Technical Notes”). In other words, this measure appears to change depending on how CMS performs its calculations and cannot be predicted with 100% certainty due to CMS’s failure to provide all necessary information to replicate its cut point calculations.

²⁹ On page 29 (page 30 of the PDF file) of CMS’s 2024 Technical Notes under “Calculation Precision” CMS indicates that, “[i]t is not possible to replicate CMS’s calculations exactly due to factors including, but not limited to: using published measure data from sources other than CMS’s Star Rating program which use different rounding rules, and exclusion of some contracts’ ratings from publicly-posted data (e.g., terminated contracts).”

I declare under penalty of perjury under the laws of the United States and the laws of the State of Florida that the foregoing is true and correct. Executed on the date identified below.

Dated: March 8, 2024

By: 
J. Mark Abernathy
Managing Director
Berkeley Research Group

**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

[PROPOSED] ORDER

UPON CONSIDERATION of Plaintiffs' Motion for Summary Judgment and Memorandum in Support, and for good cause shown and the entire record herein, it is hereby

ORDERED that Plaintiffs' Motion for Summary Judgment is GRANTED; and it is further

DECLARED that Defendants' actions are contrary to law and arbitrary and capricious in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) based upon the entire record herein; and it is further

ORDERED that Defendants shall recalculate all of Plaintiffs' 2024 Medicare Advantage and/or Medicare Part D Star Ratings, including, but not limited to, all contracts directly or indirectly through an affiliate held by Plaintiff Elevance Health, Inc.:

- (i) so as to not use the Tukey outlier deletion methodology in determining 2024 Star Ratings;
- (ii) by using actual 2023 Star Rating cut points in accordance with the guardrail requirement of 42 C.F.R. § 422.166(a)(2)(i);
- (iii) by using prior years' data for measure C25; and
- (iv) by updating measure D01 to 5 Stars where applicable by ordering the removal of the call adjudicated in Plaintiff Elevance Health, Inc.'s favor at Reconsideration from the D01 Stars rating calculation for all applicable contracts affected

IT IS FURTHER ORDERED that Defendants shall redetermine the Quality Bonus Payment eligibility for all of Plaintiffs' Medicare Advantage and/or Medicare Part D contracts, including, but not limited to, all contracts directly or indirectly through an affiliate held by Plaintiff Elevance Health, Inc., after performing the recalculation of the Star Ratings as set forth herein.

SO ORDERED:

Dated

RANDOLPH D. MOSS
United States District Judge

Attorneys to be noticed:

Lesley C. Reynolds (D.C. Bar No. 487580)

Lara E. Parkin (D.C. Bar No. 475974)

David A. Bender (D.C. Bar No. 1030503)

Reed Smith LLP

1301 K Street, N.W.

Suite 1000 – East Tower

Washington, D.C. 20005

(202) 414-9200

lreynolds@reedsmith.com

Douglas C. Dreier D.C. Bar # 1020234

Assistant United States Attorneys

601 D Street, NW

Washington, DC 20530

(202) 252-2551

douglas.dreier@usdoj.gov