UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALIGNMENT HEALTHCARE INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 25-0074 (CRC)

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Pursuant to Federal Rule of Civil Procedure 56(a), Defendants, by and through undersigned counsel, respectfully cross-move for summary judgment. A memorandum of points and authorities in support of this cross motion and in opposition to Plaintiff's motion for summary judgment (ECF No. 11) follows.

INTRODUCTION

This lawsuit concerns the Medicare Part C and D Quality Star Rating system, which allows Medicare beneficiaries to comparison shop among hundreds of available private health insurance companies offering benefit plans under Part C (also known as Medicare Advantage) and prescription drug plans under Part D. Mandated by Congress and implemented by the Centers for Medicare & Medicaid Services ("CMS"), the Star Ratings system rates health plans on dozens of measures of health outcomes, health care processes, patient experience, and other plan performance measures. The Star Ratings are based on health records, CMS administrative data, and survey data collected from millions of Medicare beneficiaries covered under these plans. Each October, CMS publishes the Star Ratings, which assign to each health plan a rating on a one through five-star scale on each performance measure, and provides an overall rating that is a weighted average of the plan contract's scores on the various individual measures.

Plaintiff, Alignment Healthcare—an insurance company offering Medicare Advantage plans—now challenges the 2025 Star Ratings that some of its contracts received. Yet, despite the sweeping claims it makes regarding CMS's Star Ratings methodology, Alignment seems perfectly content with the Star Ratings most of its contracts received in the face of these alleged deficiencies. It is only where Alignment underperformed—on a subset of contracts that saw lower ratings due to performance-based issues—that it seeks judicial intervention. Alignment's efforts, as detailed below, do not satisfy its legal burden of showing that CMS's Star Ratings are invalid.

First, Alignment contends that CMS's application of the Tukey Outlier Deletion Rule was arbitrary and capricious because it failed to include appropriate denominator adjustments. Not so. CMS's use of the Tukey Outlier Deletion Rule, codified in regulation, reflects a well-reasoned, data-driven effort to enhance the integrity of the Star Ratings system by preventing statistical distortions, ensuring fairness across all contracts, and accurately reflecting relative performance. The denominator adjustment Alignment seeks is impracticable, not required by regulation, and would harm high-performing smaller contracts that achieve high Star Ratings.

Second, Alignment argues that CMS acted arbitrarily and contrary to law by including "very low reliability" data in composite survey measures, measures that combine related survey items that address a common aspect of a beneficiary's experience. But Alignment fundamentally misunderstands the statistical methodology for calculating composite measures. The reliability of a composite measure as a whole is often greater than the reliability of any of its individual components due to the aggregation of data. Moreover, Alignment's preferred requirement—that each individual question used in a composite must meet a certain reliability threshold before inclusion—is not required by statute and is unsupported by governing regulations.

Third, Alignment maintains that CMS did not adequately address a drop in survey responses from Spanish speakers. But the record shows that CMS investigated Alignment's concerns, examined the relevant data, and reasonably concluded that the survey results for the two contracts in question were reliable and appropriately included.

Fourth, Alignment asserts that CMS's allowance of survey "oversampling" unlawfully and arbitrarily disadvantages smaller plans. CMS requires a minimum number of enrollees to be sampled for all contracts with at least 800 enrollees to ensure statistical validity. Like every other plan, Alignment had the option to request oversampling— surveying a sample of enrollees that is

larger than the required sample size—but it did not do so. It cannot now claim to have been disadvantaged by a process it declined to use.

Fifth, Alignment contends that CMS has unconstitutionally delegated governmental authority to a private entity – an independent review entity – in violation of the nondelegation doctrine. But Congress expressly directed CMS to engage external organizations to support its administration of the Medicare Advantage program, and importantly, CMS retains final decision-making authority and oversight over the entities involved as related to the Star Ratings, consistent with constitutional and statutory requirements.

Finally, Alignment challenges the independent review entity's decisions in two administrative cases as arbitrary, capricious, and contrary to law. The record, however, demonstrates that the independent review entity considered the relevant materials and reached appropriate and well-reasoned decisions in both cases.

Each year, some contracts—like Alignment's—inevitably will receive lower ratings than they would prefer. But if this Court were to grant the relief Alignment seeks, allowing plans to selectively attack the Star Ratings methodology in years when they underperform, it would invite an endless stream of similar challenges from dissatisfied plans hoping to nudge their scores upward. The Court should reject these efforts and deny Alignment's summary judgment motion.

BACKGROUND

I. Medicare Advantage Program

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. ("Medicare statute"), establishes the Medicare program, a federally funded and administered health insurance program for eligible elderly and disabled persons and certain individuals with end stage renal disease. *See* 42 U.S.C. § 1395c. The Secretary administers the Medicare program through CMS, a component agency of the United States Department of Health and Human Services.

The Medicare program is divided into four major components. Part A, the hospital insurance benefit program, provides health insurance coverage for certain inpatient hospital care, post-hospital care in a skilled facility, post-hospital home care services, and other related services. *See* 42 U.S.C. §§ 1395c, 1395d. Part B, the supplemental medical insurance benefit program, generally pays for a percentage of certain medical and other health services, including physician services, supplemental to the benefits provided by Part A. *See* 42 U.S.C. §§ 1395j, 1395k, 1395l. Under Part C, the Medicare Advantage program, a Medicare beneficiary can elect to receive his or her Medicare benefits through a public or private healthcare plan. *See* 42 U.S.C. § 1395w-21 *et seq*. Finally, Part D is the voluntary prescription drug benefit program.

This case primarily concerns two programs under which the federal government pays health insurance companies to provide coverage to participating beneficiaries. Under Medicare Advantage or Medicare Part C, private insurers provide coverage that beneficiaries would otherwise receive through Parts A and B (sometimes known, collectively, as "traditional" Medicare). *Id.* § 1395w-22(a). These insurers, known as Medicare Advantage Organizations, contract to provide coverage in a particular geographic area. Beneficiaries can then choose among the plans available where they reside. *Id.* § 1395w-21(b). Medicare Advantage Organizations receive a predetermined sum for providing coverage to each beneficiary, based in part on the demographic and health characteristics of that beneficiary. *Id.* § 1395w-23(a)(1)(A), (C). Under Medicare Part D, the federal government contracts with insurance companies (called "sponsors"), which provide subsidized prescription drug coverage to beneficiaries. *See id.* at § 1395w-101 *et seq.* Many insurers operate plans under Parts C and D, and the differences between the programs are not material to this litigation.

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

II. Medicare Part C and D Quality Star Rating System

Congress has instructed that "[t]he quality rating for a [Medicare Advantage] plan shall be determined according to a 5-star rating system (based on the data collected under section 1395w-22(e) of this title)." 42 U.S.C. § 1395w-23(o)(4)(A). Star Ratings are a means by which CMS measures the quality of Medicare Advantage plans on a scale of one to five "stars" based on Medicare Advantage data collected by CMS. 42 U.S.C. § 1395w-23(o)(4)(A); *see also id.* § 1395w-22(e)(3). Star Ratings reflect the experiences of beneficiaries in these plans and assist beneficiaries in finding the best plans for their needs. Advance Notice of Methodological Changes for 2026 for Medicare Advantage Capitation Rates & Part C & Part D Payment Policies, at 109 (Jan. 10, 2025), *available at* https://perma.cc/KWB8-VLWK.

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

Star Ratings are assigned to each individual contract held by a Medicare Advantage Organization. The overall Star Ratings are based on a 5-star scale, set in half-star increments, with 1 star being the lowest rating and 5 stars being the highest. *See* 42 U.S.C. §§ 1395w-23(o)(4)(A), 1395w-24(b)(1)(C)(v); 42 C.F.R. §§ 422.162(b); 422.166(h)(1)(ii). Star Ratings affect payments to Medicare Advantage Organization in two main ways. First, Medicare Advantage plans that earn a rating of four stars or higher qualify for Quality Bonus Payments in the form of an increased benchmark for the contract year following the ratings year (*e.g.*, the 2025 Star Ratings can increase the Medicare Advantage bidding benchmarks for contract year 2026). 42 U.S.C. § 1395w-23(o)(1) (increasing, for qualifying plans, the applicable percentage that calculates the benchmark); *id.* § 1395w-23(o)(3)(A)(i) (a qualifying plan is one that earns a rating of four stars or higher). This in turn can allow a Medicare Advantage plan to increase its bid, receive higher rebates, or lower premiums. *See id.* § 1395w-24(b)(1)(C); 42 C.F.R. § 422.260.

Second, Star Ratings affect the level of rebate received by plans that bid below their benchmarks for the contract year following the ratings year (e.g., the 2025 Star Ratings are used to set plans' rebate percentages for contract year 2026). Plans that earn a rating of four-and-a-half stars or higher receive a rebate of seventy percent of the difference between their bid and the

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

CMS publishes the Star Ratings each October for the upcoming year at the contract level, with each plan offered under that contract assigned the contract's rating. *See* 42 C.F.R. §§ 422.162(b), 422.166, 423.182(b), 423.186. It published the 2025 Star Ratings, for example, in October 2024. CMS, Fact Sheet – 2025 Medicare Advantage and Part D Star Ratings (Oct. 10, 2024) ("Fact Sheet"), *available at* https://www.cms.gov/files/document/fact-sheet-2025-medicare-advantage-and-part-d-star-ratings.pdf.

A. Measure Level Star Ratings Calculation Methodology

To calculate overall Star Ratings, CMS scores Medicare Advantage contracts on approximately 30 to 40 quality measures, depending on whether the plan is Medicare Advantage-only or also includes Part D coverage. *See* AR 0957 (2025 Part C & D Star Ratings Technical Notes). These quality measures relate to different aspects of health outcomes, patient experience, and care quality within the following five broad categories:

- Outcome measures that reflect improvements in a beneficiary's health and that are central to assessing quality of care;
- Intermediate outcomes that reflect actions taken which can assist in improving a beneficiary's health status, such as control of blood sugar in diabetes care where the related outcome of interest would be better health status for beneficiaries with diabetes;
- Patient experience measures that reflect beneficiaries' perspectives on the care they receive from a plan;
- Access measures that reflect processes and issues that could create barriers to receiving needed care, such as whether a plan makes timely decisions about benefit appeals; and
- Process measures that capture the health care services provided to beneficiaries that can assist in maintaining, monitoring, or improving their health status.

Id. at AR 0953.

To calculate these ratings measures, CMS uses a variety of different data sources, including administrative and medical record review data collected as part of the Healthcare Effectiveness Data and Information Set ("HEDIS"), survey-based data from the Health Outcomes Survey and from the Consumer Assessment of Healthcare Providers and Systems ("CAHPS"), and CMS performance measures, such as the call center measures. 83 Fed. Reg. at 16,520, 16,525.

CMS's regulations have incorporated its Technical Notes into its operative regulations. *See* 42 C.F.R. §§ 422.164(a), 423.184(c) ("CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings."). The regulations require CMS to announce, in advance of a measurement period, potential new measures and solicit feedback. *Id.* §§ 422.164(c)(2), 423.184(c)(2). Subsequently, CMS is required to propose and finalize new measures through rulemaking. *Id.* "New measures added to the Part C Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure." *Id.* §§ 422.164(c)(3); 423.184(c)(3) (same for Part D). If CMS finds reliability or validity issues with the measure specification, it will remain on display longer than two years. §§ 422.164(c)(4); 423.184(c)(4).

1. CAHPS Survey Measures

Since 1998, CMS has conducted the Medicare Advantage CAHPS surveys annually with a sample of people with Medicare, currently enrolled in a Medicare Advantage contract for six months or longer, and who live in the United States. Medicare Advantage and Prescription Drug Plan CAHPS Fact Sheet 2024, MA & PDP CAHPS Fact Sheet, *available at* https://perma.cc/4E8A-C8VT. For 2025, nine of the forty unique quality measures used CAHPS data as their primary data source. AR 1069-70.

CMS requires all Medicare Advantage contracts with at least 600 eligible enrollees to contract with CMS-approved survey vendors to collect CAHPS survey data following specific protocols established by CMS. Medicare Advantage and Prescription Drug Plan CAHPS Fact Sheet 2024, MA & PDP CAHPS Fact Sheet, *available at* https://perma.cc/4E8A-C8VT, at 1. The standard sample size is 800 for all Medicare Advantage Organizations. AR 0078. All Medicare Advantage Organizations have the option of "oversampling," i.e., surveying a sample of enrollees that is larger than the required sample size. *Id.*

The Medicare Advantage Organization contracts with a survey vendor chosen from a list of approved vendors. The survey vendors must fulfill Minimum Business Requirements for CAHPS and ensure compliance with the protocols in CAHPS Quality Assurance Protocols & Technical Specifications manual. Medicare Advantage and Prescription Drug Plan CAHPS Fact Sheet 2024, MA & PDP CAHPS Fact Sheet, *available at* https://perma.cc/4E8A-C8VT, at 4. CMS provides the annual sample of enrollees to be surveyed for each contract. *Id*. at 1.

The CAHPS surveys are administered using a web-mail-phone data collection protocol that includes emailed or mailed invitations to complete a web survey, up to two survey mailings for non-respondents to the web survey, and phone follow-up with non-respondents to the web and mail survey administration. *Id*. at 3.

2. CAHPS Measure Star Ratings Calculation

Every CAHPS survey includes several measures of patient experience. These measures include composite measures, which combine two or more related survey items that measure the same dimensions of patients' experiences with health care or health plan services; single-item measures; and rating measures, which reflect respondents' ratings on a scale of 0 to 10 of the individual's overall assessments of a provider, care, and/or healthcare organization. *See e.g.*, CAHPS Measures of Patient Experience, *available at* https://www.ahrq.gov/cahps/consumer-

reporting/measures/index.html.

The regulation describes the method for calculating the raw CAHPS survey data into measure-level stars. 42 C.F.R. §§ 422.166(a)(3), 423.186(a)(3). CAHPS measure stars are determined based on percentile cutoffs, difference from the national mean, and reliability of the measure score. The method CMS uses to calculate the CAHPS measure-level Star Ratings is called "relative distribution and significance testing." *Id.* This method "combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data." *Id*. 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 not have low reliability or be more than one standard error above the 80th percentile. *Id.* To obtain 1 star, a contract's CAHPS measure score needs to be ranked below the 15th percentile and be statistically significantly lower than the national average CAHPS measure score, as well as either not have low reliability or be more than one standard error below the 15th percentile. *Id.*

Reliability is calculated for each contract's score on each measure, indicating how well that score distinguishes the contract's performance from that of others. It is scaled from 0 (no ability to differentiate) to 1 (perfect accuracy in ranking contracts). AR 1140. "No measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60." 42 C.F.R. §§ 422.166(a)(3); 423.186(a)(3). Low reliability scores are defined as those with at least 11 respondents and reliability ≥ 0.60 but < 0.75 and in the lowest 12% of contracts ordered by reliability. For composite measures, the reliability is calculated at the composite measure level. *See* MA & PDP CAHPS Quality Assurance Protocols & Technical Specifications, Version 14.1, at AR 0202. The reliability of a composite measure is not obtained by averaging the reliabilities of its individual items. Several

factors affect the reliability of estimated scores:

- The number of respondents in a contract who answer the item (or each item within a composite measure),
- The variability of responses within the contract,
- The degree of variation among contracts nationwide on that measure.

Id.

To calculate CAHPS measure scores in accordance with the above described specifications, CMS must calculate the national average. To calculate the national average for each CAHPS measure, CMS weights the contract scores by the survey-eligible contract enrollment assessed at the time of sample design, and then averages them.

(a) Administering the CAHPS Survey in Other Languages

CMS ensures the surveys are available in English, Spanish, Chinese, Korean, Tagalog, and Vietnamese. Current Data Collection Materials, MA & PDP CAHPS, https://ma-pdpcahps.org/en/Current-Data-Collection-Materials/ (last visited Apr. 21, 2025). Spanish language questionnaires must be made available to all Spanish-speaking enrollees (in web, mail, and telephone administration). *See* MA & PDP CAHPS Quality Assurance Protocols & Technical Specifications, Version 14.1, at AR 0172. Under the Quality Assurance Protocols and Technical Specifications, sampled enrollees must be able to select their preferred language, including Spanish, when initiating the web-based version of the survey. *Id*.

The Medicare Advantage Organization can request that its chosen survey vendor do any of the following to ensure its Spanish-speaking population receives the survey in its preferred language:

- Include instructions for requesting a Spanish language questionnaire with the prenotification letter, web survey invitations, and all mailings of the English language questionnaire. Instructions must be written in Spanish.

- Include a Spanish language questionnaire in all mailings of the English language questionnaire (this is commonly referred to as "double stuffing"). Such packets may be sent to all enrollees within a contract, or to a subset of enrollees within a contract based on language preference data received from the contract or contained in the Spanish preference indicator field in the sample data.

- Send web survey invitations in Spanish only to enrollees known to prefer Spanish. Those enrollees can be identified using a) language preference data received from the contract, b) the Spanish preference indicator field in the sample data, or c) the predicted Spanish preference field in the sample data.

- Send a Spanish language questionnaire only in all mailings of the survey to enrollees known to prefer Spanish. Those enrollees can be identified using a) language preference data received from the contract, b) the Spanish preference indicator field in the sample data, or c) the predicted Spanish preference field in the sample data.

AR 0172-73. If the contract has not requested use of any of the optional questionnaire translations, CMS requires that the pre-notification letter mailed to sampled enrollees must be printed in English on one side and in Spanish on the reverse. AR 0173. This letter provides a toll-free number that enrollees can call to request a Spanish-language survey, and survey vendors are required to send such surveys within two days of the request. *Id*.

B. Non-CAHPS Measure Star Ratings Calculation

The measures predicated on the data other than the CAHPS survey data are collectively called the non-CAHPS measures. These measures come from four data sources, including data from health and drug plans such as the Healthcare Effectiveness Data and Information Set (HEDIS), administrative data, data collected from CMS contractors, and non-CAHPS survey data. AR 0957. Where the regulations require relative distribution and significance testing for CAHPS measures, they require the clustering algorithm for non-CAHPS measures. 42 C.F.R. §§ 422.166(a)(2), 423.186(a)(2); AR 0961. CMS applies the clustering algorithm to the measure's

numeric value scores from all contracts. AR 0961. Conceptually, the clustering algorithm identifies the "gaps" among the scores and creates four demarcations or "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. *Id.* Star Rating levels 1 through 5 are assigned with 1 being the worst and 5 being the best. *Id.*

1. Tukey Outlier Deletion Rule

In a 2018 and 2019 rulemaking finalizing steps for calculating the cut points for Star Ratings measures, some commenters suggested that CMS do more to address outlier data and provide cut point stability, i.e., they were concerned that extremely high or low performing contracts were causing wide swings in cut points from year to year, making it difficult for all contracts to predict cut points and plan accordingly. *See* Policy & Technical Changes to the Medicare Advantage Program for Years 2020 and 2021, 84 Fed. Reg. 15,680, 15,755 (Apr. 16, 2019). They suggested that CMS remove outlier data prior to clustering, and CMS began evaluating methods for doing so, including Tukey outer fence outlier deletion ("Tukey outlier deletion"), which is a standard statistical method for removing outlier data. *Id.* at 15,755-56. Recognizing that "the public ha[d] not had an opportunity to comment" on outlier deletion methods, CMS stated that it would evaluate the issue further and "consider proposing outlier deletion in future rulemaking." *Id.* at 15,756.

In a February 18, 2020 proposed rule, CMS proposed using Tukey outlier deletion in the calculation of the 2023 Star Ratings. *See* Contract Year 2021 & 2022 Policy & Technical Changes to the Medicare Advantage Program (the "Proposed Rule"), 85 Fed. Reg. 9,002, 9,043-44 (Feb. 18, 2020). CMS also made clear in the Proposed Rule that, in addition to increasing the stability of cut points, CMS expected Tukey outlier deletion to decrease overall payments to Medicare Advantage Organizations. CMS noted that in the simulations it ran, "[i]n general, there tend to be

more outliers on the lower end of measure scores," and, "[a]s a result, the 1 to 2 star thresholds often increased . . . when outliers were removed compared to the other thresholds that were not as impacted." *Id.* at 9,044. CMS also noted that had it implemented Tukey outlier deletion and a five percent guardrail in the 2018 Star Ratings, more contracts would have seen a decrease in their Star Ratings than an increase. Specifically, two percent of Medicare Advantage contracts offering Part D would have seen their Star Ratings increase by half a star, while sixteen percent would have decreased by half a star, and one would have decreased by a full star. *Id.*

In a June 2, 2020 final rule (the "Final Rule"), CMS responded to comments and finalized its Tukey outlier deletion proposal. Contract Year 2021 Policy & Technical Changes to the Medicare Advantage Program, 85 Fed. Reg. 33,796, 33,830-36 (June 2, 2020).

CMS has provided the public its analysis of the impact of Tukey outlier deletion. *See e.g.*, Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 88 Fed. Reg. 22,120, 22,295 (Apr. 12, 2023) (the 2024 "Technical Amendment"). For example, as part of the Technical Amendment, CMS discussed the simulation it did using 2022 and 2023 Star Ratings data, which showed that Tukey outlier deletion had no significant impact on the three, four, and five-star cut points for most measures. *Id.* at 22,296. Rather, most of the impact was on the one and two-star cut points, bringing these cut points more stability. *Id.* Further, out of twenty non-CAHPS measures in the 2023 Star Ratings, eight measures had no Tukey outliers to remove, ten measures required removal of three-and-a-half percent or less of the data, and only two measures required removal of more than four percent. *Id.* Finally, CMS compared year-over-year cut point stability in simulations of the 2022 and 2023 Star Ratings without guardrails and found that out of twenty non-CAHPS measures, ten changed by more than five percent from 2022 to 2023 when

CMS did not apply Tukey outlier deletion compared to only five that changed by that amount with Tukey outlier deletion. *Id.* Thus, Tukey outlier deletion increased overall stability year-over-year.

CMS discussed concerns commenters raised about Tukey outlier deletion causing cut points to move closer together, what was called "compression." In the Technical Amendment, CMS, in response to comments regarding closer cut points, explained "Outlier deletion may increase or decrease cut point thresholds, depending on the shape of the measure's score distribution[,]" but "[c]loser cut points do not necessarily imply lower reliability or lessen the ability to distinguish between contracts." 88 Fed. Reg. at 22,297.

C. Overall Star Ratings Calculation Methodology

CMS calculates summary and overall ratings using the forty unique quality measures. The overall rating for a contract is calculated using the average of the Part C and Part D measure Star Ratings. 42 C.F.R. §§ 422.166(d)(1), 423.186(d)(1); AR 0964. The average is weighted based on measure type because not all measures are weighted equally. CMS assigns the highest weight to the improvement measures,[1] followed by patient experience, complaints and access measures, then outcome and intermediate outcome measures, and finally process measures. *See* 42 C.F.R. § 422.166(e); AR 0964.

D. Plan Preview and Appeals Process for Star Ratings

CMS provides for two plan preview periods before the annual release of each Star Ratings in October. *See* 42 C.F.R. § 422.166(h)(2). During the first plan preview in August, CMS asks Part

[1] Both the Part C and Part D improvement measures are based on a comparison of a contract's current and prior year measure scores. AR 0965. The ultimate improvement measure score is a complicated combination of the net improvement for process measures, for outcome and intermediate outcome measures, patient experience and access measures divided by all of the eligible measures in each of those measure categories. AR 1078-79.

C and D plan sponsors to closely review the Star Ratings methodology and their posted numeric data for each measure. The second plan preview in September includes any revisions made as a result of the first plan preview and provides a preview of the preliminary Star Ratings for each measure, domain, summary rating, and overall rating. During the second plan preview, CMS asks Part C and D sponsors again to closely review the methodology and their posted data for each measure, as well as their preliminary Star Rating assignments. This is an informal administrative process in which Medicare Advantage Organizations send any comments or questions to CMS by email and CMS responds in kind.

CMS regulations also provide for a formal appeal process after the Star Ratings have been published that allows Medicare Advantage Organizations to "appeal quality bonus payment status determinations." 42 C.F.R. § 422.260(a). A Medicare Advantage Organizations must first seek reconsideration "by providing written notice to CMS within 10 business days of the release of its [quality bonus payment] status." *Id*. § 422.260(c)(1)(i). The Medicare Advantage Organization may appeal an adverse decision by the reconsideration official via an informal hearing request. *Id*. § 422.260(c)(2). A hearing officer then issues a decision to the Medicare Advantage Organization. *Id*. § 422.260(c)(2)(vi). The hearing officer's decision is then subject to review and modification by the CMS Administrator within 10 business days of issuance. *Id*. § 422.260(c)(2)(vii). If the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding. *Id*.

III. Factual and Procedural Background

Alignment challenges the 2025 Star Ratings for three of its contracts (H3443, H3815, and H9686). The specific facts are set forth below in addressing Alignment's various claims. Alignment filed a complaint on January 10, 2025. Compl. (ECF No. 1). On April 7, 2025, Alignment filed its Motion for Summary Judgment. ECF No. 11. Alignment contends that it was

harmed by CMS's allegedly improper Star Ratings calculation for the three contracts at issue and asks the Court to set aside the Star Ratings for those contracts and remand to the agency for recalculation. *See* Compl. (ECF No. 1) at 41.

LEGAL STANDARDS

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

The APA provides for courts to "hold unlawful and set aside agency action, findings, and conclusions" if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C). Under the APA's "arbitrary or capricious" standard, the Court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). An agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*

Co., 463 U.S. 29, 43 (1983) (internal quotation marks omitted). Even a decision that is not fully explained may be upheld "if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

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

ARGUMENT

I. CMS's Use of Tukey Outlier Deletion Reflects Reasoned Decisionmaking and Does Not Render the Star Ratings Arbitrary or Capricious

CMS seeks to ensure that the various Star Ratings accurately reflect a contract's true performance. For measures not based on the CAHPS survey data (non-CAHPS measures), CMS establishes cut points for each measure to determine the corresponding Star Rating so that similarly performing contracts are grouped together and that ratings reflect meaningful differences in performance. *Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program*, 85 Fed. Reg. 33,796, 33,832 (June 2, 2020). The methodology for setting cut points was established through notice-and-comment rulemaking and is codified in regulation. *See, e.g.*, 42 C.F.R. §§ 422.166(a), 423.186(a).

As part of the process to determine cut points for non-CAHPS survey-derived measures, CMS employs the Tukey outlier deletion method—a standard statistical method for removing anomalous data points, or "outliers." 85 Fed. Reg. at 33,832-36. By removing statistical anomalies, the Tukey method ensures that Star Ratings reflect a distribution of measure scores that is not distorted by a few extreme values. *See id*. at 33,833. It also limits significant year-to-year fluctuations in ratings, providing stability to Medicare Advantage contracts. *Id*. at 33,833. CMS determined how best to handle outliers after soliciting public feedback, and addressing comments regarding outlier deletion, cut point stability, and compression. *Id*. at 33,832-36; *see also* 88 Fed. Reg.22,120, 22,295-97. CMS's process demonstrated "reasoned decisionmaking," well within the bounds of its delegated authority. *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)).

A. Tukey Outlier Deletion Does Not Improperly Compress Cut Points

Alignment challenges the Tukey outlier deletion method, contending that it produces arbitrary and capricious results by compressing measure-level cut points and rendering it "impossible" for certain contracts to achieve each Star Rating for each measure. Pl. Mem. (ECF No 11-1) at 28-32. CMS's application of Tukey outlier deletion is neither arbitrary nor capricious. It reflects a well-reasoned, data-driven effort to enhance the integrity of the Star Ratings system by preventing statistical distortions, ensuring fairness across all contracts, and accurately reflecting relative performance.

Alignment incorrectly asserts that the Tukey outlier deletion method compresses cut points in a way that undermines the validity of the Star Ratings. *Id.* at 29. But the fact that cut points may be closer together after the outlier removal does not, on its own, indicate a methodological flaw. 88 Fed. Reg. at 22,297 ("Outlier deletion may increase or decrease cut point thresholds, depending on the shape of the measure's score distribution. Closer cut points do not necessarily imply lower

reliability or lessen the ability to distinguish between contracts"); *see also* AR 0105 ("Closer cut points do not necessarily imply lower reliability or lessen the ability to distinguish between contracts."). Rather, by design, the Tukey outlier deletion method removes statistical anomalies precisely to ensure that the remaining data better represents the typical range of contract performance. Without those extreme values—which CMS has determined to be unrepresentative of the broader population—cut points more accurately reflect the distribution of scores across contracts, which may make them look compressed, while still statistically valid. 88 Fed. Reg. at 22,297. CMS's approach is far from arbitrary—it is a validated, rules-based method that promotes both fairness and predictability.

Alignment's critique also fails to engage with the actual standard CMS applies—namely, whether the Star Ratings continue to reflect material differences in performance levels after outlier deletion. CMS confirmed that they do: "Tukey outlier approach lessens the influence of a few outliers on cut point formation, leading to more reliable and stable thresholds, especially for the 1–2 star cut points." *Id.* at 22,926. Evaluating whether cut points appear compressed in isolation, without considering the underlying distribution of performance scores or CMS's validation that the cut points represent reliable measures of plan performance, removes critical context. Alignment offers no evidence that the Tukey outlier deletion methodology distorts performance simply because of a shift in cut points for some measures, let alone that it is arbitrary or capricious.

In support of its assertion that cut points are "greatly compressed," Alignment cites a single email it sent to CMS in August 2024. *See* Pl. Mem. (ECF No. 11-1) at 29, *citing* AR 0102 (email from Alignment to CMS); *see also* Comp. (ECF No. 1) ¶ 81. Alignment's email includes a table it created that shows, as part of a 2023 simulation of the effect of Tukey outlier deletion, cut points shifted upward for seven measures. But there are twenty non-CAHPS measures in total for Part C

at the time of the simulation. CMS analyzed all non-CAHPS measures when evaluating the effects of outlier deletion and found that outliers did not greatly influence a majority of the cut points when removing the outliers. AR 103-04; *see also* 88 Fed. Reg. at 22,296 (describing CMS's analysis of Tukey outlier deletion which showed that outlier deletion does not significantly affect the 3-, 4-, and 5-star cut points for most measures). In fact, most measures have a very small percentage of outliers, thereby, limiting any effect on cut points.[2] *Id.* Alignment's focus on a narrow subset while ignoring the broader data set, as CMS explained to Alignment when Alignment raised this issue during the plan preview process, presents an incomplete and misleading picture. AR 0103-04.

For some measures, the removal of outliers does shift the cut points required for each Star Rating. That shift demonstrates the very reason outliers are removed: a single extreme contract can exert undue influence on cut points used to assign stars to all contracts. AR 0104. As CMS explained to Alignment, even in measures where cut point thresholds shift because of outlier deletion, the shift does not, by itself, indicate reduced reliability or an impaired ability to distinguish between contracts. AR 0105. Rather, the Tukey outlier deletion method "refines" measurement accuracy by "ensuring cut points reflect true variation in performance and are not unduly influenced by low or high performance of a few outlying contracts." *Id*.

For example, one of the measures Alignment frequently cites, "Plan Makes Timely Decisions about Appeals," where the cut points moved substantially after outliers were removed as part of a 2023 simulation CMS ran to examine the effect of Tukey Outlier deletion, shows the

[2] In the 2023 simulations for Part C non-CAHPS measures, eight measures (40%) had no outliers at all, and only two measures (10%) had more than 4% of contracts classified as outliers. 88 Fed. Reg. at 22,296. The remaining 50% of measures had 3.5% or fewer outliers—typically less than 1%. Similar patterns were observed in Part D. *Id*; *see also* AR 0103-04 (providing this analysis to Alignment directly).

reasonableness of outlier removal. AR 0104; *see also* 88 Fed. Reg at 22,926. In that instance, excluding just a few extremely low-performing contracts (deemed outliers) prevented the cut points from being skewed downward, which would have masked meaningful differences among the remaining contracts, and inappropriately inflated ratings for the remaining contracts. *Id*. What Alignment describes as "compression" is, in reality, an adjustment that strengthens the measure's ability to distinguish performance across contracts. *Id*.

In an effort to bolster its legal argument, Alignment mischaracterizes CMS's commentary in rulemaking, asserting that CMS "acknowledged in earlier rulemakings that compression of cut points in small sample sizes can undermine reliability." Pl. Mem. (ECF No. 11-1) at 30 (citing 87 Fed. Reg. 27,704, 27,766 (May 9, 2022)). But the cited language reflects CMS's response to a commenter concerned about unreliable data inputs. In that context, CMS explained that requiring a certain minimum number of inputs for a measure helps ensure measure reliability—an observation unrelated to cut point compression or Tukey outlier deletion, and certainly not an acknowledgment that compression undermines reliability. 87 Fed. Reg. at 27,766.

Alignment doubles down, again distorting CMS's rulemaking statements by claiming CMS "recognized that score compression can undermine a measure's overall reliability," quoting CMS's observation that when scores show "decreas[ed] . . . variability across contracts," it may render a measure "unreliable." Pl. Mem. (ECF No. 11-1) at 30 (citing 83 Fed. Reg. at 16,535). But CMS was not discussing score compression. Rather, it was explaining its policy of periodically evaluating whether measures are "topping out"—that is, whether contract scores are clustering near the maximum value—such that the measure no longer meaningfully differentiates performance. 83 Fed. Reg. at 16,535. That discussion did not concern Tukey outlier deletion or

cut point compression, and it certainly does not imply that CMS believes that cut point compression undermines reliability.

To the contrary, CMS directly addressed commenters who raised concerns about compression. In the 2024 Technical Amendment, CMS, in response to comments regarding closer cut points decreasing reliability, explained "[o]utlier deletion may increase or decrease cut point thresholds, depending on the shape of the measure's score distribution[,]" but "[c]loser cut points do not necessarily imply lower reliability or lessen the ability to distinguish between contracts. 88 Fed. Reg. at 22,297.

Far from introducing instability or arbitrariness, CMS has found that outlier deletion enhances the consistency of cut points over time. In CMS's simulations, thresholds changed dramatically—by more than five percentage points—for ten of the twenty non-CAHPS Part C measures when outliers were not removed. *See* 88 Fed. Reg. at 22,296. In contrast, that level of variation occurred in only five measures when outliers were removed. *Id*. The pattern held for Part D measures as well: in Medicare Advantage–Prescription Drug (MA–PD) contracts, four of nine Part D measures showed similarly large shifts without outlier deletion, compared to only two measures with deletion. *Id*. As CMS concluded, outlier deletion "results in more year-to-year stability" than simulations without it. *Id*; *see also id*. at 22,297 ("Lessening the influence of outliers on cut point formation leads to more reliable and stable cut points."). That stability ensures ratings are tied to a more consistent and more predictable benchmark that accurately represents meaningful differentiations in plan performance—precisely what the arbitrary-and-capricious standard demands.

B. Alignment's Proposal to Adjust for Compression Based on Denominator Size Is Not Required and Arguably Undermines the Integrity of the Star Ratings System

Alignment also challenges CMS's use of Tukey outlier deletion in the Star Ratings system on the grounds that "compression" of cut points allegedly unfairly disadvantages smaller contracts with small denominators by making mid-level Star Ratings unattainable. Pl. Mem. (ECF No. 11-1) at 29. The denominator is the measure level data points that form the total population for each measure. As a preferred alternative to CMS's method, Alignment proposes (1) either eliminating Tukey deletion entirely, or (2) applying Tukey outlier deletion only to contracts with large enough denominators to ensure that all star levels are theoretically attainable. *Id.* at 29-30.

As discussed above, Alignment has not shown that Tukey outlier deletion renders the Star Ratings system less accurate, fair, or reliable. On the contrary, the process promotes stability into cut points and ensures that contracts' Star Ratings are not skewed by anomalies in the data, providing a fair representation of meaningful differences between contracts. Alignment's solution to eliminate Tukey outlier deletion entirely for the contracts at issue—a process enacted through notice-and-comment rulemaking—is therefore unpersuasive.

Alignment's preferred alternative proposal—to apply Tukey outlier deletion only to contracts with sufficiently large denominators that all star levels are theoretically achievable on each measure—fails as a matter of law and policy. First, no statute or regulation requires CMS to set denominator thresholds to guarantee that each contract can achieve each star level. Alignment's argument rests on a flawed assumption that all contracts must have equal access to each star category, regardless of their data. Alignment can point to no authority, other than their stated belief, that on each individual measure, CMS is required to establish a methodology under which each contract could theoretically achieve each individual Star Rating. CMS uses minimum denominator thresholds to ensure data sufficiency—not to guarantee access to every star level. AR 0105.

Alignment's proposed adjustments would undermine consistency, requiring different processes for different contracts on different measures, and inject new arbitrariness into the system. CMS's approach is reasonable and data-driven, enhancing accuracy and fairness across all contracts.

Furthermore, increasing denominator thresholds also has disadvantages, by erasing valid high-performing results from smaller contracts. Alignment's argument ignores that small contracts can—and often do—perform well under the same conditions. *See* AR 0106 ("a contract that is high performing will still be rated as high-performing under the Star Ratings Tukey outlier deletion methodology, regardless of whether it is a small . . . contract."). Alignment's proposed fix would penalize high-performing contracts based solely on size. Far from curing an alleged inequity, Alignment's proposal would create one.

Alignment's own contracts demonstrates that small contracts are able to achieve top results. *See* CMS, Fact Sheet – 2025 Medicare Advantage and Part D Star Ratings (Oct. 10, 2024) ("Fact Sheet"), *available at* https://www.cms.gov/files/document/fact-sheet-2025-medicare-advantage-and-part-d-star-ratings.pdf. Alignment does not challenge its high Star Ratings, instead challenging Star Ratings for two contracts, H3443 and H9686, the performance of which on two measures was notably lower than other contracts. *See* 2025 Star Ratings Data Tables, *available at* https://www.cms.gov/files/zip/2025-star-ratings-data-tables.zip. The Court should reject Alignment's attempt to throw out certain of Alignment's Star Ratings under the guise of concerns regarding compression and low denominators.

II. CMS Requires Sufficient Reliability for its Underlying Data for the Star Ratings

The CAHPS survey evaluates multiple dimensions of a contract member's experience. Six CAHPS measures included in the Star Ratings are composite measures—a composite measure combines related survey items that address a common aspect of a beneficiary's experience. AR 0194. The use of composite measures simplifies the interpretation of the data,

enhances the reliability of the results, and facilitates comparisons of performance across a unit of analysis (e.g., health plan, medical practice, clinician). *See, e.g.*, CAHPS Measures of Patient Experience, *available at* https://www.ahrq.gov/cahps/consumer-reporting/measures/index.html. Alignment challenges how CMS determines the reliability of composite measures, alleging that CMS's method of how it computes the reliability of these measures does not comply with CMS's regulations. Pl. Mem. (ECF No. 11-1) at 32-36.

To ensure data sufficiency and meaningful comparisons, CMS requires that each measure meet a minimum reliability threshold. 42 C.F.R. § 422.166(a)(3). Reliability tells us how well a contract's score on a given measure reflects its actual performance compared to other contracts. The reliability scores for CAHPS measures ranges from 0 (no meaningful information) to 1 (perfectly accurate comparison). *See* AR 0200. Reliability depends on three main things: (1) How many people respond to the measure in a given contract; (2) How much the responses vary within that contract; and (3) How much contract performance varies nationwide. *Id*. If a contract's score is not reliable enough (below 0.60), it doesn't get a Star Rating for that measure. 42 C.F.R. § 422.166(a)(3); *see also* AR 0202. Scores that are borderline reliable (between 0.60 and 0.75 and in the lowest 12% ordered by reliability) are still reported, but the low reliability is factored into its Star Rating calculation. *Id*.

For composite measures, that reliability is calculated at the composite—not individual item—level. *See* Frequently Asked Questions - Contracts, https://perma.cc/QLJ2-SXZ9. And CMS measures reliability at the composite level for good reason: a well-established principle of statistics is that composite measures—by aggregating responses across multiple related items—typically achieve higher reliability than their component parts. *Id.*; *see also Composite measures of quality of health care: Evidence mapping of methodology and reporting*, (2022), PLOS ONE,

https://doi.org/10.1371/journal.pone.0268320 (2022), at 2. Composite measures are specifically designed to reduce noise and increase measurement stability. Measurement error decreases with multiple observations (i.e., multiple items from the same respondent), and the number of respondents contributing to a composite is typically greater than for any single item. *Id*. The total number of respondents providing information towards a composite or multi-item measure is usually greater than the number responding to any one item. *Id*. Consequently, the reliability of the composite measure as a whole is often higher than most or even all the reliabilities for the individual items that make up the composite or multi-item measure. *Id*.

Alignment challenges CMS's methodology of how it calculates reliability at the composite level, asserting that it violates CMS's own regulation. *See* Pl. Mem. (ECF No. 11-1) at 32–36. But that argument misreads the regulation and misunderstands how reliability is assessed for composite measures. The regulation provides that a measure must be excluded from Star Ratings if its reliability falls below 0.60. 42 C.F.R. §§ 422.166(a)(3), 422.186(a)(3). Because the provision applies to the measure as a whole—not to each individual survey question within a composite measure—the regulation says nothing about discarding the data derived from individual questions within a composite measure based on their standalone reliability.

Alignment's claim that "if any of the inputs into the final, composite score are 'very low reliability,' then so too will be the output," Pl. Mem. (ECF No. 11-1) at 33, is simply wrong. Alignment offers no supporting evidence for this proposition because it cannot; it ignores how composite measures function and why their reliability is reasonably adjudged on the composite level. As a result, the cases on which Alignment relies are inapposite. CMS, based on sound statistical methodology, is not required to discard composite measures simply because the reliability of an individual question is below the required reliability for the measure as a whole.

CMS has examined the "relevant data, and articulated a satisfactory explanation for its action." *NRDC v. Coit*, 597 F. Supp. 3d 73, 85 (D.D.C. 2022) (cleaned up, and quoting *Motor Vehicle*, 463 at 43).

Moreover, the individual survey items that comprise the composite measures are not publicly reported. *See* Frequently Asked Questions- Contracts, *available at* https://perma.cc/QLJ2-SXZ9. Only the final, composite-level Star Ratings measures are publicly reported—consistent with how those measures were finalized through notice-and-comment rulemaking. *Id*. ("Reliabilities of individual survey measures or items are for internal quality improvement use only; item-level reliabilities do not have implications for scoring and items are not removed from a composite because of low reliability. Only reliability of the composite has implications for scoring or reporting.")

CMS's approach is statistically sound and reasonable. Alignment's suggestion to the contrary misrepresents the governing regulation, and the underlying statistical methodology of composite measurement. Alignment's proposed alternative—to discard composite measures based on an individual input's metrics is unsupported by and not compelled by regulation or standard statistical practice.

III. CMS Reviewed Alignment's Concerns Regarding Survey Administration and Determined the Results Were Reliable

Alignment claims that CMS did not adequately address Alignment's concerns regarding a drop in CAHPS survey responses from Spanish speakers for two of its contracts. Pl. Mem. (ECF No. 11-1) at 36-39. Alignment raised concerns during what is known as the second plan preview, and CMS undertook a review of Alignment's concerns. CMS then reasonably concluded that based on the available information, including the response from Alignment's survey vendor, and CMS's expertise in expected results from survey administration, the CAHPS data for contracts H3815 and

H3443 were "accurate, reliable, and comparable to the scores for other plans, as intended," and thus reasonably could form the basis of the Star Ratings for the CAHPS survey. *See* AR 0053.

CMS provides for two plan preview periods before the annual release of each Star Ratings in October. *See* 42 C.F.R. § 422.166(h)(2). This is an informal administrative process in which a Medicare Advantage Organizations may send any comments or questions to CMS by email and CMS responds in kind. During the second plan preview period, Alignment raised concerns regarding the administration of the CAHPS survey to Spanish speakers. *See, e.g.*, AR 0046-0073 (email correspondence between Alignment and CMS regarding the Spanish-language survey administration).

Contrary to Alignment's characterization of events, CMS took steps to understand Alignment's concerns and to investigate whether there was an issue that impacted the CAHPS survey results. *See* AR 0053 (outlining the response from CMS to Alignment's concerns). Alignment itself acknowledged CMS's efforts, noting CMS's "thorough review of our concerns and your ongoing efforts to address the issues raised. We value CMS's validation that the CAHPS data was handled in accordance with established methodologies and acknowledge that any changes to these processes must follow the formal rulemaking procedure." AR 0056.

In responding to Alignment's concerns, CMS directed its contractor to follow up with Alignment's 2024 MA & PDP CAHPS vendor, DataStat Inc., to clarify any discrepancies regarding the administration of the Spanish-language survey for contracts H3815 and H3443. AR 0053; *see also* AR 1195. Alignment's vendor confirmed that it did, in fact, use Alignment's client-supplied language preference data to identify sampled enrollees who preferred Spanish. AR 0053 ("[T]he survey vendor has attested that they followed Quality Assurance Plan & Technical Specifications (QAP&TS) procedures and used the language preference data shared by

the plan"); *see also* AR 1194. Specifically, after completing all cleaning and formatting of the addresses in the CMS sample file, DataStat matched the client data to enrollee names and addresses. AR 1194. DataStat emphasized that it takes a conservative approach to this process and refrains from matching records when there are any conflicts between names or addresses in the plan's data and CMS's sample data. *Id*. In addition to using client-supplied language preference information, DataStat relied on the Spanish-language preference flag from CMS. *Id*. Importantly, CMS always requires that Spanish-language surveys are available upon request. AR 0068.

CMS determined that there was no evidence of any issues with the sampling process based on the information it reviewed. *See* AR 0048; *see also* AR 0053. For both Alignment contracts, the predicted probability of Spanish language preference among the sampled enrollees closely matched the probability within the broader population of enrollees eligible for the survey. AR 0053. CMS also calculated the proportion of enrollees with high predicted probabilities of Spanish preference across three groups: the full set of CAHPS-eligible enrollees, those in the random sample, and those who ultimately responded to the survey in 2023 and 2024. *Id*. The analysis considered the share of respondents who completed the survey in Spanish. *Id.* "CMS has 1) directly verified that the sample was random and representative of [eligibles] 2) specifically verified that it was representative with respect to predicted Spanish preference, and 3) verified that the relationships between predicted Spanish preference among those sampled and both language spoken at home and survey language among respondents were as expected and consistent with the correct administration of the survey." *Id.*

CMS's review of these results supported three conclusions. AR 0061 (email from CMS to Alignment outlining its review and conclusions). First, in both years and across both contracts, the proportion of sampled enrollees with high predicted Spanish preference closely matched that of

the larger eligible population. *Id*. Thus, there were no issues with the sample that CMS drew. Second, as is typical in patient surveys, response rates were somewhat lower among individuals with high predicted Spanish preference, a pattern that was slightly more pronounced in 2024. *Id*. Third, not all enrollees with a high predicted Spanish-language preference who responded to the survey chose to complete it in Spanish—again, a common occurrence in survey administration. *Id*. Taken together, CMS determined that these patterns are consistent with a properly conducted random sample and reflect typical dynamics of survey nonresponse, particularly among linguistically diverse populations. AR 0061; *see also* AR 0048 ("[O]ur analyses have established that the CAHPS sample represented Spanish-preferring members, used the language preference information you provided, and resulted in Spanish-preferring members choosing to respond in Spanish and rates that were high and higher than average. No further validation is needed."). Contrary to Alignment's assertions, CMS undertook a careful review of the situation and reasonably found, based on the information it reviewed, that the CAHPS survey data was reliable.

Many of the issues concerning the administration of the CAHPS survey to Spanish-speaking enrollees arise from decisions/actions by Alignment and its contracted survey vendor, DataStat, not by CMS. And while CMS took steps to review Alignment's concerns to ensure the Spanish language preference data Alignment provided was used by Alignment's vendor, CMS does not administer the survey directly and does not contract with the survey vendor. Rather, Alignment enters a contract with a survey vendor of its choosing based on a list of approved vendors. Medicare Advantage Organizations, such as Alignment, retain discretion over how to promote enrollee participation, including how to accommodate enrollees who speak languages other than English. *See* AR 0058 ("CMS does not get involved in how survey vendors implement language preference data. This is determined by the plan and their vendor working together."). In

correspondence with CMS, Alignment acknowledged the various roles of CMS, Alignment, and its survey vendor, as Alignment sought CMS's guidance "to enhance the survey process in partnership with [its] vendors." AR 0057.

Contracts may promote participation among non-English-speaking members by asking their survey vendor to "double stuff" mail packets with both English and translated surveys—including Spanish—or by providing the vendor with enrollee-level language preference data and instructing the vendor to send translated surveys based on those preferences. S*ee* AR 0068; 2024 Medicare CAHPS® Survey, Oct. 26, 2023, AR 0077. These approaches are optional. AR 0172. Contracts are not required to share language preference data with their vendors, and CMS does not collect or monitor that information. How a contract such as Alignment shares enrollee data with its survey vendor is a matter left to the contract and vendor to manage. CMS does not receive enrollee-level data concerning language preference provided by a contract to its survey vendor, nor does it confirm whether vendors use the information accurately, even if it is provided. *See* AR 0058 ("Whether or not Spanish-speaking members received surveys in English despite their preference is outside of CMS control. We provide administrative data on Spanish preference in the sample shared with survey vendors and offer suggestions for improving participation by non-English speaking members[.] However, CMS does not get involved in how survey vendors implement language preference data. This is determined by the plan and their vendor working together."). The only information CMS receives from survey vendors regarding the Spanish language administration is a general description of how translated surveys are distributed for each contract. *See* AR 1186 (description of each contract and the process for handling Spanish surveys). And so, while Alignment claims that the record demonstrates that Alignment's survey vendor sent English-language surveys to some members "contrary to Alignment's language preference

designation," the language preference designation was based on information shared and discussed between Alignment and its survey vendor, not Alignment and CMS.

In short, concerns about whether Spanish-speaking enrollees initially received the survey in their preferred language according to Alignment's own files relate to Alignment's coordination with its own survey vendor. And while these are not matters that fall within CMS's direct oversight or control, CMS took action to understand Alignment's complaint in this case and the actions taken by CMS were reasonable. What CMS does require is that there are multiple opportunities to complete the survey in Spanish. Under the Quality Assurance Protocols and Technical Specifications, sampled enrollees must be able to select their preferred language, including Spanish, when initiating the web-based version of the survey. *See* MA & PDP CAHPS Quality Assurance Protocols & Technical Specifications, Version 14.1, at 50-52, *available at* https://perma.cc/BAQ6-Y54Y. In addition, if the contract has not requested use of any of the optional questionnaire translations, CMS requires that the pre-notification letter mailed to sampled enrollees be printed in English on one side and in Spanish on the reverse. *Id*. at 51. This letter provides a toll-free number that enrollees can call to request a Spanish-language survey, and survey vendors are required to send such surveys within two days of the request. *Id*.

Alignment alleges that a number of enrollees it designated as Spanish-speaking nonetheless received the survey in English—specifically, 29 out of 200—for contract H3443. Pl. Mem. (ECF No. 11-1) at 22 For contract H3815, Alignment alleges the number is 20 out of 201 of such enrollees. *Id*. Alignment contends that these figures reflect a failure by CMS to verify that Spanish-language surveys were correctly distributed based on its designations. But CMS does not oversee or verify the internal data exchanges between a Medicare Advantage organization and its contracted survey vendor; nevertheless, CMS did verify that DataStat utilized Alignment's data

once Alignment raised the concerns to CMS as part of the plan preview process. AR 0053. CMS's role is to ensure that surveys are administered in compliance with its protocols, which require that all enrollees have the opportunity to complete the survey in Spanish, regardless of whether they were sent a Spanish-language paper survey initially.

Alignment speculates that the distribution of English-language surveys to some Spanish-preferring enrollees materially impacted its 2025 Star Ratings, but it provides no evidence to substantiate that claim. Pl. Mem. (ECF No. 11-1) at 20. It asserts that the declines in CAHPS scores were "anomalous" and attributes them to this issue alone, without considering other plausible explanations for a drop in performance. CAHPS scores may decline for any number of reasons unrelated to language preference or survey administration. AR 0053 ("The fact that the contracts' performance was lower than Alignment had hoped does not constitute evidence of an error--that is simply an outcome and we have extensively verified the process."); *see also id.* ("It is often the case that changes in performance over time differ between contracts from the same sponsor. It appears that Alignment has focused on two contracts for which patient experience improved less than for other contracts. Even if Alignment believes that they undertook similar quality improvement activities in all contracts, it is common that such efforts differ in effectiveness somewhat across contracts; this appears to be the case here.").

Moreover, while Alignment claims that its internal satisfaction surveys show that Spanish-speaking enrollees report approximately 10% higher satisfaction than English-speaking members (Pl. Mem. (ECF No. 11-1) at 20), this comparison is not meaningful, as CMS explained when Alignment provided this information during the plan preview. *See* AR 0067 ("[N]on-CAHPS surveys or unofficial implementation of CAHPS surveys may achieve different results due to many factors"). Internal satisfaction surveys differ in design, methodology, and focus from the CAHPS

patient experience surveys. *Id*. Results from one cannot be used to infer how changes in the other would have affected scoring outcomes. *Id*. The assertion that Spanish-language responses would have materially improved CAHPS scores is speculative and unsupported by the record.

In sum, contrary to Alignment's assertions, CMS examined the resulting data from the sample, determined that the Spanish-language response rate fell within reasonable and expected bounds, and found no evidence of noncompliance with CMS protocols. *See* AR 0053 ("[T]here is no support for the contention that survey sampling or survey administration differed from standard protocols or adversely affected scores in any way."). CMS's reliance on those data is neither arbitrary nor capricious, and this Court should reject Alignment's attempt to throw out lower than desired Star Ratings based on speculation about the impact of non-responsive enrollees.

IV. CMS's Methodology for Calculating Star Ratings Is Fair to Contracts of All Sizes

Alignment alleges that CMS's methodology for calculating CAHPS measure-level Star Ratings "arbitrarily" disadvantages smaller plans, claiming it was "unable to oversample" for its contract H3815 while larger contracts were permitted to do so. Pl. Mem. (ECF No. 11-1) at 39-40. But this claim is contradicted by CMS policy and the administrative record. For contracts with at least 800 enrollees, CMS requires a minimum sample size of 800 enrollees per contract to ensure statistically valid survey results, regardless of the size of the Medicare Advantage Organization. As outlined in the 2024 Medicare CAHPS Survey Memorandum and related protocols, all contracts—including Alignment's—are permitted to request oversampling if they so choose. *See 2024 Medicare CAHPS Survey, Memorandum*, dated Oct. 26, 2023 (AR 0078).

Oversampling is entirely optional, and CMS provides a clear process by which any contract may request a larger sample, including identification of the contract, the requested oversample size, and the total sample to be drawn. *Id*. Alignment does not claim that it submitted such a request, nor does it point to any evidence that CMS denied a request to oversample. In fact,

Alignment's contract H3815 had ample enrollment—over 91,000 eligible enrollees—to support oversampling if Alignment had determined it was strategically valuable. *See* Enrollment by Contract 2024-01, *available at* https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/monthly-enrollment-contract/enrollment-contract-2024-01. Because Alignment could have chosen to oversample and elected not to pursue that option, its after-the-fact argument that its ratings were adversely affected by the standard sample size lacks merit and is not supported by the record.

CMS's CAHPS survey methodology is grounded in longstanding programmatic standards designed to ensure fairness, comparability, and reliability across all Medicare Advantage contracts. The standard sample size of 800 enrollees per contract is not arbitrary—it is based on statistical principles that ensure a valid and representative measure of member experience. *See Frequently Asked Questions About the CAHPS® Program and Surveys, available at* https://www.ahrq.gov/cahps/faq; *see also* Orr, N., *Development, Methodology, and Adaptation of the Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Patient Experience Survey,* at 445 (2022), *available at* https://link.springer.com/article/10.1007/s10742-022-00277-9 ("Based on analyses of reliability from previous years, a fixed target of 800 sampled cases per MA plan and 1500 sampled cases per PDP plan was established, which at historical response rates is expected to yield acceptable reliability for most plans and measures."). This uniform baseline applies across the board and provides a consistent foundation for calculating Star Ratings. The option to oversample is available to any contract that wishes to obtain more granular data for quality improvement purposes, but it is not required, and it does not guarantee higher scores. CMS's consistent application of the sampling protocol supports equitable comparisons among plans while allowing flexibility for those who seek more extensive survey data.

Alignment's broader claim—that CMS's methodology unfairly penalizes smaller plans—is simply unfounded. First, Alignment's own contract, H3815, was not in fact "small"; with more than 91,000 eligible enrollees, it had enough enrollees to oversample. Second, Alignment provides no evidence that CMS treated it differently from similarly situated contracts or that any aspect of the survey design or scoring methodology prevented it from achieving high ratings. Instead, the record reflects that Alignment had the same opportunities as every other Medicare Advantage Organization to shape its survey administration, including through oversampling, and that it simply chose not to exercise those options.

V. Congress's Requirement for CMS to Utilize Private Entity for Certain Tasks Does Not Amount to an Unconstitutional Delegation

In its motion, Alignment alleges that CMS has unlawfully delegated its governmental authority to Maximus. Pl. Mem. (ECF No. 11-1) at 41-42. This is incorrect. Congress expressly required a delegation of authority, and, importantly, CMS retains ultimate authority and exercises oversight over Maximus's work.

Congress expressly required the Secretary to "contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage." *See* 42 U.S.C. § 1395w-22(g)(4); *see also* 42 C.F.R. §§ 422.592–.596. Far from an "unlawful delegation," the role of the Independent Review Entity ("IRE") is structured and overseen pursuant to statute, regulation, and CMS policy.

The Supreme Court long has recognized that Congress may authorize private entities to "operate as an aid" to agencies executing statutory responsibilities, so long as the agency retains final authority. *See Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 388, 399 (1940). This is not a case of "delegation in its most obnoxious form." *Cf. Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936). Rather, CMS retains and exercises supervisory authority, consistent with

accepted constitutional limits. *See United States Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004) ("[T]he agency must exercise its authority and not merely rubber-stamp decisions made by others.").

For purposes of Star Ratings, if a Medicare Advantage contract believes that an Independent Review Entity determination was incorrect and that it adversely impacted its Star Ratings, it has opportunities to raise those concerns during the Star Ratings plan preview periods. In fact, in the two cases that Alignment contends adversely affected its Star Ratings, CMS reviewed Alignment's concerns during the preview process and evaluated the IRE's determinations. *See* AR 0001-20; *see also id.* at AR 0006 ("Thank you for raising this. We are going back to [the IRE] to look again at these cases since we want to make sure they are accurate for the second plan preview."). CMS concluded that the record supported the IRE's conclusions in those cases. *See* AR 0001. This type of post-decision review and supervision demonstrates that CMS retains final authority over the data that impacts a contract's Star Rating.

This oversight satisfies the constitutional requirement that agencies retain ultimate authority over actions taken by private entities. Alignment's reliance on *Carter* and *Association of American Railroads*[3] (Pl. Mem. (ECF No. 11-1) at 41-42) therefore is misplaced, because the courts in both cases determined that the challenged statutory provisions empowered private parties to regulate the affairs of other parties without an independent check. *See Ass'n of Am. R.Rs. v. Dep't of Transp.*, 721 F.3d 666, 670 (D.C. Cir. 2013), *vacated and remanded on other grounds*, 575 U.S. 43 (2015); *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936). Here, in contrast,

[3] Moreover, the Supreme Court vacated the D.C. Circuit's decision in *Association of American Railroads* on the ground that Amtrak "is a governmental entity, not a private one, for purposes of determining the constitutional issues." *Dep't of Transp. v. Assoc. of Am. R.R.*, 575 U.S. 43, 55 (2015).

HHS/CMS can (and did) review the contractor determinations Alignment disputes, and so has sufficient authority and oversight to withstand constitutional scrutiny. *See Sunshine Anthracite Coal*, 310 U.S. at 399; *Nat'l Ass'n of Psych. Treatment Ctrs. for Child. v. Mendez*, 857 F. Supp. 85, 91 (D.D.C. 1994) (finding "nothing improper" with agency delegation to private contractor of "inspection and utilization review services" related to provider certification, including individual adjudications of individual cases of appropriateness of medical care in particular cases when agency "makes all final decisions regarding certification"); *Agendia, Inc. v. Becerra*, 4 F.4th 896, 902 (9th Cir. 2021) (rejecting private nondelegation challenge to certain Medicare contractor determinations, even when given "substantial deference," because agency ultimately need not follow determination); *State v. Rettig*, 987 F.3d 518, 533 (5th Cir. 2021) (CMS's requirement that private actuaries certify certain health plans was a permissible delegation when agency retained final authority to determine actuarial soundness of plans).

Moreover, the Medicare Advantage program as a whole includes sufficient mechanisms for oversight of Independent Review Entity determinations—including audits, data validation, and reopening authority—to satisfy any required standards. CMS defines the IRE's scope of work by contract, requires the IRE to follow CMS regulations and guidance, conducts regular performance evaluations and audits, and reviews and approves all contractor deliverables. *See* CMS, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, §§ 60–60.7, 80–80.6, 90– 90.2 *available at* https://perma.cc/JR8W-H7XF; s*ee also Nat'l Ass'n of Psych. Treatment Ctrs. for Child.*, 857 F. Supp. at 91 (in rejecting private nondelegation challenge, noting that private contractor applies agency-defined standards); *Agendia, Inc.*, 4 F.4th at 902 (similar).

But the Court need not reach the broader issue of whether the entire Medicare Advantage appeals process includes sufficient safeguards. This case concerns the specific use of Independent

Review Entity data in the Star Ratings program, and the oversight described above is sufficient to defeat Plaintiff's delegation challenge in that context. Accordingly, Plaintiff's argument about "wholesale outsourcing" as it applies to Star Ratings fails both legally and factually.

VI. The Independent Review Entity's Decisions on Two of Alignment's Appeals Were Consistent with CMS Rules and Guidelines

Finally, Alignment argues that this Court should vacate Star Ratings for two contracts on two measures, "Plan Makes Timely Decisions About Appeals" and "Reviewing Appeals Decisions." Pl. Mem. (ECF No. 11-1) 43–45. "Plan Makes Timely Decisions About Appeals" is a measure that addresses how fast a plan sends information for an independent review. AR 1027. "Reviewing Appeals Decisions" is a measure that addresses how often an independent reviewer found the health plan's decision to deny coverage to be reasonable. AR 1028. Alignment asserts that Maximus, the Independent Review Entity, improperly processed two appeals from adverse decisions Alignment issued, resulting in lower Star Ratings for both measures. Because Maximus followed the proper procedures and the administrative record contains substantial evidence to support its decisions, this Court should affirm CMS's Star Ratings calculations. Critically, even if Alignment were correct on the merits—which it is not—CMS's regulations provide an administrative process for Alignment to seek reopening and correction of appeals decisions by Maximus within 180 days of issuance. Alignment failed to timely avail itself of that administrative remedy in both instances and cannot now burden this Court with its attempt to correct any such failure in the first instance in this Court.

A. Maximus Appropriately Processed Case 1-13226962526

In Case 1-13226962526, Alignment challenges Maximus's decision to uphold Alignment's adverse coverage determination, arguing that Maximus should have dismissed the case instead. Pl. Mem. (ECF No. 11-1) 43–44. Alignment contends that the decision reflects an unexplained change

in agency policy and improperly affected the plan's Star Rating. *Id*. But the record demonstrates that Maximus acted in accordance with CMS regulations and that it was Alignment—not Maximus—that failed to follow required procedures.

The case arose when Alignment issued an adverse coverage decision against an out-of-network provider. AR 0019–20. The provider requested reconsideration by Alignment but failed to submit a required Waiver of Liability. Under CMS regulations, this omission required Alignment to dismiss the request and issue a Notice of Dismissal. *See* 42 C.F.R. § 422.582(g)(1), (3). Instead, Alignment forwarded the case to Maximus as if it had denied the request on the merits. *See* AR 0020, 0038; *see also* 42 C.F.R. §§ 422.582(i), 422.590(a)(2), (i).

CMS regulations and guidance make clear that plans should not send dismissed requests to the Independent Review Entity. *See* 42 C.F.R. § 422.582(i) (a dismissal "is binding unless the enrollee or other party requests review"); Appeals Guidance at 77, *available at* https://perma.cc/JR8W-H7XF ("The rule requiring that a Part C case be automatically sent to the IRE if the plan upholds a denial on the merits . . . does not apply in the case of a dismissal"). Plans are required to forward a case file to Maximus for review only when they issue a decision on the merits after reconsideration. *See* 42 C.F.R. § 422.590(a)(2).

The processes governing reconsiderations by the Medicare Advantage plan or the Independent Review Entity are set forth at 42 C.F.R. §§ 422.578–.596. As relevant here, once Alignment concluded that the provider's reconsideration request should be dismissed, the plan was required to send a Notice of Dismissal to the provider, explaining its reasons for dismissing the request and providing instructions on how the provider may "request review of the dismissal by an independent entity." *See* 42 C.F.R. § 422.582(g)(1), (3). Here, Alignment did not issue the required Notice of Dismissal and instead submitted the case to Maximus as if it had resolved the

request on the merits. AR 0002. By forwarding the case file to Maximus, Alignment itself treated the case as though it had affirmed its initial decision on the merits. *See* 42 C.F.R. § 422.590(a)(2). It was reasonable then for Maximus to treat the case as if Alignment had affirmed its initial decision and review it as a reconsideration request. *See* 42 C.F.R. § 422.590(i).

Alignment argues that if Maximus had dismissed the appeal instead of affirming Alignment's determination, it would not have been included in the "Plan Makes Timely Decisions About Appeals" metric. Pl. Mem. (ECF No. 11-1) at 43. But because Alignment received the provider's reconsideration request in February 2023 and did not forward the case file to Maximus until September 2023—seven months later and well beyond the 30-day deadline—that appeal was considered untimely and negatively affected its Star Rating. *See* 42 C.F.R. § 422.590(a)(2) (requiring plans to forward the case file to the Independent Review Entity "as expeditiously as possible, but no later than 30 days from the date it received the provider's reconsideration request); AR 0038 (explaining that Alignment "failed to process this case appropriately").

Alignment provides no evidence that Maximus departed from its usual policy or practices. Its argument relies only on two non-binding guidance documents that confirm that Alignment—not Maximus—failed to follow the correct process. *See* Pl. Mem. (ECF No. 11-1) at 43 (citing Appeals Guidance at 76; Reconsideration Process Manual at 21). Courts evaluating claims under the arbitrary-and-capricious standard ask whether the agency (1) changed an existing policy and, if so, (2) acknowledged the change and explained it. *See Food & Drug Admin. v. Wages & White Lion Invest., L.L.C.*, 145 S. Ct. 898, 917 (2025) (quoting *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009)). There is no need to reach the second step here, because there was no change. Maximus processed the case in accordance with how it was submitted—due to Alignment's own procedural error. Alignment cannot now use that mistake to challenge the Star Rating.

Accordingly, the record shows that Maximus followed the correct procedure based on the procedure Alignment chose to follow. Thus, there is nothing in the record to suggest that Maximus or CMS changed any policy or otherwise treated this case differently than others that were similarly situated, and therefore the Star Rating reflecting Maximus's treatment of that case was not arbitrary or capricious.

B. Maximus Correctly Reversed the Denial of Case 1-12757246876

For the second case, Case 1-12757246876, Alignment contends that the record lacks substantial evidence to support Maximus's decision reversing Alignment's denial of coverage for outpatient lab services. Pl. Mem. (ECF No. 11-1) at 44. The substantial evidence standard is highly deferential to an agency's findings of fact. *Biestek v. Berryhill*, 587 U.S. 97, 102 (2019) ("[T]he threshold for such evidentiary sufficiency is not high."). That standard is satisfied here. The record shows that Alignment denied the claim because the patient had other primary insurance that should be billed first, but Maximus found that Alignment failed to coordinate coverage with the other insurer. AR 0040. Alignment's contrary evidence—a remittance advice form containing the code "MISSING PRIMARY INSURANCE CARRIER(S) [EOB]"—does not establish that it actually attempted coordination of benefits. AR 0009; Pl. Mem. (ECF No. 11-1) 44–45. Alignment does not cite to any authority or countervailing evidence to support its argument that including such a code by itself constitutes "coordinating coverage." *See, e.g.*, AR. 0002, 0018, 0038. Alignment does not allege that it contacted the primary insurer or obtained a denial.

To the contrary, Alignment acknowledged that the denial code was inadequate and stated that it had updated its procedures to ensure clearer communication in the future. AR 0018 ("Alignment does not dispute payment of the claim."). And it seemingly acknowledged that merely denying a claim and including a code that the submission is "missing primary insurance carrier's EOB [Explanation of Benefits]" is not the same as affirmatively instructing a provider to

coordinate care with an enrollee's primary insurer. *Id*. (stating it "has implemented changes for Claims adjustment code to better clarify to providers [the enrollee] has other primary insurance, please submit claim to the primary insurance first. If primary Insurance already paid/denied the claim, send us a copy of primary insurance remittance advice.'").

The record therefore contains sufficient evidence from which a reasonable mind could conclude that Alignment did not in fact coordinate coverage with the enrollee's other insurance provider. No more is required under the substantial-evidence standard.

C. Alignment's Challenge to Maximus's Determinations was Untimely

Even if Alignment's claim-specific arguments had any merit—which they do not—they still fail because Alignment neglected to use the available administrative process for review of Maximus's decisions. CMS regulations and guidance provide a generous 180-day window to request reopening of Independent Review Entity decisions. *See* 42 C.F.R. § 422.616; Appeals Guidance at 106, *available at* https://perma.cc/JR8W-H7XF. Alignment missed that deadline in both cases: by 232 days in Case 1-13226962526, and by 363 days in Case 1-12757246876. AR 0017–20, 37. Maximus accordingly properly dismissed both reopening requests as untimely.

* * *

CONCLUSION

For these reasons, Defendants respectfully request that the Court grant Defendants' cross-motion for summary judgment and deny Plaintiff's motion for summary judgment.

Dated: April 28, 2025
Washington, D.C.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALIGNMENT HEALTHCARE INC., Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 25- 0074 (CRC)

[PROPOSED] ORDER

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

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

ORDERED that Defendants' Cross-Motion for Summary Judgment is GRANTED; and it is

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

This is a final appealable Order.

SO ORDERED:

_____
Date

_____
CHRISTOPHER R. COOPER
United States District Judge