et al..

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AVMED, INC., et al.,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services.

Civil Action No. 20-3385 (JDB)

Defendants.

MEMORANDUM OPINION

Medicare Advantage ("MA") insurers must submit annual data on patient care and satisfaction to the Centers for Medicare and Medicaid Services ("CMS") through standardized measurement systems, including the Healthcare Effectiveness Data and Information Set ("HEDIS") and the Consumer Assessment of Healthcare Providers and Systems ("CAHPS"). CMS rates plans from one to five stars ("Star Ratings") based on metrics from HEDIS, CAHPS, and elsewhere. By statute, higher-rated plans receive higher federal payments. In April 2020, amid the COVID-19 pandemic, CMS issued a rule ("the Challenged Rule") that, first, suspended the requirement that plans submit HEDIS and CAHPS data because data collection was unsafe and would divert resources from patients; second, the rule provided that in lieu of new data, CMS would compute 2021 Star Ratings using the prior year's CAHPS and HEDIS data along with new data for metrics derived from other sources.

Three MA plans—AvMed, Prominence HealthFirst, and Prominence HealthFirst of Texas, Inc.—bring this suit under the Medicare Act and the Administrative Procedure Act ("APA"), alleging that the first component of the Challenged Rule was <u>ultra vires</u> and the second was arbitrary and capricious. Plaintiffs have now moved for summary judgment and a preliminary injunction. Defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services ("the Secretary"), and Liz Richter, in her official capacity as Acting Administrator for CMS, have cross-moved for summary judgment.¹ For the reasons stated below, the Court will grant defendants' cross-motion for summary judgment, deny plaintiffs' motion for summary judgment, and deny plaintiffs' motion for a preliminary injunction as moot.

Background

I. Statutory and Regulatory Framework

The Medicare Act establishes a federal health insurance program for disabled and elderly beneficiaries. 42 U.S.C. § 1395 <u>et seq</u>. Parts A and B govern the traditional Medicare system, in which CMS directly reimburses healthcare providers. <u>Id.</u> §§ 1395c, 1395j. Part C, created by the Balanced Budget Act of 1997, governs the Medicare Advantage² program which allows people to receive Medicare benefits through private insurers. <u>Id.</u> § 1395w-21; Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275–327 (1997). MA insurers must provide enrollees the same level of benefits offered by traditional Medicare and may also offer supplemental benefits. 42 U.S.C. § 1395w-22. Insurers are paid a pre-determined monthly sum for each beneficiary. <u>Id.</u> § 1395w-23. Today, that sum is determined through a bidding system. Each year, CMS establishes "benchmark" rates that represent the maximum CMS will pay an MA plan to cover an average beneficiary in each county. <u>See id.</u> § 1395w-23(b)(1)(B). Plans then submit "bids" for the payment they need from

¹ Pursuant to Federal Rule of Civil Procedure 25(d), Defendants Xavier Becerra and Liz Richter are substituted, respectively, for Defendants Alex M. Azar, II and Seema Verma.

² The Medicare Advantage program was originally called Medicare+Choice. Similarly, CMS was preceded by the Health Care Financing Administration (HCFA). The Court will substitute "CMS" for "HCFA" and "Medicare Advantage" or "MA" for "Medicare+Choice" or "M+C" and will refer to defendants as both "CMS" and "the Secretary."

CMS in the coming year. See id. § 1395w-23(a)(1)(B). If a plan bids below the benchmark, CMS returns a portion of the savings to the plan as a "rebate," which the plan can use to fund additional benefits or reduce premiums. See id. § 1395w-23(a)(1)(E).

Under the Balanced Budget Act of 1997, each MA insurer was required to "have arrangements ... for an ongoing quality assurance program." 111 Stat. at 291 (codified at 42 U.S.C. § 1395w-22(e)(1) (1997)). The statute set forth twelve mandatory elements of such programs, which provided for collection, analysis, and reporting of data to allow CMS to monitor plans and to give beneficiaries information on plan quality. 42 U.S.C. 1395w-22(e)(2)(A)(i), (vi), (xii) (1997). CMS had authority to regulate the quality assurance programs and to choose the "quality and outcomes measures" that the Secretary "determine[d] to be appropriate." Id. §§ 1395w-22(e)(1), (e)(2)(A)(xii) (1997). The implementing regulations required each insurer to "[m]easure performance ... using standard measures required by [CMS]," which "may be specified in uniform data collection and reporting instruments required by [CMS]." 42 C.F.R. § 422.152(c)(1) (1998). At that time, CMS had "already begun requiring reporting of standardized quality measurement data through instruments such as [HEDIS], as well as reporting of standardized consumer satisfaction data through [CAHPS]." 63 Fed. Reg. 34,968, 34,993 (June 26, 1998). Because CMS wanted "flexibility for the specific reporting and performance requirements to progress" so it could "respond rapidly to new developments," the regulations did not "specify[] the particular measures for which reporting [would] be required." Id.

The Medicare Modernization Act of 2003 substantially amended the statutory provisions discussed above, effective 2006. Pub. L. No. 108-173, § 722(a)(2), 117 Stat. 2066, 2347–48 (2003). The amendments largely erased the former § 1395w-22(e)(2), which had set forth the twelve-point program, and added a new § 1395w-22(e)(3) entitled "Data," which remains effective

today. Subparagraph (A)(i) requires that "subject to subparagraph (B), . . . each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality." 42 U.S.C. § 1395w-22(e)(3)(A)(i). Subparagraph (B) provides, in relevant part:

(B) Limitations.—

(i) Types of data.—The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

(ii) Changes in types of data.—Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

Id. § 1395w-22(e)(3)(B)(i)–(ii).³ In its subsequent rulemaking, CMS interpreted the amendments to mean the agency could continue to collect both CAHPS and HEDIS data, which were collected as of November 1, 2003. See 69 Fed. Reg. 46,866, 46,886 (Aug. 3, 2004).

CMS has published raw data about plan quality and performance since 1998. <u>See</u> 83 Fed. Reg. 16,440, 16,520 (Apr. 16, 2018). But in 2008, CMS began publishing annual Star Ratings, which synthesize that data into ratings of one to five stars for each MA plan. <u>Id.</u>⁴ Star Ratings are based "on the type of data specified in section 1852(e) of the [Social Security] Act and on CMS administrative data." 42 C.F.R. § 422.162(c)(1). "This includes information of the following types: Clinical data, beneficiary experiences, changes in physical and mental health, benefit administration information and CMS administrative data." <u>Id.</u> The "[d]ata underlying Star Ratings

³ This provision is sometimes referred to as section 1852(e)(3)(B) of the Social Security Act.

⁴ CMS publishes Star Ratings for MA plans offering prescription drug coverage through Medicare Part D and for Part C only contracts. Since 2011, CMS has published an overall Star Rating, along with a Part C summary rating and Part D summary rating, for plans that offer Part D coverage. For Part C only plans, CMS publishes a Part C summary rating. See 83 Fed. Reg. at 16,520; 42 C.F.R. § 422.162(b)(1).

measures may include survey data, data separately collected and used in oversight of MA plans' compliance with MA requirements, data submitted by plans, and CMS administrative data." <u>Id.</u> CMS first calculates "measure-level" ratings for a variety of "measures" such as Breast Cancer Screening (the "percent of female plan members aged 52-74 who had a mammogram during the past 2 years"), Getting Needed Care (the percent of surveyed members who gave the plan "the best possible score . . . on how easy it is for members to get needed care"), and Members Choosing to Leave the Plan (the "percent of plan members who chose to leave the plan"). <u>See</u> 83 Fed. Reg. at 16,537–546. Each measure is derived from a specified data source. <u>Id.</u> For example, the Breast Cancer Screening measure is derived from HEDIS, the Getting Needed Care measure from CAHPS, and the Members Choosing to Leave the Plan measure from the Medicare Beneficiary Database Suite of Systems (which is CMS administrative data). <u>Id.</u> A plan's overall Star Rating reflects the weighted mean of the measure-level ratings, plus applicable adjustments. 42 C.F.R. § 422.162(b)(1).

At first, the Star Ratings served two purposes: to provide beneficiaries information on plan performance to consider when choosing a plan, and to assist CMS in identifying low performing plans for compliance actions. <u>See</u> 75 Fed. Reg. 71,190, 71,219 (Nov. 22, 2010). In 2010, Congress added a third purpose. The Affordable Care Act ("ACA")—as amended by the Healthcare and Education Reconciliation Act ("HCERA")—introduced the Quality Bonus Payment program, which incorporated Star Ratings into two statutory formulas to be used in determining certain payments to MA plans (effective 2012). <u>See</u> HCERA, Pub. L. No. 111-152, 124 Stat. 1029, 1043–46 (2010). The first, codified at 42 U.S.C. § 1395w-23(o), rewards MA plans rated four stars or higher with an increased benchmark against which to bid. The second formula, codified at 42 U.S.C. § 1395w-24(b)(1)(C), gives higher-rated plans a larger portion of the difference between

their bid and their benchmark back as a rebate. And in 2012, CMS finalized regulations to terminate plans that have Part C Star Ratings below three stars for three consecutive years. See 42 C.F.R. § 422.510(a)(4)(xi).

II. 2021 Star Ratings Program

In 2018, CMS promulgated regulations to govern the calculation of 2021 Star Ratings. See 83 Fed. Reg. at 16,519–589. CMS explained that, like in past years, the data underlying the 2021 Star Ratings would be consistent with the types of data collected as of November 1, 2003—as required by § 1395w-22(e)(3)(B). <u>Id.</u> at 16,531. That data includes HEDIS and CAHPS along with the Health Outcomes Survey ("HOS"), which began in 1998 to measure "changes in the physical and mental health of MA enrollees." <u>Id.</u> As in the past, the Star Ratings would also include measures related to "telephone customer service, members' complaints, disenrollment rates, and appeals; however these additional measures are not collected directly from the sponsoring organizations for the primary purpose of quality measurement so they are not information collections governed by section [§ 1395w-22(e)]." <u>Id.</u> at 16,531–532. Rather, they are "calculated from information that CMS has gathered as part of the administration of the Medicare program." <u>Id.</u> at 16,532. And as usual, the 2021 Star Ratings were to be based on measures of performance during a period two years before the year for which the ratings are issued—in this case, 2019. <u>See</u> 85 Fed. Reg. 19,230, 19,269 (Apr. 6, 2020), AR 40.⁵

On April 6, 2020, CMS issued the Challenged Rule, an interim final rule that modified the data submission requirements and rating methodology for the 2021 Star Ratings "to address the expected disruption to data collection and measure scores posed by the COVID-19 pandemic and also to avoid inadvertently creating incentives to place cost considerations above patient safety."

⁵ Citations to "AR" refer to the administrative record. <u>See</u> Joint App'x Vol. I [ECF No. 30-1]; Joint App'x Vol. II [ECF No. 30-2].

<u>Id.</u> at 19,230, AR 1. Plans had been scheduled to submit HEDIS and CAHPS data (for the 2019 measurement year) during the spring and summer of 2020 for use in the 2021 Star Ratings. 85 Fed. Reg. at 19,270–271, AR 41–42. But CMS explained that HEDIS collection involves "obtaining information directly from physician offices" in person, which would endanger staff, "put a strain on the limited resources available to these health care providers," and divert attention from patient care. <u>Id.</u> at 19,270. Similarly, collecting CAHPS data—which is done by third-party survey vendors—"cannot be completed remotely" and completing collection would "jeopardize[e] the health and safety of survey vendor[s]." <u>Id.</u> at 19,271. Due to these concerns, CMS removed the requirement that plans submit HEDIS and CAHPS data for the 2021 Star Ratings and requested that plans curtail data collection work immediately. <u>Id.</u>

CMS determined it could not "remove all of the HEDIS and CAHPS measures from the 2021 Star Ratings" because "approximately half of the Star Ratings measures come from HEDIS and CAHPS" and removing them would "severely compromise the integrity" of the ratings. <u>Id.</u> at 19,272. Instead, CMS concluded that using the previous year's measure-level Star Ratings for the missing HEDIS and CAHPS data would provide "the best approximation" of the missing data. <u>Id.</u> For measures not derived from CAHPS and HEDIS, new data was available and CMS would use it. <u>Id.</u> The 2021 Star Ratings were published in October 2020. <u>See Part C & D Performance Data</u>, Centers for Medicare & Medicaid Services, www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData (last visited May 28, 2021).

Plaintiff AvMed's overall rating declined from 4 stars for 2020 to 3.5 stars for 2021, and Prominence HealthFirst's overall rating declined from 3.5 stars for 2020 to 3 stars for 2021. See Answer [ECF No. 16] ¶¶ 69–70. As explained above, these lower ratings will reduce the payments

each plan will receive from CMS. Prominence HealthFirst of Texas received an overall rating of 2.5 for the third year in a row, which means it has been labeled a "low performing" plan. <u>Id.</u> ¶ 71.

III. Litigation History

On November 20, 2020, plaintiffs brought this action against the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services, in their official capacities, raising claims under section 706 of the APA. Compl. [ECF No. 1]. Plaintiffs allege that the Challenged Rule exceeded defendants' statutory authority and was arbitrary and capricious. Id. ¶¶ 78–85. Pursuant to a schedule negotiated between the parties, see Joint Mot. for Briefing Schedule [ECF No. 18] at 1, plaintiffs filed simultaneous motions for summary judgment and preliminary injunctive relief on March 15, 2021, Pls.' Mot. for Summ. J. [ECF No. 20]; Pls.' Mot. for Prelim. Inj. [ECF No. 21]. Because 2022 bids are due by June 7, 2021, plaintiffs requested a quick ruling on at least the preliminary injunction motion. See Pls.' Mot. for Prelim Inj. at 3.⁶ Defendants cross-moved for summary judgment. Defs.' Cross-Mot. for Summ. J. [ECF No. 22]. A hearing was held on May 12, 2021, and all three motions are now fully briefed and ripe for consideration.⁷

Legal Standard

"Because of the limited role federal courts play in reviewing . . . administrative decisions, the typical Federal Rule 56 summary-judgment standard does not apply" to the parties' crossmotions for summary judgment. <u>Conservation L. Found. v. Ross</u>, 422 F. Supp. 3d 12, 27 (D.D.C.

⁶ Plaintiffs explain that because bids must describe the benefits plans intend to provide, preparing a bid requires each plan to "analyze the expected costs of performing services as well as the potential federal funds it will receive." Mem. of Law in Supp. of Pls.' Mot. for Prelim. Inj. [ECF No. 21-1] at 2. Since Star Ratings affect funding, plans need that information to prepare their bids. <u>Id.</u>

⁷ Because this case will be decided on summary judgment, the Court need not address plaintiffs' motion for a preliminary injunction.

2019). Instead, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." <u>Am. Bioscience, Inc. v. Thompson</u>, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "The 'entire case' on review is a question of law," <u>id.</u>, and summary judgment is the proper mechanism for review, <u>Ctr. for Food Safety v. Salazar</u>, 898 F. Supp. 2d 130, 138 (D.D.C. 2012). The Court's role "is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." <u>Ass'n of Priv.Sector</u> <u>Colls. & Univs. v. Duncan</u>, 110 F. Supp. 3d 176, 184 (D.D.C. 2015), <u>aff'd</u>, 640 Fed. App'x 5 (D.C. Cir. 2016) (quoting Univ. of Mass. v. Kappos, 903 F. Supp. 2d 77, 84 (D.D.C. 2012)).

Under the APA, the Court must "hold unlawful and set aside agency action, findings, and conclusions found to be," among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; . . . [or] without observance of procedure required by law." 5 U.S.C. § 706(2). In short, plaintiffs must show that the challenged action was arbitrary and capricious or otherwise not in accordance with law. The bar for arbitrary and capricious action is high: "[i]t is not enough . . . that the court would have come to a different conclusion from the agency," nor can the court "substitute its own judgment for that of the agency." <u>Conservation L. Found.</u>, 422 F. Supp. 3d at 27–28 (quoting <u>Oceana, Inc., v. Pritzker</u>, 24 F. Supp. 3d 49, 58 (D.D.C. <u>2014)</u>). Similarly, courts have found abuse of discretion "if there is no evidence to support the decision or if the decision was based on an improper understanding of the law." <u>Id.</u> at 27 (quoting <u>Kazarian v. USCIS</u>, 596 F.3d 1115, 1118 (9th Cir. 2010)). To survive APA review, there need only be a "rational connection between the facts found and the choice made." <u>Id.</u> (citing <u>Motor</u> Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

<u>Analysis</u>

I. CMS Did Not Exceed Its Statutory Authority by Suspending Data Reporting Requirements

Plaintiffs first contend that by unilaterally suspending the submission of CAHPS and HEDIS data, CMS exceeded its statutory authority under 42 U.S.C. § 1395w-22(e)(3)(B)(ii). See Mem. of Law in Supp. of Pls.' Mot. for Summ. J. ("Pls.' Br.") [ECF No. 20-1] at 21-28. That provision dictates that "the Secretary may only change the types of data that are required to be submitted ... after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies." 42 U.S.C. § 1395w-22(e)(3)(B)(ii). It is undisputed that the Secretary did not submit such a report. But the Secretary argues that § 1395w-22(e)(3)(B), read in its entirety, requires a report to Congress only before collecting new types of data-not before eliminating or suspending existing submission requirements. See Defs.' Mem. in Supp. of Cross-Mot for Summ. J. & in Opp'n to Pls.' Mots. for Summ. J. & Prelim. Inj. Relief ("Defs.' Opp'n") [ECF No. 22-1] at 12-15. In addition, the Secretary argues that even if he violated § 1395w-22(e)(3)(B), plaintiffs lack standing to enforce the statute's procedural requirement because they were not injured by the suspension of data submission alone. Id. at 15; Defs.' Reply in Supp. of Cross-Mot for Summ. J. ("Defs.' Reply") [ECF No. 29] at 9–13.

The Court concludes that plaintiffs have standing, but that the Secretary's reasonable interpretation of the statute is entitled to <u>Chevron</u> deference. Because the Challenged Rule did not require submission of new types of data, no report to Congress was required and hence CMS did not exceed its statutory authority by suspending the submission of CAHPS and HEDIS data.

A. Standing

As an initial matter, the Secretary argues that even if the Challenged Rule violates § 1395w-22(e)(3)(B), plaintiffs lack standing because they were not injured by being relieved of certain reporting obligations. Defs.' Opp'n at 15; Defs.' Reply at 9–13. The Court disagrees.

Constitutional standing requires an injury-in-fact traceable to the challenged conduct that is redressable by a favorable judicial decision. <u>Spokeo, Inc. v. Robins</u>, 136 S. Ct. 1540, 1547 (2016). A concrete injury is "direct, real, and palpable—not abstract." <u>Pub. Citizen, Inc. v. Nat'l</u> <u>Highway Traffic Safety Admin.</u>, 489 F.3d 1279, 1292 (D.C. Cir. 2007). "Deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right <u>in vacuo</u>—is insufficient to create Article III standing." <u>Summers v. Earth Island Inst.</u>, 555 U.S. 488, 496 (2009). "Only a 'person who has been accorded a procedural right to protect <u>his concrete interests</u> can assert that right without meeting all the normal standards for redressability and immediacy." <u>Id.</u> (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 572 n.7 (1992)).

To start, the Secretary contends that "[p]laintiffs have not persuasively identified any injury to 'concrete interests' of theirs that 'the procedures in [42 U.S.C. § 1395w-22(e)(3)(B)] are designed to protect'" because the provision was only "designed to protect against the imposition of new reporting burdens on Medicare Advantage insurers." <u>See</u> Defs.' Reply at 10 (quoting <u>Lujan</u>, 504 U.S. at 573 n.8). On the other hand, plaintiffs posit that the procedures were designed, in part, to protect the reliance interests of MA plans by ensuring plans have input before CMS changes submission requirements. <u>See</u> Rough Tr. of H'rg (May 12, 2021) ("Hr'g Tr.") 13:17–14:15.⁸ Although the Court will ultimately reject plaintiffs' reading of the statute, that does not

⁸ Citations to the May 12, 2021 hearing transcript are to a rough draft of the transcript. When finalized, the transcript will be posted to the docket. Discrepancies between the rough and final transcripts may exist.

mean plaintiffs lack standing. If plaintiffs <u>were</u> to prove that CMS exceeded its statutory authority, they would be able to show a corresponding injury.

The Secretary next argues that plaintiffs cannot prove injury because it is impossible to know whether their 2021 Star Ratings would have risen or fallen if CAHPS and HEDIS reporting had continued. See Defs.' Reply at 11-13. Despite the suspension, plaintiffs kept collecting CAHPS and HEDIS data and assert that had CMS used that new data, "Prominence's Texas plan would have improved to an overall 3-star rating[,]... Prominence's Nevada and Florida plans would have maintained a 3.5-star rating, and AvMed a 4-star rating." Reply in Supp. of Pls.' Mots. for Summ. J. & Prelim. Inj. & Opp'n to Defs.' Mot. for Summ. J. ("Pls.' Reply") [ECF No. 24] at 4. But as plaintiffs conceded at oral argument, these are merely estimates. See Hr'g Tr. 19:19-22. The Star Ratings algorithm uses the data submitted by all MA plans to determine "cut points"—i.e., thresholds at which a plan's Star Rating changes for a given measure. See Defs.' Reply at 11–12. Different data sets produce different cut points and so cut points may change from year to year. Id. at 12. Put simply, Star Ratings are graded on a curve. Because plaintiffs do not know how other insurers' data would have compared to theirs, the Secretary avers that plaintiffs cannot establish that their Star Ratings would have been higher had CAHPS and HEDIS reporting continued. See id. at 13.

However, plaintiffs need not prove with certainty that their Star Ratings would have been higher but for the Challenged Rule.⁹ "[A] plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural

⁹ It would create quite the catch-22 to deny plaintiffs standing on this ground. Plaintiffs lack accurate CAHPS and HEDIS cut points for 2021 because the Secretary decided not to collect the data that would have produced those cut points. In the Secretary's view, then, no plan can ever challenge any decision to suspend or eliminate data submission requirements.

step was connected to the substantive result." <u>Sugar Cane Growers Co-op. of Fla. v. Veneman</u>, 289 F.3d 89, 94–95 (D.C. Cir. 2002); <u>see also Lujan</u>, 504 U.S. at 573 n.7 (holding that a person living next to a licensed dam "ha[d] standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered"). The decision to suspend CAHPS and HEDIS submissions was clearly connected to the decision to rate plans using old CAHPS and HEDIS data—which, in turn, resulted in plaintiffs' 2021 Star Ratings. CMS made the latter decision because, having suspended data collection, new CAHPS and HEDIS data was unavailable.

The Secretary points out that the two decisions were not necessarily connected because CMS theoretically could have continued requiring CAHPS and HEDIS data but then chosen not to use it to calculate Star Ratings, and to use the previous year's CAHPS and HEDIS data instead. <u>See</u> Defs.' Opp'n at 16. "In this scenario, there would be no argument that the Secretary had violated 42 U.S.C. § 1395w-22(e)(3)(B)(ii), because the reporting requirements would not have changed." <u>Id.</u> But there is little doubt that CMS would have used new CAHPS and HEDIS data to calculate Star Ratings had that data been collected. The Secretary admits as much. <u>See</u> Defs.' Reply at 14 (noting that "it would have been better to use newly collected CAHPS and HEDIS data, if such data had been available").

In sum, plaintiffs have persuasively alleged that CMS's decision to halt data collection led CMS to use old CAHPS and HEDIS data, which plausibly lowered plaintiffs' Star Ratings causing plaintiffs to lose millions of dollars in future payments. Hence, plaintiffs have standing to enforce the procedural protections of § 1395w-22(e)(3)(B).

B. Statutory Construction

The Court now turns to whether the Secretary had statutory authority to suspend data submission requirements without first consulting plans and reporting to Congress. The Court examines that question using the traditional <u>Chevron</u> framework, under which courts defer to the agency's reasonable interpretation of an ambiguous statute. <u>See Chevron v. Nat. Res. Def.</u> <u>Council, Inc.</u>, 467 U.S. 837 (1984). Because Congress tasked the Secretary with administering Medicare (through CMS), the Secretary "is generally entitled to <u>Chevron</u> deference on judicial review of [his] interpretations of the Medicare statute." <u>Am. Hosp. Ass'n v. Azar</u>, 964 F.3d 1230, 1239 (D.C. Cir. 2020).

Plaintiffs urge the Court not to apply <u>Chevron</u> in this case because "<u>Chevron</u> deference is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in gaps" and "[t]he Court should not presume that Congress would delegate to CMS the authority to decide when it was legally required to report to Congress and when it could ignore that mandate." Pls.' Reply at 8 n.2. But the Supreme Court has held otherwise: "a court must defer under <u>Chevron</u> to an agency's interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority." <u>City of Arlington, Tex. v. FCC</u>, 569 U.S. 290, 296 (2013). "<u>Chevron</u> applies equally to statutes designed to <u>curtail</u> the scope of agency discretion." <u>Id.</u> at 303; <u>see also Helicopter Ass'n Int'l., Inc. v. FAA</u>, 722 F.3d 430, 433 (D.C. Cir. 2013) ("[D]eference by the court extends to the agency's interpretation of statutory ambiguity that concerns the scope of the agency's jurisdiction.").¹⁰

¹⁰ Plaintiffs' sole case in support of their position, <u>Smith v. Berryhill</u>, 139 S. Ct. 1765 (2019), is inapposite. There, the Supreme Court denied an amicus curiae's request to apply <u>Chevron</u> deference to an agency's interpretation of a statute that the government's briefing had rejected: that dismissal of a Social Security claimant's untimely request for review of an Administrative Law Judge's merits decision is not a final decision subject to judicial review. <u>Id.</u> at 1778. As plaintiffs note, the Court stated that "[t]he scope of judicial review . . . is hardly the kind of question that the Court presumes that Congress implicitly delegated to an agency," <u>id.</u>—in part because there is a "strong

Under the two-step <u>Chevron</u> framework, courts first determine whether the statute is ambiguous because if "Congress has directly spoken to the precise question at issue [and]... the intent of Congress is clear, that is the end of the matter." <u>Chevron</u>, 467 U.S. at 842. If the statute is ambiguous, however, then courts consider "whether the agency's answer is based on a permissible construction of the statute." <u>Id.</u> at 843.

1. Section 1395w-22(e)(3)(B) Is Ambiguous

At step one of <u>Chevron</u>, "the court begins with the text and employs 'traditional tools of statutory construction' to determine whether Congress has spoken directly to the issue." <u>Am.</u> <u>Hosp. Ass'n</u>, 964 F.3d at 1241 (quoting <u>Prime Time Int'l Co. v. Vilsack</u>, 599 F.3d 678, 683 (D.C. Cir. 2010)). Applying those tools, the Court concludes that § 1395w-22(e)(3)(B)(ii) does not unambiguously prohibit the Secretary from suspending data submission requirements without first consulting plans and reporting to Congress. Understood in context, the statute can be read to mandate a report to Congress only before the Secretary may collect types of data it has not traditionally collected. See Defs.' Opp'n at 13.

a. Statutory Text

Statutory interpretation "begins with the text." <u>Ross v. Blake</u>, 136 S. Ct. 1850, 1856 (2016). As the Supreme Court recently reiterated, "when the meaning of the statute's terms is plain," this Court's "job is at an end." <u>Bostock v. Clayton Cnty.</u>, 140 S. Ct. 1731, 1749 (2020). But "a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." <u>FDA v. Brown & Williamson Tobacco Corp.</u>, 529 U.S. 120, 132 (2000).

presumption that Congress intends judicial review of administrative action," <u>id.</u> at 1776 (quoting <u>Bowen v. Mich.</u> <u>Acad. of Family Physicians</u>, 476 U.S. 667, 670 (1986)). This case does not concern an agency interpretation that forecloses judicial review.

And "the provisions of a text should be interpreted in a way that renders them compatible, not contradictory." <u>Maracich v. Spears</u>, 570 U.S. 48, 68 (2013) (quoting A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 180 (2012)).

Here, subparagraph (A) of § 1395w-22(e)(3) requires that "subject to subparagraph

(B), ... each MA organization shall provide for the collection, analysis, and reporting of data that

permits the measurement of health outcomes and other indices of quality." 42 U.S.C. § 1395w-

22(e)(3)(A)(i). Subparagraph (B) provides:

(B) Limitations.—

(i) Types of data.—The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

(ii) Changes in types of data.—Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

(iii) Construction.—Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1395w-21(d)(4)(D) of this title.

<u>Id.</u> § 1395w-22(e)(3)(B).¹¹

The Secretary argues that "the [first] two subclauses cannot both mean the full extent of what they say" because "[s]ubclause (i) seems to prohibit what subclause (ii) seems to permit: the collection of new types of data." Defs.' Reply at 2^{12} . From here, the Secretary reconciles this

apparent contradiction as follows:

¹¹ Section 1395w-21(d)(4)(D), referenced in subclause (iii), requires CMS to provide beneficiaries with available plan quality and performance indicators. Subclause (iii) is largely irrelevant here.

¹² The Supreme Court addressed a similar scenario in <u>Scialabba v. Cuellar de Osorio</u>, 573 U.S. 41 (2014), where the plurality opinion applied <u>Chevron</u> deference to a provision that did "not speak unambiguously to the issue" at hand because it "addresse[d] that issue in divergent ways." <u>Id.</u> at 57 (Kagan, J.) (plurality opinion). That provision, the plurality wrote, was "Janus-faced" because "[i]ts first half looks in one direction, toward the sweeping relief the respondents propose" while the "second half looks another way, toward a remedy that can apply to only a subset of beneficiaries. . . . Read either most naturally, and the other appears to mean not what it says." <u>Id.</u> at 57. When "internal

If the Secretary may add to "the types of data that are required to be submitted" so long as he prepares the necessary report—if that is a "change" permitted by subclause (ii)—then subclause (i) cannot be a blanket prohibition, despite its use of "shall not." And if subclause (i) is not a blanket prohibition, then it would seem to state the general rule to which subclause (ii) provides a limited exception. On this reading, the provision as a whole means: "The Secretary shall not collect" new "types of data," <u>see</u> subclause (i), unless he first submits "to Congress a report . . . that was prepared in consultation with MA organizations and private accrediting bodies," <u>see</u> subclause (ii).

Defs.' Opp'n at 13. Plaintiffs offer an alternative reading: "(B)(i) gives the Secretary the authority to choose among the types of data that were collected as of November 1, 2003, in determining what data [he] would collect." Pls.' Reply at 6. Then, "(B)(ii) requires the Secretary to submit a report to Congress after consulting the industry when [he] changes that selection (among the types of data that were collected on November 1, 2003)." Id. at 6–7.

Both readings have weaknesses. In the Secretary's view, only the addition of a new type of data required to be submitted constitutes a "change" covered by subclause (ii). But the ordinary meaning of "change" encompasses both additions and subtractions. Accordingly, a literal reading of subclause (ii) is that the Secretary must report to Congress before making <u>any</u> change to the types of data MA plans must submit—whether that change be adding a new data type, eliminating an existing one, or both.

Plaintiffs' interpretation has slightly stronger textual footing. As plaintiffs explain, "[t]here is nothing contradictory about Congress establishing the universe of data that the Secretary can collect in subsection (B)(i) and at the same time wanting to be informed via a report about changes in the data the Secretary is requiring MA Plans to submit in subsection (B)(i)." <u>Id.</u> at 7. Even so, plaintiffs' reading of subclause (ii) is flawed in multiple ways and "confuses 'plain meaning' with

tension makes possible alternative reasonable constructions," the plurality concluded, "<u>Chevron</u> dictates that a court defer to the agency's choice." <u>Id.</u> <u>But see id.</u> at 76 (Roberts, C.J., concurring in the judgment) (disagreeing).

literalism" by giving short shrift to the statutory context. <u>See Bell Atl. Tel. Cos. v. FCC</u>, 131 F.3d 1044, 1045 (D.C. Cir. 1997).

First, plaintiffs also distort the ordinary meaning of "change," but in the opposite direction. Both parties said at oral argument that since the statute's passage, CMS has required submission of all the same types of data that were collected as of November 1, 2003. See Hr'g Tr. 11:1-16; 24:1–7. That means, under plaintiffs' interpretation, that CMS could not require a new type of data—either in addition to current types, or as a substitute for a type it eliminates—because all of the "approved" types of data (those collected as of November 1, 2003) are already required. Hence, the only possible "change" covered by subclause (ii) under plaintiffs' interpretation would be the elimination (or temporary suspension) of a data submission requirement. The Court acknowledges that if CMS stopped requiring plans to submit a certain type of data, and then decided to reinstate that requirement, the reinstatement would presumably be a "change" under plaintiffs' interpretation of subclause (ii). But similarly, if CMS stopped requiring plans to submit a certain type of data and then replaced it with a new type of data—that is, a type not required as of November 1, 2003-the replacement would presumably be a "change" under the Secretary's interpretation of subclause (ii). Therefore, the Secretary's interpretation of "change" covers not only additions but also substitutions-and so is not much more than plaintiffs' reading of "change."

Second, when read alone, subclause (ii) appears to permit the Secretary to change the types of data that plans must submit however he likes, but only after presenting the necessary report to Congress. Subclause (ii) contains no suggestion that the Secretary's power to make changes is limited to choosing among the types of data that were collected on November 1, 2003. The absence of such language is notable because Congress <u>did</u> expressly make subclause (ii) "[s]ubject to subclause (iii)." <u>See</u> 42 U.S.C. § 1395w-22(e)(3)(B)(ii). This suggests that Congress knew how to make subclause (ii) subject to subclause (i) had it meant to achieve that result, but declined to do so. Further, plaintiffs read subparagraph (B) both stringently and disjunctively. Under plaintiffs' interpretation, CMS may not collect new types of data under any circumstances <u>and</u> must continue requiring submission of all previously collected data unless CMS first consults with plans and reports to Congress. If that is what Congress intended, subclause (ii) would be a strange way to phrase the second mandate.¹³

Hence, while subclause (ii) initially appears to prohibit the Secretary from eliminating data submission requirements without first reporting to Congress, the text—read in conjunction with subclause (i)—is unclear enough to justify further analysis. In other words, "[f]ocusing on the text alone, the plain meaning is elusive." <u>Meredith v. Fed. Mine Safety & Health Rev. Comm'n</u>, 177 F.3d 1042, 1054 (D.C. Cir. 1999). Therefore, "[i]n determining whether [the] statute is ambiguous and in ultimately determining whether the agency's interpretation is permissible or instead is foreclosed by the statute, we must employ all the tools of statutory interpretation, including 'text, structure, purpose, and legislative history." <u>Loving v. IRS</u>, 742 F.3d 1013, 1016 (D.C. Cir. 2014) (quoting <u>Pharm. Rsch. & Mfrs. of Am. v. Thompson</u>, 251 F.3d 219, 224 (D.C. Cir. 2001)). As

¹³ A third reading of subparagraph (B) seems plausible. Perhaps the Secretary is right that subclause (i) is not a blanket prohibition on collecting new types of data, but subclause (ii) does not <u>only</u> provide a limited exception to the general rule in subclause (i). Instead, subclause (ii) could mean that the Secretary must present a report to Congress before making <u>any</u> change to the types of data required to be submitted. Such a change may be (1) requiring submission of a data type that was not collected as of November 1, 2003; (2) requiring submission of a data type that was not currently required to be submitted; or (3) eliminating an existing requirement that plans submit a certain data type that was collected as of November 1, 2003—or any combination of the three. This reading gives proper meaning to the word "change" without construing the Secretary's power under subclause (ii) to narrowly. But this interpretation, too, is imperfect. Had Congress intended for subclause (ii) to operate both as an exception to subclause (i) and as a constraint on the Secretary's power to change submission requirements <u>among</u> those data types allowed by subclause (i), it likely would have said as much. Still, the existence of a third plausible interpretation suggests the statute is ambiguous.

explained above, the text and structure¹⁴ do not help much. Nor does the scant legislative history on the provision, which emerged in the conference committee that drafted the final bill. <u>See</u> H.R. Rep. No. 108-391, at 729–31 (2003) (Conf. Rep.). The Court will therefore examine congressional purpose and CMS's previous interpretations of the relevant provision.

b. Congressional Purpose

To determine the purpose of a statutory provision, courts look to the "intent of the Congress that originally enacted the provision." <u>Mackey v. Lanier Collection Agency & Serv., Inc.</u>, 486 U.S. 825, 840 (1988); <u>accord Int'l Brotherhood of Teamsters v. United States</u>, 431 U.S. 324, 354 n.39 (1977) ("It is the intent of the Congress that enacted [the provision] . . . that controls.").

Plaintiffs argue that Congress adopted § 1395w-22(e)(3)(B) because it did "not want to permit the Secretary to make wholesale changes to the data being submitted that forms the basis for significant financial payments without a report made in consultation with the plans that are impacted by those changes." Pls.' Reply at 7. But at the time § 1395w-22(e)(3)(B) was adopted as part of the Medicare Modernization Act of 2003, the data collected under § 1395w-22(e)(3) did not affect payments to insurers. In fact, CMS did not even start publishing Star Ratings until 2008—although it published raw data about plan quality starting in 1998. See 83 Fed. Reg. at 16,520. Even once CMS began publishing Star Ratings for beneficiaries, the ratings did not initially affect payments to insurers. Congress did not make payments contingent on Star Ratings until it passed the Affordable Care Act of 2010, which (as amended by HCERA) incorporated Star Ratings into two statutory formulas to be used in calculating payments to insurers starting in 2012.

¹⁴ To the Secretary's credit, stating a rule and then providing the exception is a common way to write a statute. See, e.g., Comm'r v. Clark, 489 U.S. 726, 739 (1989) (discussing "provisions . . . in which a general statement of policy is qualified by an exception"); <u>In re Woods</u>, 743 F.3d 689, 698 (10th Cir. 2014) (discussing "the statute's structure—setting forth a baseline rule and an exception").

See HCERA, 124 Stat. 1043–45. Therefore, the intent of the enacting Congress had nothing to do with payments tied to Star Ratings.

Plaintiffs suggest that "the ever-expanding role and importance of the data collected under [§ 1395w-22(e)] . . . to MA Plans" should inform the Court's assessment of congressional intent. See Pls.' Reply at 7–8. But "absent an amendment to the original language," Mackey, 486 U.S. at 840, "subsequent legislation cannot redefine the intent of the original enacting Congress," <u>Nat'l Ass'n of Broad. v. FCC</u>, 740 F.2d 1190, 1213 (D.C. Cir. 1984). As the Secretary states, "[a]ny congressional purpose that we can infer from this provision must therefore be found in the circumstances surrounding its enactment in 2003." Defs.' Reply at 4.

When Congress enacted § 1395w-22(e)(3)(B) in 2003, it was amending the Balanced Budget Act of 1997, which created the Medicare Advantage program. Under the Balanced Budget Act, each MA insurer was required to "have arrangements . . . for an ongoing quality assurance program," which would "provide for the collection, analysis, and reporting of data," "provide the Secretary with such access to information collected as may be appropriate to monitor and ensure the quality of care," and "make available information on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options." 111 Stat. at 291–92 (codified at 42 U.S.C. §§ 1395w-22(e)(1), (e)(2)(A)(i), (vi) & (xii) (1997)). The Secretary was expressly authorized to implement the quality assurance program by regulation and to choose measures he considered appropriate. Id. §§ 1395w-22(e)(1), (e)(2)(A)(xii). The implementing regulations gave CMS considerable authority to change reporting requirements. Plans were required to "[m]easure performance . . . using standard measures required by [CMS]," which "may be specified in uniform data collection and reporting instruments required by [CMS]." 42 C.F.R. § 422.152(c)(1) (1998). And because CMS wanted "flexibility" for "reporting and performance

requirements to progress" in response to new developments, the regulations did not specify particular measures for which reporting would be required. 63 Fed. Reg. at 34,993. Two years later, CMS reiterated its authority to "impos[e] further requirements" on insurers. <u>See</u> 65 Fed. Reg. 40,169, 40,221 (June 29, 2000) ("Our requirements may change in future years as the HEDIS instrument evolves and as other measurement instruments are developed.").

In light of this history, the Secretary's account of the intent of the enacting Congress is compelling: Congress was "concerned with the reporting burden that the Secretary might place on insurers, and wanted to know before the Secretary imposed new requirements—presumably, so that Congress could act if it saw the need." <u>See</u> Defs.' Opp'n at 13. To allay that concern, Congress repealed the original statutory provisions in the Balanced Budget Act and added the provision at issue here, § 1395w-22(e)(3) entitled "Data," which limited the Secretary's authority. <u>See</u> 117 Stat. at 2347–48 (amending 42 U.S.C. § 1395w-22(e)(1)–(3)). Evidently, Congress wanted to "minimize[] reporting burden for the industry." <u>See</u> 83 Fed. Reg. at 16,520.

It is much less clear that the enacting Congress would have been concerned about the Secretary reducing data submission requirements. At oral argument, plaintiffs said that one purpose of subparagraph (B) may have been to minimize reporting burdens on plans, but the purpose of collecting data in the first place was to ensure beneficiaries received consistent information about plan performance. See Hr'g Tr. 13:17–14:15. Because beneficiaries could use the raw data to choose a plan, plaintiffs have suggested, Congress thought plans had an interest in knowing what kind of data would be collected in advance and having input. See id. True enough. But that broad purpose does not explain why Congress would want a report any time CMS changed its selection of data among types of data Congress had <u>already approved</u>. CMS was already bound by APA standards; any choice to suspend or eliminate a data submission requirement had to be

non-arbitrary and follow proper procedure. Moreover, even under plaintiffs' interpretation, subclause (ii) would not require CMS to report to Congress every time the agency changes what data Star Ratings are based on. That is because in addition to measures based on HEDIS, CAHPS, and HOS, Star Ratings include measures related to "telephone customer service, members' complaints, disenrollment rates, and appeals." 83 Fed. Reg. at 16,531. These measures are "not collected directly from the sponsoring organizations for the primary purpose of quality measurement [and] so they are not information collections governed by section [§ 1395w-22(e)]." <u>Id.</u> at 16,531–32. Rather, they are "calculated from information that CMS has gathered as part of the administration of the Medicare program." <u>Id.</u> at 16,532. Put differently, the data underlying Star Ratings includes data that is not "required to be submitted." This undercuts plaintiffs' argument that the purpose of subclause (ii) was to ensure consistency in the data provided to beneficiaries, because subclause (ii) does not prevent CMS from changing the types of administrative data that feed into Star Ratings.

At oral argument, plaintiffs seemed to argue that the Congress that passed the Affordable Care Act in 2010 would not have tied significant payments to Star Ratings had it thought that the Secretary could reduce data submission requirements without consulting with MA plans or reporting to Congress. See Hr'g Tr. at 48:7–49:1. But plaintiffs fail to identify anything in the legislative history of the ACA that suggests the 2010 Congress had such an understanding. And even if it did, the Court is unclear how that would speak to the purpose of § 1395w-22(e)(3)(B).

Hence, the Court's inquiry into the purpose of the statute suggests both that § 1395w-22(e)(3)(B)(ii) does not unambiguously prohibit the Secretary from suspending data submission requirements without first reporting to Congress, and that the Secretary's interpretation is reasonable.

2. <u>The Secretary's Interpretation of § 1395w-22(e)(3)(B) Is Reasonable</u>

At step two of <u>Chevron</u>, courts ask whether the agency's interpretation "is based on a permissible construction of the statute." <u>Chevron</u>, 467 U.S. at 843. "A 'reasonable' explanation of how an agency's interpretation serves the statute's objectives is the stuff of which a 'permissible' construction is made . . . ; an explanation that is 'arbitrary, capricious, or manifestly contrary to the statute,' however, is not." <u>Northpoint Tech. Ltd. v. FCC</u>, 412 F.3d 145, 151 (D.C. Cir. 2005) (internal citations omitted) (quoting <u>Chevron</u>, 467 U.S. at 844). The agency's interpretation need not be "the only possible interpretation, nor even the interpretation deemed <u>most</u> reasonable by the courts." <u>Entergy Corp. v. Riverkeeper, Inc.</u>, 556 U.S. 208, 218 (2009). The Court has already explained during the <u>Chevron</u> step one inquiry why the Secretary's interpretation of § 1395w-22(e)(3)(B)(ii) is reasonable. The Secretary's interpretation is a plausible reading of the relevant language in the context of the whole provision and is consistent with the purpose of the statute. <u>See supra</u> Part I.B.1.

Yet plaintiffs argue that even if <u>Chevron</u> deference is otherwise warranted, the Court should not defer to the Secretary's interpretation here because it is "contrary to how CMS has previously construed this very same provision." <u>See</u> Pls.' Reply at 8–9. The Court is not persuaded. In general, "the case for judicial deference is less compelling with respect to agency positions that are inconsistent with previously held views." <u>Pauley v. BethEnergy Mines, Inc.</u>, 501 U.S. 680, 698 (1991). But CMS "has held unswervingly" to its understanding of § 1395w-22(e)(3)(B). <u>See id.</u> The 2018 interpretation that plaintiffs cite reads as follows:

Section 1852(e)(3)(B) of the Act prohibits the collection of data on quality, outcomes, and beneficiary satisfaction other than the types of data that were collected by the Secretary as of November 1, 2003[.]... The statute does not require that only the same data be collected, but that we do not change or expand the type of data collected until after submission of a Report to Congress (prepared in consultation with MA organizations and accrediting bodies) that explains the

reason for the change(s). We clarify here that the types of data included under the Star Ratings system are consistent with the types of data collected as of November 1, 2003. Since 1997, Medicare managed care organizations have been required to annually report quality of care performance measures through HEDIS. We have also been conducting the CAHPS survey since 1997 to measure beneficiaries' experiences with their health plans. HOS began in 1998 to capture changes in the physical and mental health of MA enrollees. To some extent, these surveys have been revised and updated over time, but the same types of data—clinical measures, beneficiary experiences, and changes in physical and mental health, respectively—have remained the focus of these surveys.

83 Fed. Reg. at 16,531. Plaintiffs assert that "[b]y acknowledging the Congressional reporting requirement applied to any decision to 'change or expand' and not just to 'expand,' CMS previously rejected the interpretation that it advances now." Pls.' Reply at 8. But under CMS's interpretation, "[c]overed 'change[s]' do not necessarily 'expand' the scope of data collection" because a change subject to subclause (ii) could be a substitution. <u>See</u> Defs.' Reply at 7. For example, if CMS wanted to replace the CAHPS requirement with a new "type of data" on consumer satisfaction that was not collected as of November 1, 2003, that change would require consultation with MA plans and a report to Congress. Notably, CMS's 2018 interpretation stated that a report to Congress was required before the agency could "change or expand" the type of data collected, but <u>not</u> before it could "reduce" or "contract" the type of data collected. Moreover, CMS's statement that "[t]he statute does not require that only the same data be collected" is at odds with plaintiffs' view of subclause (i) as an absolute prohibition on requiring submission of data types that were not collected as of November 1, 2003.

The Secretary's reading of § 1395w-22(e)(3)(B) is also consistent with other past agency constructions. In the rulemaking following the Medicare Modernization Act of 2003, CMS wrote:

We interpret section 1852(e)(3)(B)(i) of the Act to mean that we can continue to require MA coordinated care plans to collect, analyze, and report their performance by using the measurement systems that are currently required, such as HEDIS, Health Outcomes of Seniors (HOS), and CAHPS, as appropriate for the type of plan... If, in the future, we believe that a new measurement system should be

used to assess MA plans' performance, we are required under section 1852(e)(3)(B)(ii) of the Act to submit a report to Congress that is prepared in consultation with MA organizations and private accrediting organizations.

69 Fed. Reg. at 46,886. This statement is—without question—consistent with CMS's current reading of subparagraph (B). HEDIS, HOS, and CAHPS are all "measurement systems" (i.e. "types of data") and CMS stated that it could use a "new measurement system" so long as the agency reported to Congress first. Similarly, in 2005 CMS explained that while it was free to "mak[e] changes within each of the existing measurement systems, such as HEDIS," the agency "need[ed] to submit a Report to the Congress to add new systems." 70 Fed. Reg. 4,588, 4,635 (Jan. 28, 2005). And in 2009, CMS wrote that "Section 1852(e)(3)(B)(i) of the Act generally limits the collection of data . . . to 'the types of data' that were collected as of November 1, 2003, however, section 1852(e)(3)(B)(ii), titled 'Changes in Types of Data,' provides for the Secretary to 'change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report." 74 Fed. Reg. 54,634, 54,680 (Oct. 22, 2009) (emphasis added). All of this suggests that CMS viewed subclause (ii) as a limited exception to the general rule in subclause (i). Hence, CMS has long interpreted subclause (ii) to allow the collection of new types of data once the agency has submitted the necessary report to Congress. Although this case is not about new types of data, CMS's longstanding view supports its reasonable construction here: "If subclause (i) is a rule to which subclause (ii) provides the exception, then both subclauses have meaning; and the provision as a whole conditions the Secretary's authority to impose new requirements upon consultation with stakeholders and notification of Congress." See Defs.' Reply at 5.

Finally, CMS has previously suspended data submission requirements without submitting a report to Congress. After Hurricane Maria in 2017, CMS made it optional for plans in Puerto Rico to submit CAHPS and HEDIS data. <u>See</u> H'rg Tr. 24:7–15; 42 C.F.R. § 422.166(i)(2)(ii), (i)(4)(ii). Plans that did not submit the data would receive the prior year's measure-level ratings for measures derived from CAHPS and HEDIS. <u>See</u> 42 C.F.R. § 422.166(i)(2)(iii), (i)(4)(iii). Although government counsel suggested at oral argument that all plans chose to submit the data anyway, plans in Puerto Rico were not <u>required</u> to do so. <u>See</u> Hr'g Tr. 23:13–15. The fact that CMS did not report to Congress before suspending data submission requirements for certain plans further demonstrates that CMS has consistently interpreted subclause (ii) to require such a report only before collecting new types of data.

In sum, § 1395w-22(e)(3)(B) is ambiguous and the Secretary's construction is permissible. The Court will therefore defer to the Secretary's interpretation. Because the Challenged Rule did not require the collection of any new types of data, it did not "change the types of data that are required to be submitted" within the meaning of subclause (ii), and no report to Congress was required.

II. The Challenged Rule Is Not Arbitrary and Capricious

Plaintiffs contend that CMS not only exceeded its statutory authority by suspending data submission, but also adopted an arbitrary and capricious methodology for calculating Star Ratings. <u>See</u> Pls.' Br. at 28–37. To set aside an agency action as arbitrary and capricious, a court must find that the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or that the agency's action was "so implausible that it could not be ascribed to a difference in view or the product of agency expertise." <u>Conservation L. Found.</u>, 422 F. Supp. 3d at 27 (quoting <u>State Farm</u>, 463 U.S. at 43). Applying this standard, the Court concludes that the Challenged Rule was not arbitrary and capricious.

As plaintiffs mostly concede, CMS's decision temporarily to suspend the collection of CAHPS and HEDIS data during a pandemic was not arbitrary and capricious. See Hr'g Tr. at 8:1–17. CMS suspended HEDIS data collection to "allow health plans, providers, and physician offices to focus on caring for Medicare beneficiaries during . . . the COVID-19 pandemic," and to "minimize risk of the spread of infection by eliminating travel and in-person work for the collection of HEDIS data." See 85 Fed. Reg. at 19,271, AR 42. Likewise, CMS suspended CAHPS data collection "to ensure the safety of survey vendor staff and align with the CDC's social distancing guidance." Id. Having made that reasonable decision, CMS was left without new data for nearly half of the measures that Star Ratings reflect. See id. at 19,272, AR 43 (noting that new "data will not be available for HEDIS and CAHPS measures"). But for the other half of Star Ratings measures, CMS would have new data. See id. ("The measurement period for all other measures will not change from what was finalized in the April 2018 final rule.").¹⁵

CMS had to act quickly: "Because of the short time frame during which information is collected, analyzed, and used in the calculation of the Star Ratings published in October each year, immediate action [was] necessary to amend the methodology as a result of the extraordinary circumstances created by the [Public Health Emergency] for the COVID-19 pandemic." <u>Id.</u> In the absence of new CAHPS and HEDIS data, the Secretary made the reasonable decision to rely on the CAHPS and HEDIS data that had been collected during the previous measurement period. <u>Id.</u> CMS explained that "[g]iven measure scores and stars do not fluctuate significantly year to year, we believe using the 2020 measure-level stars and scores for the missing HEDIS and CAHPS

¹⁵ Data "gathered as part of the administration of the Medicare program," such as disenrollment and appeal rates, would not require the same type of collection. <u>See</u> 83 Fed. Reg. at 16,532. And the third type of data that CMS collects, HOS data, had already been collected for use in the 2021 Star Ratings. The HOS survey administration for the <u>2022</u> Star Ratings was scheduled to take place from April through July 2020. 85 Fed. Reg. at 19,272, AR 43. Because that survey posed similar concerns, CMS moved it to late summer and stated that if HOS data could not be collected by late summer due to COVID-19, it would use 2021 ratings for measures derived from HOS. <u>Id.</u>

data provides the best approximation of performance in [the original measurement year of] 2019." <u>Id.</u> This decision "addresse[d] the lack of HEDIS and CAHPS data that would otherwise be used for 2021 Star Ratings while permitting [CMS] to calculate and use reliable Star Ratings for 2021 enrollment and 2022 [quality bonus payment] status determinations." <u>Id.</u> The Challenged Rule did not change any other aspects of Star Ratings calculations. For all measures not derived from CAHPS or HEDIS data, the Secretary would use new data. In short, the Secretary decided to use in all cases—the newest data available. Because each plaintiff's performance on measures <u>not</u> derived from CAHPS and HEDIS data declined, their ratings each fell by one half-star from 2020 to 2021. <u>See</u> Goldstein Decl. [ECF No. 22-2] at 3–5. Of course, their scores on the CAHPS and HEDIS measures did not change.

In the face of this seemingly reasonable decision, plaintiffs present five reasons why it was arbitrary and capricious. All five arguments fail.

First, plaintiffs argue that a "system that recycles last year's data and mixes it with new data on different metrics" does not "validly reflect[] and promote[] the underlying purposes of the Star Rating system." <u>See</u> Pls.' Reply at 12–13. But the only option that would not involve "mixing" data was to ignore the new data available for half of the Star Ratings measures and use the previous year's data instead. That option makes little sense. Nothing in the record suggests that the newly collected data for measures besides CAHPS and HEDIS was innacurate. There is no reason to throw out valid, recent data just because other data is unavailable. Since the new data conveyed meaningful information about the plan's current performance on measures besides CAHPS and HEDIS, surely it was rational to convey that information to prospective enrollees. Plaintiffs' real complaint seems to be that they lost their opportunity to improve CAHPS and

HEDIS scores between the 2020 and 2021 Star Ratings. Of course, it would have been better to use newly collected CAHPS and HEDIS data, but that option was foreclosed by the pandemic.

Second, plaintiffs argue that the Challenged Rule was arbitrary and capricious because CMS "never analyzed its own policy quantitatively, and focused only on the overall distribution of Star Ratings, not on whether individual plans would be unfairly impacted." Pls.' Br. at 29. True, CMS did not produce a quantitative model of its chosen policy. But no such model was necessary. It was obvious that plans that improved performance on measures not derived from CAHPS and HEDIS data would improve their Star Ratings, and vice versa. Plans that had hoped to use improved performance on CAHPS and HEDIS measures to compensate for declining performance on other measures would, of course, see their Star Ratings drop. It is thus unclear what CMS would have gained from quantitative analysis.

Third, plaintiffs argue that the Challenged Rule arbitrarily diverged from CMS's 2019 rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances ("Disaster Policy"), which "generally hold the affected contract harmless from reductions in Star Ratings." Pls.' Br. at 12, 34–35 (quoting 84 Fed. Reg. 15,680, 15,770 (Apr. 16, 2019)). Plaintiffs are wrong. To start, the Disaster Policy did not literally apply to the 2021 Star Ratings because when the Challenged Rule was published, the Federal Emergency Management Agency ("FEMA") had not yet issued the emergency declarations that would trigger the Disaster Policy. <u>See</u> 85 Fed. Reg. 54,820, 54,845 (Sept. 2, 2020), AR 89; Defs.' Opp'n at 20–21 n.14. Nonetheless, plaintiffs insist that it was arbitrary for CMS to deviate from the "principle and promise" that plans should be "held harmless" from ratings declines caused by "disasters beyond their control." <u>See</u> Pls.' Br. at 34. But the 2019 Disaster Policy was intended for circumstances in which "specific geographic areas" would "experience[] the greatest adverse effects." 84 Fed. Reg. at 15,770–71. Because Star Ratings are a curved grading system, it makes sense to protect against ratings declines for plans uniquely harmed by a localized emergency. Otherwise, plans in affected areas would be disadvantaged in their ratings relative to plans in unaffected areas. However, COVID-19 has affected every health insurance plan, rendering meaningful comparisons possible on the measures for which new data was available.

In the Challenged Rule, CMS explained why it chose not to hold plans harmless. This decision was far from arbitrary. The agency explained that it "did not envision the unprecedented circumstances surrounding the . . . COVID-19 pandemic when [it] developed the adjustments for extreme and uncontrollable circumstances" in 2019, and it found those adjustments "not sufficient in the case of the . . . COVID-19 pandemic." 85 Fed. Reg. at 19,269, AR 40; see also 85 Fed. Reg. at 54,845, AR 89 ("The disaster policy was not designed to address global pandemics. In the past several years that we have used the extreme and uncontrollable circumstance adjustment for the . . . Star Ratings, the FEMA declarations have only been to county/county-equivalents and the declarations have only resulted in adjustments for a limited number of contracts.").

Fourth, plaintiffs argue that CMS should have abandoned its 2018 decision to increase the weight given to certain CAHPS measures in the 2021 Star Ratings formula, since the CAHPS data was stale. But plaintiffs concede that reverting to the 2020 weighting of those CAHPS measures would not change their 2021 Star Ratings, so it is not clear how this argument advances their case. See Goldstein Decl. ¶¶14–16. Moreover, because measure scores do not fluctuate much from year to year, a plan with high 2020 ratings for customer satisfaction measures are most likely plans that will continue to perform well on those measures. Hence, increasing the weight of CAHPS measures will still further the agency's goal of prioritizing patient experience.

Finally, plaintiffs contend that CMS did not adequately analyze alternatives. See Pls.' Br. at 36-37. "While an agency must consider and explain its rejection of reasonably obvious alternative[s], ... it need not consider every alternative proposed nor respond to every comment made." Nat'l Shooting Sports Found., Inc. v. Jones, 716 F.3d 200, 215 (D.C. Cir. 2013) (internal quotation marks and citations omitted). Here, CMS ran a detailed simulation to determine whether it "could remove all of the HEDIS and CAHPS measures from the 2021 Star Ratings." See 85 Fed. Reg. at 19,272, AR 43; see also AR 527–43. But removing those measures would leave CMS without "enough measures to rate plans and to have a complete picture of performance given approximately half of the Star Ratings measures come from HEDIS and CAHPS." 85 Fed. Reg. 19,272, AR 43. Even though CMS seriously considered an alternative rule, plaintiffs argue that the agency arbitrarily failed to consider two specific alternatives: (1) using overall 2020 Star Ratings instead of calculating 2021 Star Ratings at all, and (2) calculating 2021 ratings but not permitting any plan's rating to fall. This is essentially the same argument plaintiffs have already made: that CMS should have thought more seriously about discarding or limiting the impact of new data available for measures not derived from CAHPS or HEDIS. As explained above, there is no reason to throw out this new data-it conveys useful information. Likewise, there is no reason to hold plans harmless. CMS prevents rating declines for plans uniquely impacted by localized emergencies because Star Ratings are a curved grading system. But COVID-19 has affected all plans, making meaningful comparisons possible on the measures for which new data is available.

The Court recognizes that the Challenged Rule hurt plans whose CAHPS and HEDIS would have improved between the 2020 and 2021 ratings. But had CMS used overall 2020 Star Ratings instead of calculating 2021 ratings, that would have hurt plans whose scores on measures

not derived from CAHPS or HEDIS would have improved between the 2020 and 2021 ratings. And had CMS permitted plans' ratings to rise but not fall, that would have caused "[grade] inflation." <u>See Hr'g Tr. at 44:10–22</u>. Any plan whose performance on non-CAHPS and HEDIS measures had fallen would have its rating remain steady, and any plan whose performance on those measures had improved would receive a higher rating. As a result, the distribution of scores would shift upwards—making plans appear higher-performing on average than they really were and forcing CMS to increase total payments to plans. <u>See id.</u>

"While an agency is required to adequately explain its decision, . . . [i]t is enough that a reviewing court can reasonably discern the agency's analytical path." <u>Van Hollen, Jr. v. FEC</u>, 811 F.3d 486, 496–97 (D.C. Cir. 2016) (citing <u>Bowman Transp. Inc. v. Ark.-Best Freight Sys. Inc.</u>, 419 U.S. 281, 286 (1974)). Here, CMS's analytical path was clear. The agency decided that the previous year's CAHPS and HEDIS data was the best information available for those measures, and that new data for measures not derived from CAHPS and HEDIS was a meaningful indicator of plan performance. Therefore, CMS used the best information available for each measure. The Court concludes that this decision was not arbitrary and capricious.

CONCLUSION

For all these reasons, the Court will grant defendants' cross-motion for summary judgment, deny plaintiffs' motion for summary judgment, and deny plaintiffs' motion for a preliminary injunction as moot. A separate order has been issued on this date.

/s/

JOHN D. BATES Senior United States District Judge

Dated: June 1, 2021