**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MARYLAND**

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| CITY OF COLUMBUS, *et al.,*<br><br>*Plaintiffs*,<br><br>v.<br><br>DONALD J. TRUMP, *et al.,*<br><br>*Defendants*. | Civil Action No. 1:18-cv-02364-DKC |

**DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT**

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, defendants the U.S. Department of Health and Human Services (the "Department"); Alex M. Azar, II, in his official capacity as Secretary of the Department; the Centers for Medicare and Medicaid Services ("CMS"); and Seema Verma, in her official capacity as CMS Administrator hereby move the Court to enter summary judgment in their favor.[1] This motion is supported by the attached memorandum of points and authority and by the administrative record previously filed in this case. A proposed order is also attached.

Dated: September 28, 2020

Respectfully submitted,

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General

JEAN LIN
Special Litigation Counsel

*/s/ Kathryn L. Wyer*
KATHRYN L. WYER
Federal Programs Branch

[1]The Court has dismissed all claims against defendant Donald J. Trump, in his official capacity as President of the United States. Order of Apr. 10, 2020 [ECF 103].

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**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that on September 28, 2020, a true and accurate copy of the foregoing was electronically filed with the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record in this matter.

*/s/ Kathryn L. Wyer*
KATHRYN L. WYER

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

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## INTRODUCTION

Plaintiffs challenge a final rule, promulgated by defendants the Department of Health and Human Services ("HHS"), the Secretary of HHS, the Centers for Medicare & Medicaid Services ("CMS"), and the Administrator of CMS (collectively, "HHS" or "Defendants"), governing aspects of the health insurance markets for the 2019 plan year and beyond, 83 Fed. Reg. 16930 (Apr. 17, 2018) (the "2019 Rule"). HHS promulgates such rules every year pursuant to HHS's express rulemaking authority under the Patient Protection and Affordable Care Act ("ACA") and the Public Health Service Act ("PHS Act"). These rules are the mechanism by which HHS makes ongoing adjustments in the regulations and processes that govern the ACA insurance markets, including but not limited to Federal and State Exchanges—the marketplaces where consumers may enroll in qualified health plans. The adjustments reflect HHS's experience operating and administering the Exchange program, as well as implementing the ACA's federal insurance market requirements.

Although Plaintiffs do not seek to invalidate the 2019 Rule as a whole, or any major part thereof, they challenge nine discrete aspects of the Rule as arbitrary, capricious, or not in accordance with law pursuant to the Administrative Procedure Act ("APA"). However, the nearly 100-page preamble to the 2019 Rule, supported by the administrative record, thoroughly explains HHS's rationale for promulgating each of the challenged provisions, defeating any contention that they are arbitrary or capricious, or that HHS failed to articulate its reasoning or failed to respond to significant comments during the rulemaking process. Moreover, to the extent Plaintiffs seek to challenge the 2019 Rule's implementation of relevant ACA provisions, HHS's statutory interpretations are entitled to deference under the framework set forth in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Plaintiffs' contrary assertions rely on misinterpretations of the governing statutory provisions and disagreements with HHS's policy choices. But they identify no basis to set aside HHS's actions, and summary judgment therefore should be granted in Defendants' favor.

## BACKGROUND[1]

### I. STATUTORY AND REGULATORY BACKGROUND

In 2010, Congress enacted the ACA with the aim of "increas[ing] the number of Americans covered by health insurance and decreas[ing] the cost of health care." *Nat'l Fed'n of Indep. Bus. v. Sebelius* ("*NFIB*"), 567 U.S. 519, 538 (2012). The ACA established, among other things, a series of new insurance market reforms in the individual and small group markets and also imposed a number of other requirements for health insurance plans in those markets, such as mandatory provision of essential health benefits. *See City of Columbus I*, 2020 WL 1820074, at *1-3 (describing ACA's reforms). To facilitate a market for health insurance products that conform to its market reforms, the ACA established "Health Benefit Exchanges" or State-based virtual marketplaces where consumers can purchase qualified health plans [hereinafter, "State Exchanges"]. 42 U.S.C. § 18031. The ACA also provided for the establishment of Federal-facilitated Exchanges [hereinafter, "Federal Exchanges"] in States that chose not to establish their own. 42 U.S.C. § 18041(c)(1).

Since the ACA's enactment, HHS has engaged in numerous rulemakings in order to implement various aspects of the law. *See* 83 Fed. Reg. at 16933-34 (describing prior rulemakings). These rulemakings have addressed the frameworks for Exchanges, *e.g.* 77 Fed. Reg. 18310 (Mar. 27, 2012) ("Exchange Establishment Rule"); 82 Fed. Reg. 18346 (Apr. 18, 2017) ("Market Stabilization Rule"); essential health benefits, *e.g.*, 78 Fed. Reg. 12834 (Feb. 25, 2013) ("Essential Health Benefits, Actuarial Value, and Accreditation Final Rule" or "EHB Rule"); health insurance market standards, *e.g.*, 79 Fed. Reg. 30240 (May 27, 2014) ("2015 Market Standards Rule"); the federal rate review

[1] Because Plaintiffs' remaining claim seeks review of final agency action based on an administrative record, the Court "sits as an appellate tribunal" and the "entire case" is decided as a matter of law. *City of Columbus v. Trump* ("*City of Columbus I*"), No. CV DKC 18-2364, 2020 WL 1820074, at *17 (D. Md. Apr. 10, 2020). Thus, this case does not present any disputed issues of material fact. Rather than a statement of undisputed material facts, Defendants therefore provide general background in this section and provide more detailed background relevant to the 2019 Rule provisions at issue in the respective subsections of the Argument addressing those provisions.

program, *e.g.*, 76 Fed. Reg. 29963 (May 23, 2011) ("2011 Rate Review Rule") (amended in final rules published in 2011, 2013, 2014, 2015, and 2016); the medical loss ratio program, *e.g.*, 77 Fed. Reg. 28790 (May 16, 2012) (amended in final rules published in 2014, 2015, and 2016); premium stabilization, 77 Fed. Reg. 17219 (Mar. 23, 2012) ("Premium Stabilization Rule"); and program integrity standards, e.g., 78 Fed. Reg. 54070 (Aug. 30, 2013) ("first Program Integrity Rule"); 78 Fed. Reg. 65046 Oct. 30, 2013) ("second Program Integrity Rule").

Since 2013, HHS has also undertaken an annual rulemaking process to make adjustments, as the Secretary deems necessary or appropriate, in various aspects of the ACA insurance markets and Exchanges for the upcoming plan year. 78 Fed. Reg. 15410 (Mar. 11, 2013) ("2014 Payment Notice"); 79 Fed. Reg. 13744 (Mar. 11, 2014) ("2015 Payment Notice"); 80 Fed. Reg. 10750 (Feb. 27, 2015) ("2016 Payment Notice"); 81 Fed. Reg. 12204 (Mar. 8, 2016) ("2017 Payment Notice"); 81 Fed. Reg. 94058 (Dec. 22, 2016) ("2018 Payment Notice"). For 2019, HHS issued a Proposed Rule on November 2, 2017. HHS Notice of Benefit and Payment Parameters for 2019, 82 Fed. Reg. 51052 (Nov. 2, 2017). Following a comment period, HHS issued the final 2019 Rule at issue here on April 17, 2018. *See* 83 Fed. Reg. 16930. In addition to providing certain payment and cost-sharing parameters and user fees for Federal and State Exchanges, the 2019 Rule also increases the States' flexibility in operating the Exchanges and enhances the States' role regarding the certification of qualified health plans. *See id.* Additionally, the Rule includes changes to the rate review program, the medical loss ratio program, and a number of other issues related to the operation and functioning of the Exchanges and the ACA insurance markets. *See id.*

## II. PROCEDURAL HISTORY

Plaintiffs, consisting of five cities and two individuals then residing in Charlottesville, Virginia, filed suit on August 2, 2018, Compl. [ECF 1], and filed an Amended Complaint ("Am. Compl.") on January 25, 2019 [ECF 44]. Count I of the Amended Complaint asserts a claim under the APA, 5

U.S.C. § 706(2)(A), alleging that nine separate aspects of the 2019 Rule are arbitrary, capricious, or otherwise not in accordance with law. In addition to their APA challenge, Plaintiffs also sought to assert a claim under the Take Care Clause, set forth in Count II, alleging that the President and other Defendants had failed to faithfully execute the ACA. Am. Compl. ¶ 285. Defendants moved to dismiss Plaintiffs' claims for lack of subject matter jurisdiction and failure to state a claim. Def Mot. to Dismiss [ECF 52 filed Mar. 8, 2019].

On April 10, 2020, the Court granted Defendants' motion in part and denied it in part. Order of Apr. 10, 2020 [ECF 103]. In its Memorandum Opinion [ECF 102], the Court held that Plaintiffs had sufficiently established their standing and the ripeness of their claims at the pleading stage. *City of Columbus I*, 2020 WL 1820074, at *14-15. In regard to Plaintiffs' APA claims in Count I, the Court indicated that any arguments regarding Plaintiffs' "arbitrary and capricious" assertions were premature, and that any "contrary to law" issues, which Plaintiffs had raised with respect to six of their nine APA challenges, were underdeveloped. *Id.* at *15. The Court therefore declined to resolve the merits of Plaintiffs' APA claims on consideration of Defendants' motion to dismiss. *Id.* at *18, 21. However, the Court dismissed Plaintiffs' Take Care Clause claim in Count II in its entirety. *Id.* at *24.

The parties then agreed to proceed by cross-motions for summary judgment based upon the administrative record of the 2019 Rule. [ECF 104.] The parties' cross-motions seek judgment as a matter of law with respect to the nine aspects of the 2019 Rule that Plaintiffs challenge in Count 1 of their Amended Complaint, specifically:

1. The 2019 Rule's amendment of the eligibility notification requirements for advance payments of premium tax credits. *See* Am. Compl. ¶¶ 52-56, 282(a); *see also* 83 Fed. Reg. at 16982-84.

2. The 2019 Rule's elimination of duplicative Federal and State network adequacy reviews for qualified health plans offered on Federal Exchanges by incorporating the results of the States' reviews. *See* Am. Compl. ¶¶ 57-63, 282(b); *see also* 83 Fed. Reg. at 17024-26.

3. The 2019 Rule's implementation of a new operational readiness review and audit approach pursuant to which health insurance agents, brokers, and insurers participating in direct enrollment select their own independent third-party auditors to conduct the annual

operational readiness review. *See* Am. Compl. ¶¶ 64-68, 282(c); *see also* 83 Fed. Reg. at 16981-82.

4. The 2019 Rule's cessation of the practice of designating some plans in Federal Exchanges as "standardized options" in an effort to encourage competition and innovation in the individual market. *See* Am. Compl. ¶¶ 70-74, 282(d); *see also* 83 Fed. Reg. at 16974-75.

5. The 2019 Rule's removal of the regulatory requirements that one of the two Navigators for an ACA Exchange must be a community non-profit organization and that the Navigators must maintain a physical presence in the State. *See* Am. Compl. ¶¶ 75-79, 282(e); *see also* 83 Fed. Reg. at 16979-80.

6. The 2019 Rule's reduction of regulatory burdens associated with the Small Business Health Options Program ("SHOP")—which provides qualified health plan options for small employers in each State with an Exchange—including enhancing States' flexibility to respond to decreases in issuer participation and lower-than-expected enrollment in the Federal SHOPs and SHOPs operated by State Exchanges on the Federal platform. *See* Am. Compl. ¶¶ 80-82, 282(f); *see also* 83 Fed. Reg. at 16996-16706.

7. The 2019 Rule's modification of the ACA's income verification requirements for receipt of advance payments of premium tax credits to require an individual who attests to a household income within 100% to 400% of the federal poverty level ("FPL"), but whose income according to trusted electronic data sources is below 100% FPL, to submit additional documentation supporting the attested to income. *See* Am. Compl. ¶ 282(g); *see also* 83 Fed. Reg. at 16985-87.

8. The 2019 Rule's amendment of the ACA's rate review program regulations to, *inter alia*, (1) exempt student health insurance coverage from the federal rate review process prior to issuance, and (2) increase the federal minimum threshold that triggers an "unreasonableness" review of an issuer's proposed premium rate increase for any single plan within a filing from 10% to 15%. *See* Am. Compl. ¶¶ 88-93, 282(h); *see also* 83 Fed. Reg. at 16972-73.

9. The 2019 Rule's amendment of medical loss ratio (MLR) requirements to allow issuers to submit either a detailed, itemized report of quality improvement activity (QIA) expenditures or to report a single, fixed QIA amount. *See* Am. Compl. ¶¶ 94-98, 282(i); *see also* 83 Fed. Reg. at 17032-36.

Additional background with respect to each issue identified above is set forth below in the respective section addressing that challenge. *See also City of Columbus I*, 2020 WL 1820074, at *3-6.

## STANDARD OF REVIEW

The 2019 Rule is a final agency action reviewable under the APA, 5 U.S.C. §§ 701 *et seq*. In an APA case, the court's review is limited to the administrative record. *See* 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Thus, the "entire case is a question of law," and "the district court sits as an

appellate tribunal." *City of Columbus I*, 2020 WL 1820074, at *17 (internal quotation omitted). In such cases, the normal summary-judgment standards of Federal Rule of Civil Procedure 56(c) do not apply. *Se. Conference v. Vilsack*, 684 F. Supp. 2d 135, 142 (D.D.C. 2010). Summary judgment instead "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." *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).

In order to prevail on their claim, Plaintiffs must demonstrate that the challenged portions of the 2019 Rule are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In undertaking its review, the Court "perform[s] only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment." *Holly Hill Farm v. United States*, 447 F.3d 258, 263 (4th Cir. 2006) (internal quotations omitted). This standard of review is "narrow," and does not authorize a district court "to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

Further, where, as here, the court is tasked with reviewing the statutory interpretation that an agency has advanced pursuant to a delegation of substantive rulemaking authority, the court must apply the familiar two-step framework established by *Chevron, U.S.A., Inc. v. NRDC, Inc.* ("*Chevron*"), 467 U.S. 837 (1984). First, the Court "must determine 'whether Congress has directly spoken to the precise question at issue.'" *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (quoting *Chevron*, 467 U.S. at 842). If so, "'that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expessed intent of Congress.'" *Id.* (quoting *Chevron*, 467 U.S. at 842-43). Second, if the statute is ambiguous and "does not directly foreclose [the agency's] understanding," the court must "defer to the agency's reasonable interpretation." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 828 (D.C. Cir. 2020). To whatever extent an issue of statutory interpretation "presents a close question," "*Chevron*

makes the outcome clear": The court "must uphold an agency interpretation as long as it is a 'permissible construction of the statute.'" *CASA de Maryland, Inc. v. Trump*, 971 F.3d 220, 250 (4th Cir. 2020) (quoting *Chevron*, 467 U.S. at 843).

## ARGUMENT

### I. PLAINTIFFS' REQUEST FOR JUDICIAL NOTICE SHOULD BE DENIED, AND THE DECLARATION OF CHRISTEN YOUNG SHOULD BE EXCLUDED, AS IMPROPER ATTEMPTS TO SUPPLEMENT THE ADMINISTRATIVE RECORD

As an initial matter, the Court should reject Plaintiffs' Request for Judicial Notice [ECF 108-2] ("RJN"), which improperly seeks to introduce materials outside the administrative record to bolster Plaintiffs' challenge to the 2019 Rule, and should also exclude from its consideration the Declaration of Christen Young [ECF 108-10], attached to Plaintiffs' filing, which purports to provide expert "observations and opinions" on the aspects of the 2019 Rule at issue. Both filings are contrary to established restrictions on the consideration of extra-record material in an APA case. The APA provides that, "[i]n making the [] determinations [regarding the lawfulness of agency action], the court shall review the whole record," 5 U.S.C. § 706, and the Supreme Court has long held that the whole record is limited to "the full administrative record that was before the Secretary at the time he made his decision," *Citizens to Pres. Overton Park, Inc.*, 401 U.S. at 420. *See also Camp*, 411 U.S. at 142 (holding that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court"); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard . . . to the agency decision based on the record the agency presents to the reviewing court.").

As the Fourth Circuit has explained, "[t]here is a presumption that the record compiled by the agency is the record on which it rested its decision," and thus "courts will ordinarily assume that the administrative record is complete and exclusive for purposes of judicial review." *Sanitary Bd. v. Wheeler*, 918 F.3d 324, 334 (4th Cir. 2019) (citing *Fla. Power & Light Co.*, 470 U.S. at 744). Plaintiffs thus bear "a special burden of demonstrating that the court should reach beyond the record, either to examine information that should have been before the agency but was not, or to introduce extra-record

evidence that the agency actually relied on that was omitted from the administrative record." *Id.*

Rather than seeking to satisfy any such burden here, Plaintiffs improperly request judicial notice of extra-record materials based solely on the ground that they are publicly available. *See* Pl. RJN, at 1. They also attach what appears to be a purported expert declaration with no explanation as to why that declaration is admissible and cite it extensively in their brief. *See generally* Plaintiffs' Memorandum in Support of their Motion for Summary Judgment [ECF 108-1] ("Pl. Mem."), at 6-24 (repeatedly citing "Young Decl."). However, "judicial notice is typically an inadequate mechanism for a court to consider extra-record evidence when reviewing an agency action." *Level the Playing Field v. FEC*, 381 F. Supp. 3d 78, 92 (D.D.C. 2019), *aff'd*, 961 F.3d 462 (D.C. Cir. 2020) (quoting *Dist. Hosp. Partners, L.P. v. Sebelius*, 971 F. Supp. 2d 15, 32 n.14 (D.D.C. 2013), *aff'd sub nom Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46 (D.C. Cir. 2015)). In other words, Federal Rule of Evidence 201 cannot be used to circumvent the statutory restriction on APA review in 5 U.S.C. § 706. *See Level the Playing Field*, 381 F. Supp. 3d at 92 ("[P]laintiffs should not be permitted to exploit the standard for judicial notice to circumvent the strict standard for supplementing the administrative record."). Significantly, as was true in *Level the Playing Field*, *see id.*, none of the cases Plaintiffs cite in support of their Request are APA cases. *See* Pl. RJN, at 1. Attempts to submit purported expert material without even attempting to meet the heavy burden for supplementing an administrative record are equally inappropriate. *See CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) (rejecting plaintiff's attempt to submit an "expert analysis" to the court where it "did not even move to supplement the administrative record"). Moreover, Plaintiffs make no attempt to show how the extra-record material they have submitted fits within any of the exceptions that may allow supplementation of an administrative record. *See Sanitary Bd.*, 918 F.3d at 334 (citing *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989), as listing the possible exceptions). They therefore fail to meet their burden. Accordingly, their Request should be denied and the Young Declaration should be excluded.[2]

[2] To the extent Plaintiffs seek to rely on the other declarations attached to their filing to support the merits of their claims, in addition to Plaintiffs' standing, those declarations should also be excluded.

## II. PLAINTIFFS' APA CLAIMS FAIL AS A MATTER OF LAW

Plaintiffs' suit seeks to nitpick at nine specific details in the 2019 Rule as supposedly contrary to law or unreasonable. However, as discussed below, HHS examined "the relevant data" and articulated "a satisfactory explanation" for each of these aspects of the 2019 Rule, "including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 45 (1983) (internal quotation omitted). It therefore has satisfied its obligations under the APA.

### A. The 2019 Rule's removal of the direct notification requirement for advance payments of premium tax credits does not violate the Internal Revenue Code and is a reasonable way to alleviate burdens on State Exchanges while protecting taxpayer interests. [Am. Compl. ¶ 282(a)]

Plaintiffs first challenge the 2019 Rule's removal of a notification requirement that HHS had established in 2016 in regard to Exchanges' advance payments of premium tax credits that certain taxpayers can claim on their federal income tax returns. However, HHS's decision to remove a requirement that involved conveying private tax information, and thus imposed significant burdens on some State Exchanges, is not contrary to law, nor is it arbitrary and capricious.

#### 1. Relevant Background

A taxpayer's eligibility to claim a premium tax credit on his or her federal income tax return is governed by a provision of the Internal Revenue Code ("IRC"), 26 U.S.C. § 36B. That provision indicates that a taxpayer whose household income is below a certain level, whose health plan cost reaches a certain percentage of household income, and who meets other eligibility criteria, may claim the credit. *See* 26 U.S.C. § 36B(b)(2)(A). The credit amount is based on the cost of the monthly premiums for qualifying health plans covering the taxpayer, the taxpayer's spouse, and any eligible dependents. *See id.* The Internal Revenue Service, and not HHS, processes the premium tax credit filing as part of taxpayers' annual federal income tax filing.

Separately, the ACA directed the Secretary to establish a program under which *advance payments* of these tax credit amounts might be made. 42 U.S.C. § 18082(a). Under the advance payment program, eligible health insurance plan enrollees may not need to wait until their household federal

income tax return is filed to get the benefit of the premium tax credit. *Id.* § 18082(c)(2); 45 C.F.R. § 156.460(a). Thus, instead of enrollees paying the entire insurance premium up front, and then claiming a credit toward that amount on the eligible taxpayer's tax return, in some circumstances HHS may make an advance payment of all or some of the estimated amount of the premium tax credit directly to a qualified health plan in order to offset the out-of-pocket cost of an eligible enrollee's premium. 42 U.S.C. § 18082(c)(2). *Id.* § 156.460(a).

The IRS requires taxpayers with any household members whose insurance premium costs were reduced by such advance payments to report those amounts on their federal income tax returns and reconcile those advance payments with their tax credit amount, calculated based on their actual income for the tax year. 26 U.S.C. § 36B(f). The amount of the tax credit that the taxpayer can claim on the return is thus adjusted by the amount that was already received as an advance payment. *See id.* If the advance payments exceeded the credit to the taxpayer allowed under § 36B(b), the taxpayer may be required make up for that excess in the final calculation of tax liability for that year, subject to certain income-based caps. *Id.* § 36B(f)(2).

Although HHS does not enforce tax filing requirements, it does play a role in helping Exchanges verify whether health plan applicants are eligible for certain benefits under the ACA, in part by receiving and conveying tax return information from and between Exchanges and the Secretary of the Treasury. *See* 45 C.F.R. § 155.320(b)(1), (c). Pursuant to that process, HHS may notify an Exchange that a tax filer or his or her spouse failed to file a tax return or to "reconcile" prior "advance payments of the premium tax credit," in tax liability calculations for previous years, as required pursuant to 26 U.S.C. § 36B(f). 45 C.F.R. § 155.305(f)(4). In that circumstance, the Exchange is prohibited from determining any member of the tax filer's tax household eligible for advance payments of the tax credit for the current year's premium costs. *See id.* However, any tax filer who is eligible for a tax credit under 26 U.S.C. § 36B(b) remains able to claim the credit on his tax return for that year. In that circumstance, the credit amount would not be reduced by the amount of any advance payment because no advance payment would have been made.

In the 2018 Payment Notice, HHS had recognized "ongoing challenges for consumers and

Exchanges" in implementing the reconciliation requirement. 81 Fed. Reg. at 94124. To address the issue, HHS revised 45 C.F.R. § 155.305(f)(4) to require direct notification to the applicable tax filer, on behalf of the enrollee, identifying the tax filer's failure to file an income tax return that reconciled advance payments of premium tax credits paid on the enrollee's behalf. *See* 81 Fed. Reg. at 94124.

The 2019 Rule removed the direct notification requirement in § 155.305(f)(4). 83 Fed. Reg. at 16982. HHS explained that this change was warranted because the direct notices contained federal tax information, which required special handling, and thus increased the burden on the Exchanges. *See id.* at 16982-83. HHS stated that Federal Exchanges would continue to provide direct notices while State Exchanges were encouraged to do so "where feasible." *Id.* at 16983-84. HHS also recognized that, either instead of or in addition to direct notices, Exchanges would continue prior notification practices, whereby notifications were sent to the individual that the enrollee had identified as the household contact—which in many cases would be the tax filer—identifying the failure to satisfy the reconciliation requirement as only one of three possible reasons that the Exchange had determined it could not make the advance payment. *Id.* at 16983; *see also* 82 Fed. Reg. at 51086. These "combined notices" avoided disclosing private tax information. 83 Fed. Reg. at 16983. And enrollees who were identified as not having met the reconciliation requirement would receive, in addition to a combined notice, a warning notice providing a full explanation of appeal rights if their advance payments are discontinued. *Id.* During any appeal, enrollees may continue receiving the advance payments, *id.*, and the applicable taxpayer may amend or belatedly file his tax return in order to comply with the reconciliation requirement.

Plaintiffs assert that HHS's decision to remove the direct notice requirement is both contrary to law and arbitrary and capricious. Both of these arguments fail.

**2. HHS's Removal of the Direct Notification Requirement Is Not Contrary to Law**

Plaintiffs first assert that the change is contrary to law on the ground that it conflicts with 26 U.S.C. § 36B, the IRC provision that governs taxpayers' ability to claim the tax credit on their tax returns. *See* Am. Compl. ¶ 54; Plaintiffs' Memorandum in Support of their Motion for Summary

Judgment [ECF 108-1] ("Pl. Mem.") at 32. However, the regulatory provision at issue, 42 C.F.R. § 155.305(f)(4), does not implement 26 U.S.C. § 36B and does not address taxpayers' eligibility to claim tax credits on their federal income tax returns. Instead, it implements 42 U.S.C. § 18082 and governs when an Exchange will determine that an Exchange enrollee is eligible for *advance payments* of those tax credits directly to a health plan. A taxpayer's eligibility to claim the tax credit in tax filings under § 36B remains unaffected. Thus, there is no conflict between the IRC provision and the HHS regulation.

Plaintiffs' argument to the contrary improperly conflates the tax credits themselves—which are governed by 26 U.S.C. § 36B—and the Exchanges' advance payments of the estimated amounts of those credits—eligibility for which is separately governed by 42 U.S.C. § 18082 and 45 C.F.R. § 155.305(f). Simply put, a tax filer's ability to claim a tax credit pursuant to § 36B is in no way harmed by an Exchange's determination under § 155.305(f) that a plan enrollee is ineligible for advance payments. As noted above, the tax filer in that circumstance remains eligible to claim the credit on his federal income tax return. Thus, Plaintiffs' argument that the 2019 Rule "[d]epriv[es] an applicable taxpayer of the credit that the statute says 'shall be allowed'" is simply wrong. Significantly, although § 36B acknowledges the possibility that tax filers may have received advance payments, *see* 26 U.S.C. § 36B(c)(2)(A)(ii), and requires tax filers to reconcile any such payments with their claimed credits, *id.* § 36B(f), the IRC provision does not set forth any criteria for when such advance payments should be made. Rather, the criteria for advance payments (as opposed to the credits themselves) are administered by HHS, not by the IRS. The Court therefore should reject the notion that the 2019 Rule is contrary to law on this basis.

Plaintiffs now also appear to suggest that the Secretary may not "make a previous failure to reconcile a basis for withholding advance payment of a tax credit" because no such requirement is set forth in 42 U.S.C. § 18082. Pl. Mem. at 32. This assertion does not appear in Plaintiffs' Amended Complaint and thus cannot be considered by the Court now. *See Mylan Labs., Inc. v. Akzo, N.V.*, 770 F. Supp. 1053, 1068 (D. Md. 1991); *see also Cape Hatteras Access Pres. All. v. Jewell*, 28 F. Supp. 3d 537, 552 (E.D.N.C. 2014) (arguments raised "for the first time in [plaintiff's] motion for summary

judgment" are waived); *Pickern v. Pier 1 Imports (U.S.), Inc.*, 457 F.3d 963, 969 (9th Cir.2006) (district court did not err in finding that plaintiff failed to provide adequate notice of new allegation when raised for first time at summary judgment stage); *Fleming v. Lind–Waldock & Co.*, 922 F.2d 20, 24 (1st Cir. 1990) ("summary judgment is not a procedural second chance to flesh out inadequate pleadings.").

Plaintiffs' argument regarding § 18082 is also precluded because the 2019 Rule did not promulgate the restriction in 34 C.F.R. § 155.305(f)(4) on advance payments when the taxpayer failed to reconcile those payments on his federal income tax return. Rather, that restriction was established in 2012. *See* Exchange Establishment Rule, 77 Fed. Reg. at 18352-53. Any attempt to amend the Amended Complaint now to challenge the 2012 Exchange Establishment Rule would be futile because the claim would be barred by the six-year statute of limitations in 28 U.S.C. § 2401(a). *Outdoor Amusement Bus. Ass'n, Inc. v. DHS*, 334 F. Supp. 3d 697, 712-13 (D. Md. 2018) (applying § 2401(a) when holding challenge to federal regulation was time-barred). Given that this argument is not properly before the Court on two separate grounds, Defendants do not further address it here.

Plaintiffs also argue that the 2019 Rule's removal of the 2016 notification requirement "raises significant due process concerns." Pl. Mem. at 33. But the Amended Complaint does not allege a procedural due process violation, which is not surprising because the only two individual Plaintiffs were not eligible for advance payments. Am. Compl. ¶ 276. The argument cannot be considered by the Court now. But even if the Court were to do so, it should conclude the argument lacks merit. Contrary to Fourth Circuit requirements, Plaintiffs fail to provide any meaningful assessment of due process in the particular circumstances at issue here. *See Mallette v. Arlington Cty. Emps.' Supplemental Ret. Sys. II*, 91 F.3d 630, 640 n.6 (4th Cir. 1996) (recognizing that "due process has no fixed content; it is 'flexible and calls for such procedural protections as the particular situation demands"). Indeed, Plaintiffs fail to identify a liberty or property interest at stake when, as discussed, the procedures governing advance payments do not affect a taxpayer's ability to claim the premium tax credit. Only the timing of the benefit is conceivably at issue. In addition, a due process analysis allows "the fiscal and administrative burdens" of additional procedural protections to be taken into account. *Id.* at 640 (quoting *Matthews v. Eldridge*, 424 U.S. 319, 335 (1976)). Here, § 155.305 did not contain a direct

notification requirement when originally promulgated in 2012; rather, the requirement was only added in the 2018 Payment Notice, and the 2019 Rule then removed it due to the burdens involved, where State Exchanges did not have systems that allowed them to send direct notices while protecting private tax information. 83 Fed. Reg. at 16982–84.

At the same time, a taxpayer has notice and an opportunity to correct a past failure to reconcile. Federal Exchanges continue to provide combined and direct notices; and State Exchanges are encouraged to take a similar approach if they are technologically able to do so. *Id.* at 16983-84 (encouraging State Exchanges to provide direct notices "where feasible"). Regardless of whether an Exchange provides a direct or combined notice, or both, HHS "expect[s] Exchanges to send appropriate notices to households affected by [a past failure to reconcile] that alert the tax filer that [failure to reconcile] may be the reason enrollees' eligibility for [advance payments] is at risk." *Id.* at 16983. If an enrollee's eligibility for advance payments is terminated based on a past failure to reconcile, the enrollee "will receive an updated eligibility determination notice that contains a full explanation of appeal rights" and may continue receiving advance payment during any appeal pursuant to the Department's standard procedures. *Id.* (citing 45 C.F.R. § 155.525). Importantly, the applicable taxpayer may regain eligibility simply by amending or belatedly filing his tax return in order to comply with the reconciliation requirement. 77 Fed. Reg. at 18353. The Department deemed these procedures consistent with any due process requirements, 83 Fed. Reg. at 16983, and Plaintiffs fail to establish otherwise. Plaintiffs' assertion that the Secretary acted contrary to law thus fails.

### 3. HHS's Removal of the Direct Notification Requirement Is Not Arbitrary or Capricious

Plaintiffs also fail to establish that the 2019 Rule's removal of *required* direct notices was arbitrary and capricious. Plaintiffs argue that HHS "turned a blind eye" to the importance of direct notices and failed to explain its removal of a direct notification requirement that had been added in the 2018 Payment Notice. Pl. Mem. at 34. However, HHS acknowledged the competing interests involved in its decision. 83 Fed. Reg. at 16982-83. In fact, the 2019 Rule agreed that direct notices are a good idea for Exchanges that have the capacity to provide them. Instead of requiring something that

was technologically challenging for some Exchanges, HHS explained that the Federal Exchanges had and would continue to provide direct notices to the taxpayers, and it encouraged State Exchanges to do the same "where feasible." 83 Fed. Reg. at 16984.

Contrary to Plaintiffs' contention, HHS explained why it removed the direct notification requirement in the 2019 Rule. In particular, HHS came to understand that, given current technological limitations faced by both Federal and State Exchanges, the Exchanges had to hire outside contractors in order to prepare direct notices that would comply with taxpayer privacy requirements. *See id.* at 16983. Plaintiffs suggest that these concerns are "speculative," Pl. Mem. at 35, but they are supported by the record. *See* 83 Fed. Reg. at 16984 (reporting comment from State Exchange highlighting burdens imposed by direct notice requirement and describing "heavy undertaking" that State Exchange would face, involving "not only changes to its notice generation and storage infrastructure, . . . but also substantial modification to its entire account creation framework"); AR 2838 (Washington HealthPlanFinder) ("direct notification" requirement would have "presented some significant challenges to implement," and current practices by most exchanges "provide adequate notice to consumers while also safeguarding sensitive tax information"). HHS explained that, due to the burdens involved in hiring such contractors, not all State Exchanges were able to use this option. *See* 83 Fed. Reg. at 16984. Although Plaintiffs attempt to dismiss these burdens by citing a single comment, from the Center on Budget and Policy Priorities, referencing an announcement by HHS's Center for Consumer Information and Insurance Oversight ("CCIIO") of direct notification letters sent by *Federal* Exchanges, *see* Pl. Mem. at 35 (citing AR 1627), that comment does nothing to undercut HHS's understanding that some *State* Exchanges have faced technological difficulties in attempting to implement direct notifications. HHS explained that it would continue to evaluate whether further improvements to the notification process could be made. *See* 83 Fed. Reg. at 16985.

Because HHS adequately explained its rationale for this change and addressed commenters' concerns, its decision is not arbitrary or capricious. Indeed, the Supreme Court has held that, when an agency changes its policy, "it need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible

under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). That standard is met here. The Court therefore should grant judgment in favor of Defendants on this issue.

**B. The 2019 Rule's extension of HHS's 2018 approach to network adequacy for qualified health plans offered in Federal Exchanges does not violate the ACA and is a reasonable way to reduce regulatory burdens and duplicative oversight. [Am. Compl. ¶ 282(b)]**

Plaintiffs fare no better in their second APA claim. Plaintiffs challenge HHS's extension of its prior decision to rely on States and accrediting entities to evaluate health plans' compliance with the ACA's network adequacy requirement. However, this decision is neither contrary to law nor arbitrary and capricious.

**1. Relevant Background**

The ACA requires the Secretary to, "by regulation, establish criteria for the certification of health plans as qualified health plans." 42 U.S.C. § 18031(c)(1). The statute also lists a set of minimum criteria, which include a requirement that "a plan shall . . . ensure a sufficient choice of providers," consistent with the rules set forth for network plans in the Public Health Service Act ("PHS Act"), 42 U.S.C. § 300gg-1(c). *See id.* § 18031(c)(1)(B). HHS fulfilled this obligation to promulgate a network adequacy standard for certifying qualified health plans in the Exchange Establishment Rule by promulgating 45 C.F.R. § 156.230. *See* 77 Fed. Reg. at 18418-20. That provision sets forth a "minimum standard" for network adequacy by requiring a qualified health plan's provider network to "maintain a network of a sufficient number and type of providers, including providers that specialize in mental health and substance abuse, to assure that all services will be available without unreasonable delay." *Id.* at 18419. It also requires qualified health plan issuers to ensure the adequacy of any provider network, consistent with § 300gg-1(c). 45 C.F.R. § 156.230(a)(3). From the beginning, this standard was intended to give Exchanges discretion to structure their network adequacy standards as they deem appropriate within their markets and local areas. *See* 77 Fed. Reg. at 18419.

Aside from promulgating network adequacy standards in § 156.230, HHS has also established

a process for how Federal Exchanges apply the standards in order to determine whether to certify a health plan as a "qualified" health plan. In the Market Stabilization Rule, HHS indicated that, for the 2018 plan year, it would rely on States and accrediting entities to evaluate health plans' compliance with the network adequacy requirement set forth in 45 C.F.R. § 156.230. 82 Fed. Reg. at 18371. This decision was intended to eliminate duplicative evaluations by both Federal Exchanges and States of the same network adequacy criteria, which remain unchanged. 83 Fed. Reg. at 17024 ("States are already performing reviews that are duplicative of the Federal [qualified health plan] certification process," and therefore, it makes sense from a regulatory burden perspective to "incorporat[e] these reviews into the [qualified health plan] certification process.").

The 2019 Rule "reaffirmed this approach," and extended the policies for network adequacy that had been temporarily adopted in the Market Stabilization Rule. *Id.* at 17025. Thus, each Federal Exchange continues to rely on State determinations of network adequacy, so long as the Federal Exchange determines that the State's network adequacy review process is adequate. *See id.* If the State's process is inadequate, the Federal Exchange will conduct its own evaluation or rely on determinations by accrediting entities, which typically also require plans to meet network adequacy standards. *See id.* HHS indicated that it would continue coordinating with States to monitor network adequacy. *See id.* Moreover, unaccredited issuers "would be required to submit an access plan" with their qualified health plan application that "would need to demonstrate that an issuer has standards and procedures in place to maintain an adequate network consistent with the National Association of Insurance Commissioners' Health Benefit Plan Network Access and Adequacy Model Act," upon which HHS would rely as establishing compliance with the requirements in § 156.230(a)(2). 83 Fed. Reg. at 17025.

Plaintiffs challenge the 2019 Rule's extension of the process by which plans' network adequacy is assessed as both contrary to law and arbitrary and capricious. Neither argument has merit.

**2. HHS's Network Adequacy Approach Is Not Contrary to Law**

First, Plaintiffs allege that the 2019 Rule's process for assessing network adequacy violates the Secretary's statutory obligation in 42 U.S.C. § 18031(c)(1). This claim fails at *Chevron* step one because § 18031(c)(1) merely directs the Secretary to "by regulation, establish *criteria*" for network adequacy of

qualified health plans. 42 U.S.C. § 18031(c)(1) (emphasis added). The Secretary long ago satisfied that requirement by promulgating 45 C.F.R. § 156.230—which Plaintiffs do not challenge here. The plain language of § 18031(c)(1) does not address how Federal or State Exchanges should *apply* the Secretary's criteria when certifying qualified health plans, let alone require HHS itself to apply the criteria in every instance. Accordingly, no "contrary to law" claim can arise based on a statutory provision—here, § 18031(c)—that does not even encompass the agency action at issue.

Moreover, to the extent a separate subsection of the statute addresses how, or by whom, the criteria should be applied, it simply requires Exchanges to "implement procedures" to certify qualified health plans that are "consistent with guidelines developed by the Secretary under subsection (c)." 42 U.S.C. § 18031(d)(4)(A). That provision also fails to require HHS to make its own network adequacy determination to certify every qualified health plan in a Federal Exchange. Instead, the Secretary "implement[ed] procedures" for Federal Exchanges, in accord with § 18031(d)(4)(A), through the process that the Secretary established in the Market Stabilization Rule and extended in the 2019 Rule.

Because Plaintiffs have identified no applicable statutory requirement that could conceivably have been violated, they fail to establish that this aspect of the 2019 Rule is "contrary to law." The situation here is markedly different from that in *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554 (D.C. Cir. 2004), upon which Plaintiffs rely for the notion that the 2019 Rule improperly "delegates" the requirements of § 18031(c) to outside entities. *Cf.* Pl. Mem. at 36. In *U.S. Telecom*, the Federal Communications Commission ("FCC") "adopted a provisional nationwide rule [for market access by broadband companies], subject to the possibility of specific exclusions, to be created by state regulatory commissions under a purported delegation of the [FCC']s own authority." *U.S. Telecom Ass'n*, 359 F.3d at 563. The FCC did so because it was concerned that a nationwide standard might not adequately account for local conditions. Nevertheless, the court held that the agency's formulation amounted to an improper sub-delegation of the agency's statutory obligation to promulgate standards. *Id.* at 565-66. *U.S. Telecom* is inapposite because there is no such sub-delegation here; in fact, the 2019 Rule does not even change the standards for network adequacy set forth in § 156.230—which was adopted in 2012 and must be adhered to by any Exchange, whether State or Federal. 83 Fed. Reg. at

17025. Rather, the 2019 Rule addresses how Federal Exchanges should implement those standards on an ongoing basis. Plaintiffs' "contrary to law" argument therefore should be rejected.

**3. HHS's Network Adequacy Approach Is Not Arbitrary or Capricious**

Plaintiffs also fail to show that this aspect of the 2019 Rule is arbitrary or capricious. Plaintiffs contend that HHS "overlooked" comments that opposed its proposal to extend the 2018 process for determining whether health plans satisfied the network adequacy requirement in order to be certified as "qualified." Pl. Mem. at 37. However, they acknowledge that the 2019 Rule "responded" to those comments. *Id.* at 38; *see also* 83 Fed. Reg. at 17025 (responding to comments). In fact, HHS responded in detail to comments that questioned the adequacy of States' and accrediting entities' review processes, stating:

> We have relied on State and accrediting entities for this review in the past, and believe they provide appropriate review because both typically have requirements in place that specifically address access to adequate networks. Many States already address issuer network adequacy in State-specific regulation. The National Committee for Quality Assurance requires accredited plans to create standards for the number and geographic distribution of providers and establish standards regarding the ability of consumers to access care. Similarly, URAC requires that plans have proper methods in place to build, manage, and evaluate their networks. We will also continue to monitor enrollee complaints for access concerns.

*Id.* Plaintiffs argue that HHS was not entitled to rely on its experience over the preceding year or its familiarity with State and accrediting entities' review processes to conclude that those processes were adequate but instead was required to "provide *evidence*" of such adequacy. Pl. Mem. at 38. They suggest, for example, that HHS could have conducted "an analysis of the rigor of state procedures or assessments of plans certified by state regulators" and presented the result of that analysis in the Preamble. *Id.*

But Plaintiffs fail to support the notion that HHS was required to conduct or cite evidentiary studies in this situation. Plaintiffs cite *NTEU v. Horner*, 854 F.2d 490 (D.C. Cir. 1988), but the court in that case merely concluded that the agency could not reasonably cite high costs as justification for its action without any evidence that costs were actually high. *Id.* at 499. Nothing in *NTEU* suggests that HHS was obligated to meet an evidentiary burden when responding to comments that questioned

the reliability of State and accrediting entities' review processes, let alone dispense with HHS's own knowledge of and experience with such entities' processes. And courts have consistently rejected arguments that an agency must "undergo an independent investigation in search of evidence to support its rationale" when it sets forth a reasoned explanation based on its experience. *PhRMA v. FTC*, 44 F. Supp. 3d 95, 130–31 (D.D.C. 2014) (citing *Nat'l Tour Brokers Ass'n v. ICC*, 671 F.2d 528, 533 (D.C. Cir. 1982)). Indeed, nothing in the APA's deferential standard allows the plaintiff to dictate the evidentiary showing that HHS must make, or to insist that HHS prove that its decision will guarantee that its adopted policy will work as intended. *See id.* The "sole question" for a reviewing court is "whether [the agency] has acted reasonably, not whether it has acted flawlessly." *Nat. Res. Def. Council v. EPA*, 529 F.3d 1077, 1086 (D.C. Cir. 2008).

The reasonableness of HHS's decision is underscored here by the fact that numerous commenters supported HHS's proposal. A number of commenters recognized States' experience and expertise in assessing network adequacy. *E.g.*, AR 869-71 (Anthem) (recognizing, in light of states' "very long history of actively regulating the business of insurance," that "accrediting agencies and state organizations regularly assess networks to ensure access to a wide breadth of providers, and have processes for working with health plans to develop appropriate networks"); 970 (Centene) (agreeing state insurance regulators "understand the market they regulate," resulting in "the best balance of consumer protection and network design"); 1258 (BCBSA) (strongly supporting network regulation at state level); 1484 (NMHC); 1558, 1562-63 (Kaiser Permanente) (welcoming HHS's acknowledgement that "states may have valuable, alternative approaches to network adequacy beyond 'time and distance' methodologies"); see also AR 2003 (American Hospital Association); 2083 (ACAP); 2116 (Cigna); 2284 (U.S. Chamber of Commerce); 2535 (AAAHC); 2688 (AHIP); 2763-64 (American Pharmacists Association); 2905 (NAHU); 3393 (UnitedHealthcare).

Moreover, some commenters representing or having specific knowledge of particular States either supported the change or acknowledged that they did maintain network adequacy standards. AR 883 (Idaho Dept. of Insurance) (finding proposal "acceptable"); 2769 (Ore. Dept. of Consumer & Business Servs.) (taking no position because "Oregon has developed its own network adequacy

standards"), 3435 (Mass.-based non-profit Health Care For All) (stating it is "sensible to defer to state oversight for network adequacy" if federal minimum standards are not reduced); 3443 (Colo. Consumer Health Initiative) (recognizing "Colorado has adopted robust network adequacy regulations"); *see also* AR1345 (Tenn. Health Care Campaign) ("most states have adopted some sort of regulatory framework for network adequacy"); 1948 (Young Invincibles), 3242 (Utah Health Policy Project), 3304 (Consumers for Affordable Health Care), 3337 (Cal. Pan-Ethnic Health Network), 3407 (Mo. Health Care for All), 3427 (N.C. Justice Center) (same though warning of uneven oversight and application).

Plaintiffs also ignore that the policy set forth in the 2019 Rule would only rely on States' reviews where States (1) have "a sufficient network adequacy review process," (2) have the "authority to enforce standards that are at least equal to the 'reasonable access standard' defined in § 156.230," nad (3) have the " means to assess issuer network adequacy." 83 Fed. at 17025. Otherwise, HHS would rely on accrediting agencies or on an unaccredited plan's compliance with the National Association of Insurance Commissioners' Health Benefit Plan Network Access and Adequacy Model Act. *See id.* Plaintiffs do not suggest that HHS's review processes are inadequate. Instead, they cite a comment stating that "[p]rivate accreditors also have virtually no method of enforcing such standards beyond revoking or suspending an insurer's accredited status." Pl. Mem. at 37 (quoting AR 906-07). But if an accrediting entity revokes or suspends the insurer's accredited status, HHS would be aware of this and know that it could not rely on the accreditation. Plaintiffs fail to explain why such a mechanism would be insufficient.

Plaintiffs otherwise simply emphasize the importance of network adequacy—but nothing in the 2019 Rule suggests it is not important. To the contrary, the 2019 Rule emphasizes that HHS will continue to monitor network adequacy in cooperation with States. *See* 83 Fed. Reg. at 17025. Unlike the court's conclusion in *Gresham v. Azar*, 950 F.3d 93 (D.C. Cir. 2020), which Plaintiffs cite, Plaintiffs fail to identify any "important aspect of the problem" that HHS ignored. *Id.* at 103. HHS's approach is a reasonable way to continue efforts to ensure that plans have adequate networks while reducing administrative burdens caused by duplicative efforts on the Federal and State levels. Judgment on this

issue should be entered in Defendants' favor.

### C. The 2019 Rule's removal of the requirement that HHS provide advance approval of third-party auditors for entities participating in direct enrollment is a reasonable way to reduce regulatory burdens and duplicative oversight. [Am. Compl. ¶ 282(c)]

Plaintiffs' third APA challenge also fails as a matter of law. The subject of this challenge is the 2019 Rule's adoption of new standards in 45 C.F.R. § 155.221, governing the selection of third-party entities to annually audit agents, brokers, and issuers participating in direct enrollment. HHS's adoption of this approach for selecting third-party auditors is not arbitrary or capricious.

#### 1. Relevant Background

The ACA directed the Secretary to establish procedures for agents or brokers to enroll individuals and employers in qualified health plans offered through an Exchange in the individual or small group market. 42 U.S.C. § 18032(e). The ACA also directed the Secretary to establish, subject to certain minimum requirements, a streamlined process for enrollment in qualified health plans and all insurance affordability programs. *Id.* § 18083(a), (b). Before the 2019 Rule, HHS required agents, brokers, and issuers participating in direct enrollment to demonstrate operational readiness. 2018 Payment Notice, 81 Fed. Reg. at 94119-20, 94152 (adding operational readiness requirement at 45 C.F.R. § 155.220(c)(3)(i)(K) for agents and brokers and at 45 C.F.R. § 156.1230(b)(2) for issuers).[3] Pursuant to § 155.220, HHS "or its designee" was authorized to "periodically monitor and audit" agents and brokers. 2017 Payment Notice, 81 Fed. Reg. at 12339 (adding 45 C.F.R. § 155.220(c)(5)). HHS also added a provision, 45 C.F.R. § 155.221, setting forth a process by which it would annually review and approve third-party vendors to conduct the operational readiness review audits. 81 Fed. Reg. at 94122, 94176.

The 2019 Rule expanded the applicability of 45 C.F.R. § 155.221 to require issuers, as well as agents and brokers, participating in direct enrollment to engage third-party entities to conduct required

[3] HHS exercised its authority under § 18083 when originally promulgating 45 C.F.R. § 156.1230, which allows issuers to participate in direct enrollment. *See* CMS, ACA Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards, Proposed rule, 78 Fed. Reg. 37031, 37065-66 (June 19, 2013); first Program Integrity Rule, 78 Fed. Reg. at 54124-26.

operational readiness reviews on an annual basis. 83 Fed. Reg. at 16981 (indicating that conforming edits would also be made to § 156.1230(b)(2)); 45 C.F.R. § 155.221(b)(4), (e).[4] The third-party auditors would use their "own audit processes and methods subject to HHS-defined specifications and requirements," including those listed in a new subsection (formerly (b) and now (f)). 83 Fed. Reg. at 16981. The 2019 Rule also provides that these direct enrollment entities "would select their own third-party entities for conducting audits, rather than requiring HHS to initially review and approve" those vendors. *Id.* Those third-party entities will "be subject to HHS oversight," *id.*, and the new standards in § 155.221(f) codified the right of HHS or its designee, when undertaking an audit, inspection, or other evaluation, to access the third-party entities' records and systems relating to their audits of a direct enrollment entity. *See* 45 C.F.R. § 155.221(f)(7). In addition, "the agent, broker, or issuer will remain responsible for compliance with all applicable direct enrollment requirements." 83 Fed. Reg. at 16981. Given that agents, brokers, and issuers likely "already conduct audits for compliance with HHS requirements," HHS determined that this approach would "reduce duplicative HHS oversight" and "expand the available number of qualified third-party entities to perform the audits." Proposed Rule, 82 Fed. Reg. at 51084. That would, in turn, enable more agents, brokers and issuers to demonstrate operational readiness to participate in direct enrollment," thus "expand[ing] consumer access to direct enrollment pathways for enrolling in Exchange coverage." 82 Fed. Reg. at 51084. As one commenter observed, because the third-party entities "would need to perform the operational readiness reviews in accordance with HHS-defined specifications and standards," the new provision "would support an equivalent level of compliance as the [previous] standard." AR 995 (AWHIB); *accord* AR 1206 (NAIFA); 2907 (NAHU).

**2. HHS's Removal of an Advance Approval Requirement for Third-Party Auditors Is Not Arbitrary or Capricious**

Plaintiffs assert that the 2019 Rule's removal of an advance HHS approval requirement for third-party auditors is arbitrary and capricious because, they contend, it will ultimately "increase the

[4] The 2019 Rule promulgated these requirements at § 155.221(a) and (b). The regulation has since been revised.

likelihood that consumers enroll in non-ACA-compliant plans that undermine the risk pool, decline to enroll in other programs for which they may be eligible, like Medicare and Medicaid, receive inadequate information about their rights and responsibilities under the ACA, and expose their personal information to brokers that lack stringent compliance with privacy and security standards." Pl. Mem. at 39. In other words, Plaintiffs quarrel with the policy choice reflected in the regulatory change based on their assumption that the change will lead to less effective audits of direct enrollment entities, and thus, inadequate agents, brokers, and issuers.

But contrary to Plaintiffs' contention, HHS did not "ignore" or fail to address "head-on" these asserted potential "problems," *see id.* Instead, in the Preamble to the 2019 Rule, HHS directly addressed concerns about a lack of "proper oversight and controls" over the direct enrollment process. 83 Fed. Reg. at 16982. As HHS explained, the 2019 Rule merely replaced a system requiring advance HHS approval of auditors with one that retained robust standards for third-party auditors, set forth in a new subsection within the regulation itself. *See* 83 Fed. Reg. at 16981–82; 45 C.F.R. § 155.221(f); AR 995 (agreeing that the new framework would "support an equivalent level of compliance as the [previous] standard"), 1206 (same). HHS thus pointed to these standards—which, as described above, give HHS access to third-party entities' records in order to ensure their compliance with applicable federal requirements, *id.* § 155.221(f)(7)—as well as other "guidelines and processes" in place "to oversee the activities of agents, brokers, and issuers participating in direct enrollment." *See* 83 Fed. Reg. at 16982. HHS further emphasized its commitment to "continuous monitoring and oversight" of such entities. *Id.*

HHS also responded to expressed concerns about "the potential for conflicts of interest arising from relationships between the agents, brokers, and issuers and the third-party auditors they select to conduct their audits." *Id.* But again, HHS concluded that these concerns are mitigated by the requirements and processes the agency put in place. *Id.* HHS indicated that it intends to continue "to monitor enrollments through the direct enrollment pathway for evidence of fraud and abuse." *Id.* And, although the agency "acknowledge[d] the potential for conflicts of interest," in its view, the "required disclosures, continuous monitoring and oversight, and standards established for third-party auditors

will sufficiently mitigate these concerns." *Id.* Plaintiffs cannot invalidate HHS's decision based on their own unsubstantiated fear that there will be widespread fraud or abuse by insurance issuers, agents, or auditors. *See Am. Whitewater v. Tidwell*, 770 F.3d 1108, 1116 (4th Cir. 2014) ("[T]he APA does not give us license to second-guess an agency's well-reasoned decision simply because a party disagrees with the outcome."). HHS's desire to reduce regulatory burdens while maintaining the role that third-party auditors play is sufficient "good reason" to meet APA requirements. *See FCC*, 556 U.S. at 515. The Court therefore should enter judgment on this claim in Defendants' favor.

### D. The 2019 Rule's cessation of the practice of designating "Simple Choice" plans is a reasonable way to foster innovation while eliminating potentially misleading preferential display of certain plans. [Am. Compl. ¶ 282(d)]

Plaintiffs next challenge as arbitrary and capricious the 2019 Rule's elimination of the practice of designating certain plan designs as "standardized options" or "Simple Choice plans." *See* Pl. Mem. at 40; 83 Fed. Reg. at 16974. HHS's decision to no longer designate plans as Simple Choice plans, or require their display in online marketplaces in a preferential manner, reasonably reflects its policy choice to promote innovation and is not arbitrary or capricious.

#### 1. Relevant Background

Standardized option, or "Simple Choice," plans existed during the 2017 and 2018 benefit years. 83 Fed. Reg. at 16974; *see also* 82 Fed. Reg. at 51081. While recognizing that the ACA "gives Exchanges considerable flexibility in certification and oversight of" qualified health plans, HHS had established these plans on the theory that they would simplify consumers' decisionmaking processes and thus increase enrollment. CMS, HHS Notice of Benefit and Payment Parameters for 2017, Proposed rule, 80 Fed. Reg. 75488, 75542 (Dec. 2, 2015).

In the 2019 Rule, however, HHS discontinued the Simple Choice plans. 83 Fed. Reg. at 16974. HHS explained that promoting enrollment in a small number of Simple Choice plans had discouraged issuers from designing and offering more innovative plans to consumers, even though "encouraging innovation is especially important now, given the stresses faced by the individual market." 82 Fed. Reg. at 51081; 83 Fed. Reg. at 16974. HHS cited many commenters agreeing that standardized options

"stifled issuers' ability to develop innovative plan designs" and that because such plans are promoted on Exchange websites, consumers may have purchased Simple Choice plans even when those plans "did not best meet consumers' needs." *Id.* at 16974-75. Instead of steering consumers' choice through such differential display, one commenter pointed out that HealthCare.gov and many State Exchanges "have implemented sort and filter tools that allow consumers to compare plans based on formulary and network inclusion," thus providing a better way for consumers to find their optimal plan. AR 856 (Anthem); *see also* AR 1032 (PCMA); 2251 (EmblemHealth); 2679 (AHIP); 2787 (Highmark Inc.); 3392-93 (UnitedHealthcare).

HHS also pointed out that the Simple Choice plans had been designed at the outset to "be as similar as possible to the most popular (weighted by enrollment) [qualified health plans]" in Federal Exchanges—suggesting that similar plans had been available before Simple Choice plans existed and would continue to be available without them. 83 Fed. Reg. at 16975 (concluding that it was not necessary to provide any further incentive for such plans). At the same time, commenters suggested that consumers may have mistakenly believed that Simple Choice plans were superior to other plans based solely on the way they were displayed on Exchange websites. *Id.*; *see, e.g.*, AR 822 (Express Scripts) ("We vigorously support CMS' decision" to eliminate Simple Choice plans in order to "provide a level playing field for all plans while eliminating the implied (and misleading) message to enrollees" that standardized plans "are better than others" due to their differential display on the enrollment website); *see also* AR 969 (Centene); 1232 (BCBSA); 1484 (NMHC); 1770 (PriorityHealth); 2083 (ACAP); 2640 (Medica); 2905-06 (NAHU); 2767-68 (Oregon) (stating it has designed its own standardized options).

In response to commenters' concern that withdrawing Simple Choice plans could create confusion for consumers and make plan selection more difficult, HHS agreed with other commenters who stated that HealthCare.gov provided sufficient filters and other tools "to enable most consumers to make plan selections." 83 Fed. Reg. at 16975. For example, the website allows consumers to select plans based on whether they were bronze, silver, gold, or platinum plans. *See id.* HHS also noted that it would "continue to explore strategies to make shopping on HealthCare.gov as easy as possible and

to better support consumers in choosing coverage that is best for them." *Id.*

**2. HHS's Discontinuation of Simple Choice Plans Is Not Arbitrary or Capricious**

Plaintiffs first argue that HHS faced a heightened burden when explaining its decision to discontinue Simple Choice plan options because the decision "rests upon factual findings that contradict those which underlay [its] prior policy." Pl. Mem. at 41 (quoting *FCC*, 556 U.S. at 515). However, courts have consistently rejected the notion that an agency is "required to refute the factual underpinnings of its prior policy with new factual data." *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 626 (D.C. Cir. 2016). Rather, the agency only needs to "provide a reasoned explanation for discounting the importance of the facts that it had previously relied upon." *Id.*; *see also U.S. Telecom Ass'n*, 825 F.3d at 708 (accepting agency's explanation for its policy change even in the absence of changed factual circumstances).

The situation here is different from that in *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279 (D.C. Cir. 2019), where the Mine Safety and Health Administration was statutorily prohibited from adopting a safety standard that would reduce the previous level of protection. The court there held that the agency had failed to provide sufficient factual support for its conclusion regarding the relative protection provided by its new standard (assessing miners' work area after miners' arrival) versus the old standard (assessments before miners began work). *See id.* at 1283. Here, HHS's decision does not rely on a counterfactual conclusion that discontinuing Simple Choice plans, with their preferential treatment on Exchange websites, would lead to greater enrollments in those plans. Rather, HHS reasoned that encouraging Simple Choice plan enrollment was no longer desirable because it could lead enrollees to choose unsuitable plans while also stifling the development of more innovative plans. At the same time, plans similar to Simple Choice plans would continue to be available, and the HealthCare.gov website continued to allow consumers to find such plans. HHS thus provided a reasoned explanation for its decision to remove plans designated as Simple Choice plans. That is all that the APA requires.

Plaintiffs also argue that HHS "failed to respond to extensive comments explaining the

benefits of standardized options." Pl. Mem. at 41. But as described above, HHS did respond by offering a reasoned explanation for rejecting these comments, explaining its belief that the removal of standardized options would better encourage issuers to offer coverage with innovative plan designs, and that issuers are in the best position to decide which areas are most appropriate for innovation. *See* 83 Fed. Reg. at 16975. HHS was not obligated to refute every supposed benefit of standardized options where its policy choice favored innovation over those benefits. *Perez v. Mtg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("An agency must consider and respond to *significant* comments received during the period for public comment." (emphasis added)). Comments that raise points that are not "relevant to the agency's decision" do not require a response. *HBO, Inc. v. FCC*, 567 F.2d 9, 35-36 & n.58 (D.C. Cir. 1977).

HHS also noted that issuers would still have market incentives to offer certain features that were popular in plans offered on the Federal Exchange but that consumers would not be encouraged to choose a plan simply because it was labeled as a "Simple Choice" plan, when another plan might provide better coverage for an individual's specific situation. *See* 83 Fed. Reg. at 16975. Moreover, HHS's decision was supported by its own ever-growing experience with administering the Federal Exchanges as well as by many commenters who agreed that eliminating Simple Choice plans would encourage innovation and would also level the playing field by dispensing with potentially misleading website displays. *See id.*; *see also, e.g.*, AR 856 (Anthem); AR 822 (Express Scripts). Again, Plaintiffs apparently disagree with HHS's policy priorities, but they fail to support the notion that HHS's policy choice is arbitrary or capricious. Judgment on this claim therefore should be granted in Defendants' favor.

**E. The 2019 Rule's modification of standards for Navigator certification is permissible under the ACA and is a reasonable way to give Exchanges more flexibility in choosing Navigators that will best serve their needs. [Am. Compl. ¶ 282(e)]**

Equally without merit is Plaintiffs' challenge to the 2019 Rule's changes to Navigator program requirements. HHS's decision to provide Exchanges with greater flexibility in selecting Navigators is neither contrary to law nor arbitrary and capricious.

**1. Relevant Background**

The ACA requires each Exchange to establish a Navigator program, pursuant to which the Exchange awards grants to "Navigators"—entities that will conduct public education and other activities aimed at increasing public awareness about qualified health plans and enrollment in qualified health plans. 42 U.S.C. § 18031(d)(4)(K), (*i*). The Secretary is vested with the authority to "establish standards" for these Navigators, "including provisions to ensure that any private or public entity that is selected as a navigator is qualified, and licensed if appropriate, to engage in . . . navigator activities . . . and to avoid conflicts of interest." *Id.* § 18031(*i*)(4)(A); *see also id.* § 18041(a)(1). The Secretary has promulgated these standards for all Exchanges at 45 C.F.R. § 155.210, and has identified additional standards for Federal Exchanges at 45 C.F.R. § 155.215.

Prior to the 2019 Rule, § 155.210 required that each Exchange have "at least two Navigator[s]"; "that one of these [two] entities . . . be a community and consumer-focused nonprofit group"; and that each Navigator entity "maintain a physical presence in the Exchange service area." 83 Fed. Reg. at 16979. In the 2019 Rule, HHS revised the relevant regulatory provisions to make these standards optional for each Exchange. *Id.* at 16979–80 (amending 45 C.F.R. § 155.210(c)(2) by removing the two-Navigator requirement, and amending § 155.210(e)(7) by removing the physical presence requirement); *see also* 82 Fed. Reg. at 51083–84. These amendments are intended "[t]o maximize the flexibility and efficiency of the Navigator program" by granting the Exchanges "flexibility to award funding to the number and type of entities that will be most effective for the specific Exchange." 83 Fed. Reg. at 16979. For example, under these amendments, an Exchange may conclude that "selecting a single, high performing grantee" would be the best option for its service area. *Id.* HHS also explained that the ACA continued to require Navigators to "demonstrate to the

Exchange that they have existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment" in a qualified health plan." *Id.* (citing 42 U.S.C. § 18031(*i*)(2)(A)). HHS indicated that, in its experience, Navigators "with strong relationships in their [Exchange] service areas tend to deliver the most effective outreach and enrollment results," but that "each Exchange is best suited to determine the weight to give a physical presence in the Exchange service area when selecting Navigator entities, as long as the Exchange's Navigator grantee selection process is consistent with" 42 U.S.C. § 18031(*i*)(2)(A). 83 Fed. Reg. at 16979-80.

**2. HHS's New Navigator Selection Standards Are Not Contrary to Law**

Plaintiffs first contend that the 2019 Rule's changes to 45 C.F.R. § 155.210 are contrary to law because they "permit[] entities to qualify as Navigators" without "satisfy[ing] the relevant statutory criteria" in 42 U.S.C. § 18031(*i*)(2)(A) and (3)(A)-(E). Pl. Mem. at 43. However, this contention misreads the statute and fails at *Chevron* step one. Section 18031(*i*)(2)(A) imposes an obligation on Navigators to "demonstrate to the Exchange involved" that it has or could readily establish relationships with those eligible to enroll in the relevant qualified health plans, and § 18031(*i*)(2)(B) requires that Navigators be "capable of carrying out" their statutory duties under § 18031(*i*)(3), *in addition to* "meeting the standards" promulgated by the Secretary. 42 U.S.C. § 18031(*i*)(2)(A), (B)(i), (ii). The 2019 Rule does not purport to relieve Navigators of their statutory duties. Consistent with the statutory text, the 2019 Rule expressly acknowledges, for example, that, regardless of its amendment of the regulatory standards at § 155.210, both Exchanges and Navigators are still bound by § 18031(*i*)(2)(A). 83 Fed. Reg. at 16979-80. The same is true for § 18031(*i*)(3)(A)-(E). Plaintiffs' suggestion that an Exchange might rely solely on an out-of-state commercial fishing industry organization, Pl. Mem. at 44, assumes the Exchange will willfully violate these statutory requirements. But such speculation does not render the regulatory amendments at issue contrary to law.

Moreover, HHS has incorporated these requirements in its regulations. It includes the "strong relationships" requirement of § 18031(*i*)(2)(A) at 45 C.F.R. § 155.210(c)(1)(ii). It similarly includes the statutory duties set forth in § 18031(*i*)(3)(A)-(E) at 45 C.F.R. § 155.210(e)(1)-(5). These provisions

were not changed by the 2019 Rule. Plaintiffs therefore are incorrect when they argue that the 2019 Rule is inconsistent with statutory requirements because all the statutory requirements they point to are reflected in the regulation. And to the extent an Exchange determines that a Navigator physically present in the service area would best be able to fulfill these statutory and regulatory requirements, or that more than one Navigator is needed, nothing in the amended § 155.210 prevents it from selecting Navigators based on those determinations. Several State Exchanges thus submitted comments indicating that they took no position on the proposed change because they would still retain control over their selection of Navigators. *E.g.*, AR 2769 (Oregon); 2837-38 (Washington); 2988-89 (Colorado). The 2019 Rule, like the statute itself, simply gives the Exchanges the flexibility to select Navigators that will best serve their service areas consistent with statutory requirements. 83 Fed. Reg. at 16980 ("We agree with commenters who stated that [the revisions] will provide Exchanges with improved flexibility to award funding to the number and type of entities that would be most effective for each specific Exchange."). The 2019 Rule's revisions of § 155.210 thus are not contrary to law.

**3. HHS's New Navigator Selection Standards Are Not Arbitrary or Capricious**

The 2019 Rule's revisions to § 155.210 also are not arbitrary or capricious. As discussed above, the ACA does not require Navigators to have a physical presence in the Exchange's service area, nor does it mandate that every Exchange have at least two Navigators. *See* 42 U.S.C. § 18031(i)(2)(A). HHS determined that the amendments to § 155.210 would give Exchanges greater flexibility in selecting Navigators while complying with the relevant statutory requirements. When adopting this change, HHS explained that Exchanges could still award grants to two Navigator entities, including a community and consumer-focused nonprofit group, if they wished, but could also award a single grant to a Navigator entity that is deemed the strongest candidate, even if it is not a community or consumer-focused nonprofit. 83 Fed. Reg. at 16980. HHS also explained that the elimination of the physical presence requirement would allow Exchanges to determine what weight to give a Navigator entity's physical presence in the service area, as opposed to other considerations such as relationships with the community. *See id.* HHS indicated that this proposal would provide Exchanges with improved

flexibility to use Navigators in the manner that would be most effective for the Exchanges' particular needs. *See id.* at 16981.

In response to this reasoned explanation, Plaintiffs cite comments that favored HHS's previous approach and that "highlighted the diverse populations that Navigators may serve, and which a single Navigator could not conceivably cover." Pl. Mem. at 44-45. However, as explained, Exchanges retain flexibility to select the Navigators they believe will best serve their population, and several Exchanges' comments recognize as much. AR 2769 (Oregon); 2837-38 (Washington); 2988-89 (Colorado). HHS acknowledged comments suggesting that removing the two-Navigator requirement "could potentially negatively affect consumer access to in-person assistance" and that having two Navigator entities allowed an Exchange to select one Navigator "more tailored to specific needs within an Exchange." 83 Fed. Reg. at 16980. However, HHS concluded that improved flexibility would "allow each Exchange to optimally use available funding amounts" and did not agree that the change "will have a detrimental effect on the availability of professional, unbiased, in-person consumer assistance." *Id.*

HHS also responded to comments expressing concern about the removal of the requirement that one Navigator entity be a community and consumer-focused nonprofit. HHS agreed that "nonprofit Navigator entities often have expertise with one or more hard-to-reach populations within their communities." *Id.* But HHS noted that nothing in the amendments "prevents an Exchange from selecting and funding a nonprofit Navigator entity if it determines that such an entity best meets the needs of the community served by the Exchange." *Id.* On the other hand, HHS recognized that other Exchanges may face different circumstances, in which their strongest applicant may not be a community and consumer-focused nonprofit group. *See id.* Thus, HHS concluded that Exchanges should be given the flexibility to make such decisions based on their individual circumstances. *See id.* The same is true when it comes to whether the Navigator should have a physical presence. HHS recognized similar concerns about the removal of that requirement but reached similar conclusions regarding the importance of flexibility. *Id.* at 16981. Plaintiffs thus fail to identify factors that HHS failed to consider or significant comments to which HHS failed to respond.

Plaintiffs also suggest that HHS has inappropriately decided to rely on entities other than Navigators to "pick up the slack for deficient Navigators." Pl. Mem. at 47. But that is not the case. Rather, HHS responded to comments by agreeing that collaborations with other entities could be helpful in reaching marginalized communities. 83 Fed. Reg. at 16981. Nowhere did HHS suggest that such entities would take over functions that the ACA assigns to Navigators. Rather, HHS stated that it "intend[ed] to continue to work with these stakeholders to ensure consumers in [Federal Exchanges] have access to a range of enrollment assistance, including Navigators." *Id.*

The situation here is not remotely similar to that in *MCI Telecomms. Corp. v. FCC*, 842 F.2d 1296 (D.C. Cir. 1988), cited by Plaintiffs, where the agency failed to comply with a statutory requirement that it compare actual costs of two different approaches to determine whether the costs of one approach were unreasonable. *See id.* at 1303-04. Here, by contrast, no statutorily-required comparison is at issue. Rather, Plaintiffs simply disagree with HHS's policy choice. Plaintiffs fail to establish that HHS's decision to give Exchanges more flexibility in selecting Navigators is arbitrary or capricious, and Defendants should be granted judgment as a matter of law on this issue.

### F. The 2019 Rule's modifications to the Small Business Health Options Program are permissible under the ACA and a reasonable response to low SHOP enrollment. [Am. Compl. ¶ 282(f)]

Plaintiffs' challenge to the 2019 Rule's modifications to the Small Business Health Options ("SHOP") Program also fails. These modifications reasonably reduce administrative burdens related to SHOPs in light of low SHOP enrollments and are neither contrary to law nor arbitrary and capricious.

#### 1. Relevant Background

The SHOP program is designed to assist qualified small businesses in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the State. *See* 42 U.S.C. § 18031(b)(1)(B). The ACA directs the Secretary to "issue regulations setting standards" for SHOP operations. 42 U.S.C. § 18041(a)(1)(A). Pursuant to that authority, HHS has promulgated regulations establishing standards and processes governing SHOP operations. *See, e.g.*, Exchange

Establishment Rule, 77 Fed. Reg. at 18395; 2014 Payment Notice, 78 Fed. Reg. at 15413. Earlier versions of those regulations required all SHOPs to determine employer and employee eligibility for SHOP plans and to provide certain enrollment functions, including premium aggregation functions. 83 Fed. Reg. at 16996. The 2019 Rule removed some of those regulatory burdens on SHOPs, including verification of employee eligibility, premium aggregation, and online enrollment functionality. *Id.*

As HHS explained, it decided to remove those burdens, thus allowing SHOPs to "operate in a leaner fashion" if they so choose, as a practical response to significant decreases in SHOP qualified health plan issuer participation and enrollments. *Id.* at 16996, 16997. HHS noted that 2018 enrollments in SHOPs had been even lower than anticipated and that many SHOPs continued to face challenges in managing all the original regulatory requirements. *See id.* at 16996 (noting "the significant decreases in SHOP [qualified health plan] issuer participation and enrollment for plan year 2018," and the "lower than expected enrollment" in SHOPs on the federal platform); *see* AR 3599 (link to 2017-0078-0874), at 1-2 (Minutemen Health) (identifying problems with pre-2019 SHOP marketplace), 3609 (link to 2017-0078-1444), at 6-7 (NFIB) (similar). According to HHS, it is no longer "cost effective for the Federal government to continue to maintain certain [Federal] SHOP functionalities, collect significantly reduced user fees on a monthly basis, maintain the technologies required to maintain a[] [Federal] SHOP website and payment platform, generate enrollment and payment transaction files, and perform enrollment reconciliation." 83 Fed. Reg. at 16996.

Although HHS decided to remove many of these regulatory requirements, it made clear that "SHOPs that opt to operate in a leaner fashion, such as the [Federal] SHOPs, will still assist qualified employers . . . in facilitating the enrollment of their employees in [qualified health plans] offered in the small group market in the State." *Id.* at 16997. HHS explained that these changes are consistent with the ACA's provisions governing SHOPs "because the basic functionalities of an Exchange will still be provided." *Id.* HHS also explained that, despite the removal of certain previously mandatory features that imposed significant administrative burdens on the Exchanges, "State Exchanges will continue to have the flexibility to operate their SHOPs as they choose, in accordance with applicable Federal and State law." *Id.* at 16996.

**2. HHS's Amendment of SHOP Program Standards Is Not Contrary to Law**

Plaintiffs first argue that the 2019 Rule's amendment of the standards governing SHOPs is contrary to law because, in their view, the regulatory burdens removed by the 2019 Rule were "the very requirements needed to ensure that SHOPs fulfill [their statutory] duties." *See id.* However, the only statutory provision related to SHOPs that Plaintiffs cite, 42 U.S.C. § 18031(b)(1)(B), merely sets forth a broad requirement that Exchanges establish SHOPs "designed to assist" small businesses "in facilitating the enrollment of their employees" in qualified health plans in the small group market *See* 42 U.S.C. § 18031(b)(1)(B). This provision, by its plain terms, does not require the SHOP administrative features removed by the 2019 Rule.

Because the ACA vests in the Secretary the authority to set the standards governing SHOP operations in order for SHOPs to meet their statutory duties, Plaintiffs' "contrary to law" challenge is governed by *Chevron* step two and necessarily fails because HHS's interpretation is permissible. HHS has interpreted § 18031(b)(1)(B), in conjunction with the consumer choice provisions in 42 U.S.C. § 18032(a)(2) and (f)(2), as requiring "basic [SHOP] functionalities," including certifying plans for sale, providing small employers the option to offer a choice of plans, and providing eligibility determinations for small employers, which will continue to apply under its revised standards. 83 Fed. Reg. at 16997. Those are the functionalities that, in the Secretary's view, are essential to ensure that SHOPs will meet their statutory obligation to assist small businesses help their employees' enrollment in qualified health plans. *Id.* The Secretary permissibly determined that the 2019 Rule's removal of certain specific requirements for SHOPs would not affect their statutorily required functions. *Id.* at 16996 (reiterating that removing certain functionality "that is not expressly required by the [ACA]" does not affect the "appropriate implementation of statutorily required functions of the SHOP").

Plaintiffs fail to support their theory that the 2019 Rule's amendments to SHOP standards make statutory compliance "impossible" and are contrary to law on that basis. Again, despite the 2019 Rule's revisions, the regulations continue to require SHOPs to provide all functionalities required by statute, and the SHOPs operated by HHS are doing so. Moreover, in allowing SHOPs to "opt to operate in a leaner fashion," should they choose to do so, 83 Fed. Reg. at 16997, the 2019 Rule does

not *prohibit* Exchanges from taking any additional action they deem helpful in order to advance the statutory purpose of helping small business employees' enrollment in qualified health plans. Plaintiffs' only rejoinder is a commenter's opinion, in regard to the DC Health Link SHOP, that, in addition to online enrollment, premium aggregation is important. Pl. Mem. (citing AR 1715). But that commenter did not provide any evidence that SHOPs are unable to facilitate small business employees' enrollment in qualified health plans without premium aggregation Premium aggregation was originally offered to "simplify the administration of health benefits among small employers" when employees are enrolled in multiple qualified health plans. 77 Fed. Reg. at 18396. But HHS explained in the 2019 Rule that premium aggregation was not a function mandated by the ACA, and that SHOP-registered agents and brokers could provide similar assistance. 83 Fed. Reg. at 16976-77, 16997-98. Additionally, "SHOPs electing not to provide premium aggregation functions, like the [Federal] SHOPs, would still be required to provide an opportunity for employers to offer employees a choice of plans." *Id.* at 16999.

Plaintiffs also argue that SHOPs that opt not to directly enroll employees will not be in compliance with the statutory requirement to make plans "available." Pl. Mem. at 47-48 (quoting 42 U.S.C. § 18031(d)(2)(A)). However, the statute does not require SHOPs to process enrollments. SHOPs operating in a leaner fashion, as provided for by the 2019 Rule, continue to make qualified health plans available to qualified employers by certifying plans for sale through the SHOP; providing an internet website that displays and provides qualified health plan information, a premium calculator that generates estimated prices of the available qualified health plans, and a call center to answer questions related to the SHOP; and providing small employers with eligibility determinations from the SHOP website. *See* 83 Fed. Reg. at 16997. By providing these functions, SHOPs make plans "available," consistent with § 18031(d)(2)(A), and also satisfy the requirement that SHOPs be "designed to assist" qualified small employers in "facilitating the enrollment" of their employees, *see* 42 U.S.C. § 18031(b)(1)(B). HHS also explained that an enrollment "with a SHOP-registered agent or broker, or with a [qualified health plan] issuer participating in a SHOP[,] . . . will be considered to be an enrollment through a SHOP." 83 Fed. Reg. at 16997. Nothing in § 18031(b)(1)(B) or (d)(2)(A) requires that SHOPs take on the entire administrative burden associated with the purchase of health

insurance. HHS's interpretation of these provisions as allowing the reduction of SHOPs' administrative burdens is permissible and reasonable, given the low enrollments in SHOPs prior to the 2019 Rule. *See* 83 Fed. Reg. at 16996. Plaintiffs fail to establish that the 2019 Rule's removal of regulatory burdens on SHOPs is contrary to law.

### 3. HHS's Amendment of SHOP Program Standards Is Not Arbitrary or Capricious

Plaintiffs also fail to support their claims that these changes are arbitrary or capricious. Plaintiffs argue that HHS overlooked "important aspect[s] of the problem." Pl. Mem. at 48 (citing *State Farm*, 463 U.S. at 43). However, HHS considered and addressed the comments that Plaintiffs cite. 83 Fed. Reg. at 16998-99, 17000-01, 17002. That is all that the APA requires.

Plaintiffs' reliance on *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032 (D.C. Cir. 2012), is misplaced. Pl. Mem. at 49. There, the agency conducted an economic analysis of whether "the benefits of the amended rule outweigh its costs," even though no such analysis was required by the governing statute. *See Nat'l Ass'n of Home Builders*, 682 F.3d at 1039. The court held that, once the agency decided to rely on such an analysis, a flaw in the analysis could undermine the agency's decision. *See id.* at 1041.

Here, HHS used the phrase "cost effective" when concluding that, in light of decreases in issuer participation and lower enrollments in SHOP plans in 2018, "it is not cost effective for the Federal government to continue to maintain certain [Federal] SHOP functionalities, collect significantly reduced user fees on a monthly basis, maintain the technologies required to maintain a[] [Federal] SHOP website and payment platform, generate enrollment and payment transaction files, and perform enrollment reconciliation." 83 Fed. Reg. at 16996. However, HHS did not claim to have conducted an *economic* analysis of costs and benefits, like the one at issue in *Nat'l Ass'n of Home Builders*. Rather, HHS made an observation reflecting its *policy* assessment that, in light of the low use of SHOPs, the costs of these extra functionalities were not justified. HHS therefore concluded that it wished to reduce regulatory burdens on SHOPs that wished to operate in a "leaner fashion." 83 Fed. Reg. at 16996; *see also* AR 1606, 3628 (Doc. ID CMS-2017-0078-2577) (Vermont Exchange supporting direct enrollment for SHOPs based on its own use of such a model for its small group market); 1616

(Alaska Division of Insurance supporting direct enrollment as providing greater access to tax credits for small employers, thus increasing incentives for small business to provide health insurance); 3587 (Doc. ID 2017-0078-0138) (West Virginia Insurance Commissioner, seeking disbandment of SHOP market, and replacement with direct enrollment, due to SHOP administrative costs); 3629 (Doc. ID CMS-2017-0078-2686, at 8-9) (BCBSA supporting direct enrollment).

HHS also pointed out that a few State Exchanges had already been operating, on a transitional basis, SHOPs that made qualified health plans available in a manner similar to the leaner fashion adopted in the 2019 Rule, and that this experience supported its decision to adopt a leaner approach in an effort to reduce programmatic expenses, which was critical for State Exchanges "to maintain financial sustainability" as required under 42 U.S.C. § 18031(d)(5)(A). *See* 83 Fed. Reg. at 16996–97; *see also, e.g.*, AR 1242 (BCBSA) (citing transition as precedent for direct enrollment without the need for a SHOP enrollment website or certified SHOP qualified health plans. HHS's removal of costly and underutilized functionality requirements was a reasoned response to decreased utilization of SHOPs. Plaintiffs fail to establish that HHS's decision on this point was arbitrary or capricious. The Court therefore should grant judgment on this issue in Defendants' favor.

### G. The 2019 Rule's modification of income verification requirements for advance payments of premium tax credits is a reasonable program integrity measure. [Am. Compl. ¶ 282(g)]

Plaintiffs' seventh APA claim is similarly flawed. HHS's revision of income verification requirements relating to advance payments of premium tax credits is a reasonable program integrity measure and is not arbitrary or capricious.

#### 1. Relevant Background

As discussed above, the ACA and its implementing regulations provide that Exchanges may make advance payments of premium tax credit amounts to plans on behalf of eligible enrollees. Taxpayers enrolled in qualified health plans through an Exchange may be eligible for such advance payments if their expected household income for the year falls between 100 and 400 percent of Federal Poverty Level ("FPL"). (Those with income below 100 percent of FPL generally are not eligible for

advance payments because the ACA contemplated that they would instead be eligible for Medicaid. *See, e.g.*, 42 U.S.C. §§ 1396a(a)(10)(A)(i)(III), (IV), (VI), (VII) and (VIII), 1396u-1(b), (d); 26 U.S.C. § 36B(c)(1)(B)).

Before the 2019 Rule, HHS had directed Exchanges that, when applicants' attestations of income are higher than indicated by electronic data sources from the Social Security Administration or IRS, the Exchanges should rely on applicants' attestations of their income, without verification. *See* 83 Fed. Reg. at 16985. In the 2019 Rule, HHS explained that this approach makes sense, from a program integrity perspective, as long as the electronic data sources indicate an annual income over 100 percent of FPL. That is so because any increase in income above that level could only result in lower advance payments, so there was no incentive to falsify such attestations. *Id.* However, this is not true where electronic data sources indicate an income under 100 percent of FPL, while the applicant attests to an income between 100 and 400 percent of FPL. In that situation, the applicant would *not* be eligible for advance payments based on the electronic data sources (because he may instead be eligible for Medicaid) but *would* be eligible based on the attestation. *See id.* From a program integrity perspective, reliance on attestations in that circumstance created a loophole through which enrollees might receive advance payments of premium tax credits when they are not, in fact, eligible for such payments. *See id.*

In the 2019 Rule, HHS revised 45 C.F.R. § 155.320(c)(3)(iii) by directing Exchanges to request verifying documentation from applicants asserting eligibility for advance payments of premium tax credits if information from the IRS or Social Security Administration indicates that their income is below 100 percent of FPL, but the applicants attest to projected annual income at least 10 percent greater than what the electronic sources indicate, and is between 100 and 400 percent of FPL. 83 Fed. Reg. at 16985; *see also* 82 Fed. Reg. at 51086. In response to comments, HHS revised its proposal to exclude lawfully present non-citizen applicants from this requirement because they would be ineligible for Medicaid by reason of immigration status. *See* 83 Fed. Reg. at 16985. However, with respect to other applicants, HHS explained that it regarded this change as a "critical program integrity measure" that would also help limit tax filers' potential liability to repay excesses when reconciling the advance

payments on their tax returns. *See id.* HHS also pointed out that the income verification could help identify individuals who were inaccurately determined not to be eligible for Medicaid. *See id.* at 16986.

**2. HHS's Amended Income Verification Requirements Relating to Advance Payments of Premium Tax Credits Are Not Arbitrary or Capricious**

Plaintiffs claim that this revision is arbitrary and capricious because HHS "failed to adequately 'consider an important aspect of the problem' and to 'respond to relevant, significant issues.'" Pl. Mem. at 49. However, as Plaintiffs concede, the 2019 Rule expressly acknowledges the very issue that they raise, regarding potential difficulties that lower-income households may have when attempting to verify their income. *Id.* (recognizing that "Defendants acknowledged" this issue). HHS responded to this issue by pointing to the significant income discrepancy threshold (at least 10 percent) before verification is required. 83 Fed. Reg. at 16986. HHS also outlined the available resources to assist such individuals. *Id.* (citing the "modified" calculator used by HHS "to handle instances where income fluctuates, or is seasonal in nature"; the "consumer guide to households to help them provide correct documentation"; and "a worksheet for households to help verify their attested income"). Indeed, not only have these resources significantly improved the income verification process since the launch of the advance payments program, HHS further emphasized its intent to "explor[e] strategies to promote more timely and accurate reporting of changes in circumstances by consumers." *Id.*.

Plaintiffs also argue that the revision is arbitrary and capricious because HHS acknowledged that it lacked "firm data" identifying how many applicants might be inflating their income in order to get advance payments. Pl. Mem. at 50-51. However, courts have rejected the notion that an agency needs to defend every regulatory change with technical data, particularly where such data cannot be "readily obtained." *Huntco Pawn Holdings, LLC v. U.S. Dep't of Defense*, 240 F. Supp. 3d 206, 225 (D.D.C. 2016). Indeed, in *Huntco*, the court pointed out that those involved in submitting false information "are not likely to report" it, making it difficult to collect data regarding such falsification. *See id.*; *see also BNSF Ry. Co. v. U.S. Dep't of Transp.*, 566 F.3d 200, 203 (D.C. Cir. 2009) (concluding it was "illogical" to require statistical evidence of cheating on drug tests). It is "illogical" that HHS would have data showing how many enrollees have submitted inaccurate income information and thus have obtained

advance payments for which they were ineligible. Such information would only be revealed to the IRS if these individuals ultimately file federal income tax returns and reconcile the discrepancy based on their actual income. However, HHS can reasonably identify a risk based simply on its recognition of the loophole that the previous regime had created. *Stillwell v. Off. of Thrift Supervision*, 569 F.3d 514, 519 (D.C. Cir. 2009) ("agencies can, of course, adopt prophylactic rules to prevent potential problems before they arise").

The decision to require income verification to resolve discrepancies in reported income that exceed 10% is a far cry from the highly technical scientific question at issue in *Tripoli Rocketry Ass'n, Inc. v. ATF*, 437 F.3d 75 (D.C. Cir. 2006), cited by Plaintiffs. There, the court denied deference to ATF on the question of whether a particular fuel used by hobbyists for model rockets qualified as "explosive" under a specific regulatory definition. *Id.* at 77, 83. Although the court recognized that it would normally defer to an agency's "technical expertise and experience" when faced with a "purely factual question" requiring evaluation of "technical evidence, or how to adjudicate between rival scientific theories," it declined to do so where ATF relied solely on the general notion that all "rocket propellants" would meet the regulatory definition, with no specific evidence that the fuel at issue did so. *Id.* at 82-83. Here, in contrast, no such scientific question is at issue. HHS instead made a policy choice that program integrity concerns warranted an income verification requirement, and it reasonably set a 10% threshold for that requirement and described other measures it had taken to make income verification easier. 83 Fed. Reg. at 16986.

Plaintiffs also argue that consumers eligible for Medicaid would have no incentive to try to inflate their income in order to become eligible for advance payments of premium tax credits. Pl. Mem. at 51. However, that suggestion is plainly incorrect because States may opt not to provide Medicaid coverage to individuals within this income range. While Congress originally contemplated that States would be required to provide such coverage, the Supreme Court determined that a mandatory Medicaid expansion was invalid. *NFIB*, 567 U.S. at 585. Congress has not amended the ACA since that decision to expand the availability of premium tax credits where a State has not expanded its Medicaid program. Plaintiffs therefore fail to identify an important aspect of the problem

that was not considered during the rulemaking. HHS acted reasonably by seeking to ensure program integrity under the terms of the program that Congress established. Plaintiffs thus fail to establish that this revision was arbitrary or capricious, and Defendants should be granted judgment on this claim.

### H. The 2019 Rule's amendments to federal rate review requirements are permissible under the ACA. [Am. Compl. ¶ 282(h)]

Plaintiffs' eighth APA claim also fails. This challenge focuses on two changes to regulatory rate review provisions, which implement the Public Health Service ("PHS") Act federal rate review requirements. In particular, Plaintiffs challenge HHS's decisions in the 2019 Rule that (1) due to its similarity to large group coverage, student health insurance coverage should be excluded from the federal rate review process by which HHS reviews issuers' rate filing justifications for proposed rate increases for qualified health plans before the plans are issued; and (2) the default threshold for a federal reasonableness review of an issuer's proposed rate increase should be raised from 10% to 15% because the burdens of subjecting lower rate increases to reasonableness review had not proven justified.

#### 1. Relevant Background

The relevant PHS Act provision, 42 U.S.C. § 300gg-94, directs the Secretary, in conjunction with States, to "monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange." 42 U.S.C. § 300gg-94(b)(2)(A). The Secretary is also delegated authority to promulgate "such regulations as may be necessary or appropriate to carry out" rate review. *Id.* § 300gg-92. Pursuant to this authority, HHS promulgated regulations in 2011, setting forth a process by which issuers submit rate filing justifications for proposed rate increases, and HHS or State regulators review the proposed rate increases before a plan is issued. HHS indicated that this rate review process would apply to "all health insurance issuers offering coverage in the small group or individual markets in a State." 2011 Rate Review Rule, 76 Fed. Reg. at 29966. HHS explained in that rulemaking that grandfathered health plan coverage, as defined in 45 C.F.R. § 147.140, as well as insurance coverage meeting the "excepted benefits" definition in 42 U.S.C. § 300gg-91(c), are statutorily excluded from the federal rate review requirements. 76 Fed. Reg. at 29966. HHS also

explained its conclusion that the large group market would not be subject to the same review of proposed rate increases because large employers are "sophisticated purchasers," and rates in that market "generally are based on each large employer's own experience." *Id.* HHS did not specifically address student health insurance coverage in the 2011 Rate Review Rule. *See id.* However, in a separate rulemaking, HHS stated that student health insurance coverage was subject to the federal rate review requirements as implemented in 45 C.F.R. Part 154. CMS, Student Health Insurance Coverage, Proposed rule, 76 Fed. Reg. 7767, 7771 (Feb. 11, 2011); *see also* CMS, Student Health Insurance Coverage, Final rule, 77 Fed. Reg. 16453, 16458 (Mar. 21, 2012).

In the 2019 Rule, HHS concluded that student health insurance coverage should not be subject to the federal rate review process for review of issuers' proposed rate increases before their plans are issued. 83 Fed. Reg. at 16972. In the Proposed Rule, HHS explained that student health insurance coverage "is considered by HHS to be a type of individual market coverage and is generally subject to the PHS Act individual market requirements including rate review." 82 Fed. Reg. at 51078 (citing Student Health Insurance Coverage, Final rule, 77 Fed. Reg. 16453). However, student health insurance coverage was already exempt from certain PHS Act requirements that typically apply to individual market coverage, including single risk pool requirements, as well as guaranteed availability and guaranteed renewability requirements that would otherwise require such plans to accept enrollment or renew coverage of individuals who are not students or dependents of students. *Id.*; *see* 45 C.F.R. § 147.145(b)(1); *see also* 2015 Payment Notice, 79 Fed. Reg. at 13749, 13752; 2017 Payment Notice, 81 Fed. Reg. at 12214-15; CMS, Health Insurance Market Rules; Rate Review, Final rule, 78 Fed. Reg. 13406-01, 13424 (Feb. 27, 2013) (exempting student health insurance coverage from the ACA's single risk pool requirement due to the reality that student health insurance policies are "generally rated on a group basis," based on the college's or university's students enrolled in the plan). Such coverage is also exempted from the ACA requirement that coverage be offered on a calendar year basis; student health insurance coverage generally is instead offered based on the academic calendar year. 45 C.F.R. § 147.145(b)(1)(ii).

Moreover, student health insurance coverage is not included in the ACA's individual market

single risk pool in a State because issuers of student health insurance coverage typically contract with colleges and universities to issue a blanket health insurance policy based on total expected claims from students who may buy coverage. *See id.* § 147.145(b)(3). Thus, as HHS specifically explained, in regard to the way rates are determined, student health insurance coverage is more like large group coverage because institutions of higher education are "well informed, with significant purchasing power." 82 Fed. Reg. at 51078–79; *see also* 83 Fed. Reg. at 16972 ("States have allowed rating practices for student health insurance coverage to be more in line with large group pricing, in which experience rating and other factors can be used to determine rates.").

HHS thus determined that, in light of these characteristics that it shares with large group coverage, student health insurance coverage should be exempt from the federal rate review process for proposed rate increases prior to a plan's issuance. *Id.* As the 2019 Rule explained, even though student health insurance issuers will not be subject to automatic reviews of proposed rate increases, HHS will continue to generally review such rates "[i]n States that do not have an Effective Rate Review Program," in order to "monitor the compliance of student health insurance coverage with applicable market rating reforms based on complaints and as part of targeted market conduct examinations." *Id.* HHS also acknowledged that States retain the flexibility to review rate increases prior to issuance for any type of product, including student health insurance coverage. *Id.* In making this change, HHS sought to "reduce the regulatory burden on States and issuers of student health insurance plans," consistent with its "general approach of providing tailored flexibility with respect to the PHS Act individual market reforms for student health insurance coverage." 82 Fed. Reg. at 51079. Most commenters supported this change. *See* 83 Fed. Reg. at 16972; *see also, e.g.*, AR 806 (Aetna) (strongly supporting exemption due to "unique nature of student health insurance"); 1687 (UPMC) (recognizing student health insurance "is experience rated and sponsored by an entity (school) that has both effective market leverage and sophistication"); *see also* 854 (Anthem); 1229 (BCBSA); 1508 (Viva Health); 1872 (EXL LLC); 2023 (N.Y.S. Dep't of Financial Servs.); 2284 (U.S. Chamber of Commerce); 2540 (Healthcare Leadership Council); 2675 (AHIP); 3391 (UnitedHealthcare); 3557 (American College Health Ass'n).

The 2019 Rule also increased the threshold for reasonableness review of premium rate increases under the federal rate review process. Previously, HHS regulations specified that a rate increase for single risk pool coverage was subject to a reasonableness review if the premium rate increase for any plan within the issuer's filing for a particular market and State met or exceeded 10 percent (the default threshold), or a State-specific threshold approved by the Secretary. 83 Fed. Reg. at 16972. The 2019 Rule revised the default threshold to 15 percent. *See id.*; *see also* 45 C.F.R. § 154.200(a)(1). HHS explained that this change was based on HHS's "recognition of [the] significant rate increases in the past number of years." 83 Fed. Reg. at 16972. In response to comments expressing concern that the increase "may normalize excessive increases," or suggesting that a lower threshold would be appropriate, HHS explained that it had proposed the 15 percent threshold after reviewing all rating filings "since the inception of the review threshold" to identify those that were subject to review and ultimately determined to be "unreasonable." *Id.* at 16973. The result of HHS's analysis was that "only one filing" that fell "between the 10 to 15 percent range" over a seven year period was deemed "unreasonable" after further review. *Id.* Moreover, HHS reasoned that many States already "apply a stricter (lower threshold) standard" and thus, the 15 percent threshold would merely set "a [federal] minimum standard." *Id.*; *see also* 2011 Rate Review Rule, 76 Fed. Reg. at 29967. HHS also eliminated the requirement that States seek the Secretary's approval in order to set a lower threshold within their jurisdiction. 83 Fed. Reg. at 16972. HHS received significant support for these changes. *See, e.g.*, AR 807 (Aetna); 854 (Anthem); 1230 (BCBSA); 1508 (Viva Health); 2284 (U.S. Chamber of Commerce); 2540 (Healthcare Leadership Council); 2675-76 (AHIP); 3391 (UnitedHealthcare).

**2. HHS's Exemption of Student Health Insurance Coverage From Pre-Issuance Rate Review Is Not Contrary To Law.**

Plaintiffs argue that HHS's decision to exempt student health plans from the federal rate review process, pursuant to 42 U.S.C. § 300gg-94(b)(2)(A), for proposed rate increases prior to issuance, is contrary to the definition of "health insurance coverage" in 42 U.S.C. § 300gg-91(b)(1), which generally includes "benefits consisting of medical care . . . under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization

contract offered by a health insurance issuer." They also suggest that HHS has improperly "implied" an exception where other categories of insurance are expressly excluded from PHS Act requirements. Pl. Mem. at 53 (citing definition of "excepted benefits" in § 300gg-91(c) and description of grandfathered health plans in 42 U.S.C. § 18011). They thus invoke the canon of statutory construction that "[w]here Congress explicitly enumerates certain exceptions . . . , additional exceptions are not to be implied." *Id.* (citing *TRW Inc. v. Andrews*, 534 U.S. 19, 28 (2001)).

However, that canon is inapposite here because HHS has not interpreted the *definition* of "health insurance coverage" in 42 U.S.C. § 300gg-91(b)(1) to exclude student health insurance. Instead, it has exercised its discretion to determine that student health insurance should not be subject to the process for revising proposed rate increases prior to plan issuance. Plaintiffs focus on the wrong statutory provision and ignore the controlling one. Despite the broad definition of "health insurance coverage" in § 300gg-91(b)(1), the PHS Act delegates significant authority to the Secretary to promulgate any regulations deemed "necessary or appropriate" to carry out its provisions. 42 U.S.C. § 300gg-92. Moreover, nothing in § 300gg-94 expressly requires the Secretary to apply uniform rate review requirements to all health insurance coverage. Section 300gg-94(a)(1), for example, directs the Secretary to "establish a process for the annual review . . . of unreasonable increases in premiums for health insurance coverage," while § 300gg-94(b)(2)(A) directs the Secretary to "monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange." The statute thus vests considerable discretion in the Secretary to determine *how* to review and monitor premium increases.

Plaintiffs' challenge thus fails at *Chevron* step two because the Secretary's interpretation does not violate plain statutory language and is permissible. Contrary to Plaintiffs' suggestion, the Secretary did not need to imply an exception to a uniform statutory requirement because § 300gg-94 establishes no uniform requirement. Indeed, from the beginning, HHS determined that it was not necessary to subject large group coverage to the same rate review requirements as individual and small group coverage. *See* 76 Fed. Reg. at 29966. The determination in the 2019 Rule to exclude student health insurance coverage from the federal rate review process prior to issuance was equally consistent with

the statute and was based on similar reasoning. 83 Fed. Reg. at 16972.

Significantly, Plaintiffs do not argue that HHS's original implementation of rate review, excluding large group coverage, was contrary to law. Rather, they argue that HHS's exclusion of student health insurance coverage is inconsistent with HHS's own past treatment of such coverage as individual market coverage. *See* Pl. Mem. at 51-52. But HHS explained that despite its general classification as individual market coverage, student health insurance coverage shares significant characteristics with large group coverage—the very characteristics that led HHS to exclude large group coverage from rate review requirements. *Compare* 76 Fed. Reg. at 29966 (excluding large group coverage because large employers are "sophisticated purchasers," and rates in that market "generally are based on each large employer's own experience"), *with* 82 Fed. Reg. at 51078–79 (recognizing institutions of higher education are similarly "well informed, with significant purchasing power"); *see also* AR 1687 (UPMC) (recognizing student health insurance "is experience rated and sponsored by an entity (school) that has both effective market leverage and sophistication"). These similarities reflect the fact that, unlike other forms of individual market coverage, the contract in the case of student health insurance coverage is between the issuer and the school; students then get insurance coverage through the school. The situation is thus structurally similar to that of large group coverage, where the contract is between the issuer and an employer. HHS reasonably concluded these similar characteristics warranted the exclusion of student health insurance coverage from the federal rate review process prior to issuance.[5]

[5] Plaintiffs cite an earlier rule in which CMS stated that a separate statutory provision, 42 U.S.C. § 18118(c), "'does not allow CMS to except student health insurance coverage from compliance with all Federal requirements.'" Pl. Mem. at 52-53 (quoting 77 Fed. Reg. at 16458). But contrary to Plaintiffs' characterization, CMS did not suggest that any statute required "the Federal rate review process" to be applied to student health insurance coverage. *See id.* Rather, CMS simply recognized that, under the regulations in effect at the time, student health insurance coverage was subject to rate review, among other federal individual market requirements. 77 Fed. Reg. at, 16458 (student health insurance issuers "must comply with the Federal rate review process in 45 CFR Part 154").

### 3. HHS's Rate Review Changes Are Not Arbitrary or Capricious.

Plaintiffs challenge both the student health insurance coverage exclusion and the increase in the default rate review threshold as arbitrary and capricious. In regard to student health insurance coverage, Plaintiffs argue that HHS failed to provide "adequate reasons" for its decision. Pl. Mem. at 53. However, as explained above, HHS explained that its decision was based on a recognition that, for purposes of setting rates, student health insurance coverage resembled large group coverage, which was already excluded from the federal rate review process for proposed rate increases for plans before their issuance. 83 Fed. Reg. at 16972. Just as with large employers, institutions of higher education are sophisticated entities with considerable negotiating power, and HHS reasonably concluded that the coverage that they negotiate for their students should similarly be excluded from the federal rate review process prior to issuance of the plans. *See id.*; 82 Fed. Reg. at 51078–79. Indeed, HHS had already exempted student health insurance coverage from the ACA's single risk pool requirement based on its recognition that student health insurance policies are "generally rated on a group basis." 78 Fed. Reg. at 13424. The decision in the 2019 Rule to exempt student health insurance coverage from the federal rate review process thus simply parallels its earlier decision, upon which it expressly relied. 83 Fed. Reg. at 16972 & n.37.

Although Plaintiffs cite four negative comments as providing "evidence that eliminating systematic review of student health plans would allow for unjustifiable rate increases," Pl. Mem. at 53, none of the cited comments identifies any such evidence. Rather, to the extent they address the issue, they merely speculate that there may be a negative impact. *See* AR 1622 (stating only that large insurers would not face burden from rate review of student plans); 1697 (Nat'l Psoriasis Found.) (citing no basis for concern other than the fact that psoriasis "often develops between the ages of 15 and 35"); 1782 (Health Care for All New York) (citing no clear basis for opposition); 1945 (Young Invincibles) (speculating that, "[w]ithout rate review, students *could* see their premiums skyrocket and insurers *could* be incentivized to generate higher profits" (emphasis added)) HHS therefore was not required to address these non-significant comments. *See Perez*, 575 U.S. at 96; *see also HBO, Inc.*, 567 F.2d at 35 n.58 ("comments which themselves are purely speculative and do not disclose the factual or policy

basis on which they rest require no response"). In fact, HHS noted that most comments supported this change. 83 Fed. Reg. at 16972; *see, e.g.*, AR 806 (Aetna); 854 (Anthem); 1229 (BCBSA); 1508 (Viva Health); 1687 (UPMC); 1872 (EXL LLC); 2023 (N.Y.S. Dep't of Financial Servs.); 2284 (U.S. Chamber of Commerce); 2540 (Healthcare Leadership Council); 2675 (AHIP); 3391 (UnitedHealthcare); 3557 (American College Health Ass'n). Finally, Plaintiffs ignore States' roles, expressly recognized in the PHS Act. *See* 42 U.S.C. § 300gg-94(a)(1) (any process established for rate review is to be "in conjunction with States"). HHS emphasized in the 2019 Rule that "States maintain the flexibility to review rate increases of any size and any other aspects of student health insurance coverage." 83 Fed. Reg. at 16972. States are thus free to continue to review student health rates, and many do.[6]

In regard to the increase in the rate review threshold, Plaintiffs fail to identify any deficiency in HHS's reasoning. Plaintiffs assert that HHS's decision is not justified by the increasing frequency of rate increases. Pl. Mem. at 54. But HHS acknowledged and addressed those comments, among other things explaining that it had analyzed "all rates subject to review that were determined to be 'unreasonable' since the inception of the review threshold" and found that only one of these had an increase that fell between 10 (the previous threshold) and 15 (the new threshold) percent. 83 Fed. Reg. at 16973. HHS concluded that it therefore did not believe the change "will normalize excessive increases." *Id.*

Plaintiffs also suggest that Defendants "overlooked the reasons behind rising premiums" that were suggested in several comments. Pl. Mem. at 55. They also cite a comment that, according to Plaintiffs, cited "Defendants' own data" as "suggest[ing] that premium growth would be slower in the

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[6] *See, e.g.*, Ill. Dep't of Insurance, Student Blanket Rate Review Checklist, *available at* https://insurance.illinois.gov/LAH_HMO_IS3_Checklists/LAH-Checklist.html; Md. Insurance Admin., Bulletin 19-23 (Dec. 16, 2019) (requiring rate review if issuer plans to use different forms or to revise its rates), *available at* https://insurance.maryland.gov/Insurer/Documents/bulletins/19-23-Student-Health-Plan-Form.pdf; Ohio Dep't of Insurance, ACA Compliant Student Blanket Health Plans, *available at* https://insurance.ohio.gov/wps/portal/gov/odi/about-us/divisions/product-regulation-and-actuarial-services/resources/aca-compliant-student-blanket-health-plans; Penn. Insurance Dep't, 2020 – 2021 ACA-Compliant Health Insurance Filing Guidance – Student Health Insurance), *available at* https://www.insurance.pa.gov/Companies/ProductAndRateRequire/Pages/default.aspx.

future." *Id.*[7] However, the possibility of a change in circumstances in the future, such that premiums would not continue to rise, does not make HHS's response to current circumstances unreasonable. After all, if warranted in the future, HHS may adjust the threshold again at that time.

For these reasons, HHS rationally decided to increase the threshold for review under the federal rate review process to 15 percent. *See Am. Whitewater,* 770 F.3d at 1116 ("so long as the agency 'provide[s] an explanation of its decision that includes a rational connection between the facts found and the choice made,' its decision should be sustained") (citation omitted). Defendants thus should be granted judgment on this claim.

## I. The 2019 Rule's option to allow issuers to report quality improvement activity as a single fixed percentage is permissible under the ACA. [Am. Compl. ¶ 282(i)]

In their final APA challenge, Plaintiffs argue that HHS impermissibly adopted an optional fixed 0.8 percent of earned premiums figure for the amount that issuers could report as having been spent on activities that improve health care quality ("QIA expenditures").

### 1. Relevant Background

The QIA expenditure amount is included in issuers' annual medical loss ratio ("MLR") reports, submitted to the Secretary pursuant to 42 U.S.C.§ 300gg-18(a), which essentially identify how much an issuer paid out in claims and QIA expenditures versus how much it collected in earned premiums. The ACA specifies the items that an issuer must include in its MLR report, including, as relevant here, expenses "for activities that improve health care quality." 42 U.S.C. § 300gg-18(a)(2). The ACA does

[7] The comment that Plaintiffs cite, by Families USA, does not purport to rely on the results of federal rate review, nor is it clear whether the decreases in rates occurred during a reasonableness review or a general compliance review, which occurs even for rates below the threshhold. *See* AR 2734 & n.1. Indeed, the data cited in the comment are from states where HHS is not involved in rate review. *See* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/rate_review_fact_sheet (identifying only Oklahoma, Texas, and Wyoming as States that lack their own adequate rate review process). The 2019 Rule's rate review changes to the federal minimum standards left intact States' ability to review student health insurance rate increases of any size, as well as any other aspects of student health insurance coverage.

not further delineate how QIA expenditures should be calculated but directs the Secretary to "promulgate regulations for enforcing the provisions of" § 300gg-18. *Id.* § 300gg-18(b)(3). The resulting regulations are set forth at 45 C.F.R. §§ 158.101 to 158.615. In addition to providing information about how issuers use funds obtained as premiums, an issuer's MLR also determines whether an issuer must provide an annual rebate to enrollees. 42 U.S.C. § 300gg-18(b)(1)(A). Generally, rebates are required if the issuer's MLR is less than "85 percent in the large group market and 80 percent in the small group or individual market." CCIIO, Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the ACA, Interim final rule, 75 Fed. Reg. 74864, 74865 (Dec. 1, 2010); *see also* 42 U.S.C. § 300gg-18(b)(1)(A)(i), (ii). The rebate provision is designed to "encourage use of premium income to provide benefits to insureds and discourage its use to offset administrative costs, thus serving the primary goal of expanding affordable care." *Morris v. Cal. Physicians' Serv.,* 918 F.3d 1011, 1014 (9th Cir. 2019) (citing 45 C.F.R. § 158.140(b)(3)(iii)).

HHS regulations identify categories of eligible QIA expenditures for purposes of reporting and calculating MLR, *see* 45 C.F.R. § 158.150(b), and also exclude certain expenditures and activities from inclusion in the total QIA expenditure amount, *see id.* § 158.150(c). Prior to the 2019 Rule, issuers were required to report QIA expenditures in alignment with the separate categories identified in § 158.150(b)(2)(i)-(v) and "to use and disclose specific allocation methods to report expenses, including QIA expenditures." 83 Fed. Reg. at 17032 (citing 45 C.F.R. § 158.170). In the course of conducting MLR audits in the years since 2011, when MLR reports were first required, "HHS observed that [those detailed calculation methods] require[d] a substantial effort by issuers to accurately identify, track[,] and report QIA expenses." *Id.* HHS also observed that "between 2011 and 2015, issuers that did report QIA expenses . . . reported spending, on average, a consistent percentage of premium on total QIA: approximately 0.7 percent in 2011, and 0.8 percent in 2012 through 2015." *Id.* In order to address the "significant burden associated with identifying, tracking[,] and reporting

[QIA] expenditures," HHS added subsection (b)(8) to 45 C.F.R. § 158.221, which allows issuers the "option to report on their MLR reporting form a single QIA amount equal to 0.8 percent of earned premium in the relevant State and market, in lieu of tracking and reporting the issuer's actual expenditures for QIA." 83 Fed. Reg. at 17032. Issuers that expend more than 0.8 percent of earned premium on QIA retain the option "to report the total actual, higher amount spent and, if choosing this option, . . . [must] report QIA in the five categories described in" the MLR regulations governing the allocation of expenses. *Id.*

**2. HHS's Provision of a Standardized QIA Expenditure Reporting Option Is Not Contrary to Law.**

Plaintiffs argue that HHS's decision to permit issuers the option of reporting a single QIA expenditure amount is contrary to § 300gg-18(a)(2) because, they contend, that provision requires insurers to report how much they "expend[]" on QIA, but the 0.8 percent figure is "untethered to their actual investment." Pl. Mem. at 55. However, under *Chevron* step one, the statute does not require issuers to detail each QIA expenditure that contributes to the calculation of the MLR. Instead, it directs insurers to report "the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that such coverage expends . . . for activities that improve health care quality." 42 U.S.C. § 300gg-18(a)(2). In addition, the statute authorizes the Secretary to promulgate regulations to enforce the MLR requirements. *Id.* § 300gg-18(b)(3). HHS's regulations, promulgated pursuant to this authority, had previously required an itemization, but after several years' implementation, HHS found that this requirement was overly burdensome given the generally low amount expended on QIA overall and the minimal fluctuation in QIA expenditures from year to year. 83 Fed. Reg. at 17032 (pointing to the "relatively low and consistent reported expenditures on QIA and the significant burden associated with identifying, tracking and reporting these expenditures").

Under *Chevron* step two, HHS's interpretation is permissible. The new provision comports

with the statutory requirement. For one thing, contrary to Plaintiffs' assertion, it is not "untethered" to actual expenditures at all, Pl. Mem. at 55, but instead reflects the reality that QIA expenditures are consistently, on average, 0.8 percent from one year to the next. 83 Fed. Reg. at 17032. Plaintiffs suggest that, in the absence of the itemization requirement, issuers will be able to "claim a credit whether they improve quality or not." Pl. Mem. at 56. But HHS modified its proposal in response to similar comments in the 2019 Rule that raised concerns about potential gaming. Specifically, HHS added requirements that issuers that elect the standardized 0.8 percent reporting option use that option across all of the States and markets where they operate; require their affiliates to use the same option; and apply the same reporting method for a minimum of three consecutive years. 83 Fed. Reg. at 17033. HHS explained that those additions would "ensure that the new QIA reporting option is appropriately utilized by issuers to simplify reporting, rather than to inflate the MLR based on the experience of a particular year." *Id.* HHS also explained that issuers still have an option to itemize QIA expenditures if they exceed 0.8 percent, and that issuers "also have financial incentives," beyond the MLR rebate, to make QIA expenditures because improving the health of their enrollees would reduce the issuer's overall costs. *Id.* Reducing the administrative burden associated with tracking QIA would also "free up funds that issuers can invest in QIA." *Id.* HHS also indicated that it would continue to monitor QIA reporting and review available data and "may modify the QIA reporting policy in the future if HHS determines it to be necessary." *Id.* The standardized QIA reporting option in the 2019 Rule therefore is not contrary to law.

**3. HHS's Provision of a Standardized QIA Expenditure Reporting Option Is Not Arbitrary or Capricious.**

Plaintiffs' alternative claim that the standardized QIA expenditure reporting option is arbitrary and capricious fails for similar reasons. As explained, HHS introduced this option based on its experience over several years of conducting audits of issuers' MLR reports, which led it to conclude that the existing requirements for detailed tracking and reporting of individual QIA expenditures were

costly and burdensome. HHS's decision to allow issuers to claim a standard QIA cost of 0.8 percent of earned premiums was reflective of what most health insurance issuers would claim under the itemized method. 83 Fed. Reg. at 17032-17033. Plaintiffs argue that HHS failed to provide evidence of the burdens associated with itemizing QIA expenditures. Pl. Mem. at 57. However, HHS noted that "[m]ost commenters who supported the proposal stated that the current process for identifying, tracking and reporting QIA expenses is burdensome, time consuming and costly." 83 Fed. Reg. at 17033. Plaintiffs offer nothing to suggest that HHS's assessment of these burdens was incorrect. Moreover, HHS did not simply rely on the burden of tracking itemized expenditures; its conclusion was that such burdens were not justified in relation to the very low and consistent average expenditures made on QIA from year to year. 83 Fed. Reg. at 17032. And HHS's decision was informed by its years of experience performing audits of issuers' MLR reports. *Id.*

Plaintiffs also argue that HHS failed to consider alternatives that would not involve using a flat percent, such as removing the need to split QIA expenditures into five categories. Pl. Mem. at 57. However, agencies need not "consider *all* policy alternatives in reaching decision." *State Farm*, 463 U.S. at 51 (emphasis added) (recognizing that a "rulemaking 'cannot be found wanting simply because the agency failed to include every alternative device and thought conceivable by the mind of man"). Here, the suggested alternative that Plaintiffs cite cannot be deemed "significant," so as to require a response. *See Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000). Such an alternative would not reduce the burdens involved in tracking QIA expenditures and would require revising the entire framework for reporting those expenditures, including for issuers reporting QIA expenditure amounts above 0.8 percent. Such an alternative is a far cry from that addressed in *State Farm*, where the airbag at issue was "a technological alternative within the ambit of the existing standard." *State Farm*, 463 U.S. at 51. HHS did not act unreasonably by not addressing this suggestion when HHS's proposal was intended to leave the overall framework intact, while reducing the burdens associated with the MLR

reporting requirements.

In addition, HHS also considered and responded to comments that raise the same concerns that Plaintiffs raise here, explaining that those concerns do not justify maintaining the prior rule. *See, e.g.,* 83 Fed. Reg. at 17033 ("While we acknowledge commenters' concerns that the standardized QIA reporting option may in some cases give issuers credit for activities that they do not perform, we note that issuers also have financial incentives to improve the health of their enrollees because healthier populations incur lower medical costs, and reducing the administrative burden associated with tracking QIA will free up funds that issuers can invest in QIA."). Moreover, far from dismissing such comments in a "conclusory manner" as Plaintiffs allege, Pl. Mem. at 58, HHS modified its original proposal in order to further reduce any risk that issuers would try to inappropriately claim costs they had not incurred. *See* 83 Fed. Reg. at 17033 (explaining that "the requirement that the new QIA reporting option be applied in a consistent manner across all States, relevant markets, and affiliates will additionally eliminate gaming incentives for companies to use the standardized 0.8 percent of premium QIA amount for some of their issuers, States, or markets and simultaneously maximize the allocation of the actual QIA costs to their other issuers, States, or markets"). In sum, HHS reasonably weighed the burdens and benefits of the previous requirement and determined that offering a fixed percentage option was warranted, particularly given the consistently low amounts of such expenditures from year to year. *See* 83 Fed. Reg. at 17032. HHS's decision was neither arbitrary nor capricious. Judgment on this claim therefore should be granted in favor of Defendants.

## CONCLUSION

For the reasons stated herein, the Court therefore should deny Plaintiffs' motion for summary judgment and grant Defendants' cross-motion.

Dated: September 28, 2020

Respectfully submitted,

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*/s/ Kathryn L. Wyer*
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*Attorneys for Defendants*

**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that on September 28, 2020, a true and accurate copy of the foregoing was electronically filed with the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record in this matter.

*/s/ Kathryn L. Wyer*
KATHRYN L. WYER

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MARYLAND**

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|---|---|
| CITY OF COLUMBUS, *et al.,*<br><br>*Plaintiffs*,<br><br>v.<br><br>DONALD J. TRUMP, *et al.,*<br><br>*Defendants*. | Civil Action No. 1:18-cv-02364-DKC |

**ORDER**

Upon consideration of the parties' cross-motions for summary judgment and the entire record herein, it is hereby

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

ORDERED that Defendants' Cross-Motion is GRANTED; it is further

ORDERED that judgment is hereby entered in favor of Defendants.

SO ORDERED.

ENTERED this _____ day of _____, 2020.

_____
DEBORAH K. CHASANOW
United States District Judge