IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

vs.

XAVIER BECERRA, et al.

Defendants.

Civil Action No. 8:21-cv-198-PWG

Memorandum In Support of Plaintiff Pharmaceutical Research and Manufacturers of America's Cross-Motion For Summary Judgment, and In Opposition to Defendants' Motion to Dismiss or For Summary Judgment

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provisions

Statutes

Regulations

Other Authorities

INTRODUCTION

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") brought this suit challenging the Administrative Dispute Resolution Rule ("ADR Rule") issued by the Health Resources and Services Administration ("HRSA"), a component of the Department of Health and Human Services ("HHS"). As PhRMA explains in detail below, the ADR Rule is unconstitutional, inconsistent with the governing 340B statute, and arbitrary and capricious.

In its efforts to defeat this challenge, defendants resort to baseless and overheated rhetoric, claiming that this suit "culminates a brazen strategy" to "upend" the 340B Program and shield PhRMA's members from agency enforcement efforts. Mem. in Supp. of Defendants' Mot. to Dismiss or, in the Alternative, Mot. for Summ. J., ECF No. 26-1 ("Br."), at 1-2.[1] In reality, PhRMA supported the creation of a robust ADR process and this suit is the "culminat[ion]" of its decade-long advocacy before HRSA concerning that process. The 340B Program is designed to serve an important purpose, requiring manufacturers to offer prescription medications at a steep discount to particular health care providers (known as "covered entities") that serve underinsured and otherwise vulnerable patient groups. But the program also includes important statutory safeguards to prevent diversion of discounted drugs or multiple discounts on them, and Congress gave manufacturers the right to audit covered entities to ensure compliance with these

[1] In another suit involving the Rule, a court recently chastised defendants for employing similar rhetoric. *See AstraZeneca Pharms. LP v. Becerra*, 2021 WL 2458063, at *4 n.6 (D. Del. June 16, 2021).

prohibitions. In comments submitted in 2010 and 2016, PhRMA and others explained that HRSA's audit guidelines created significant barriers to manufacturer audits, which in turn would improperly prevent manufacturers from bringing claims under the ADR process. Most recently, in November 2020, PhRMA petitioned HRSA to refresh the record and consider new evidence underscoring the need for meaningful manufacturer access to the ADR process, as problems of diversion and duplicate discounts in the 340B Program have greatly increased in recent years.

HRSA, however, chose to ignore PhRMA's comments and its petition. Instead, after years of inaction, the agency rushed to finalize its proposed rule in order to defeat lawsuits that had been filed in late 2020 challenging its failure to establish an ADR process. Defendants' attempt to impugn PhRMA's motivations in bringing this challenge under the Administrative Procedure Act ("APA") cannot disguise the fatal defects in HRSA's hastily finalized Rule.

First, the ADR Rule violates the Appointments Clause of Article II of the Constitution. *See United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021). Although political appointees select and may influence the members of the ADR Board, Board members make final precedential determinations on behalf of the Executive Branch with no review by a properly-appointed principal officer. The Supreme Court recently confirmed that such a scheme impermissibly "blur[s] the lines of accountability demanded by the Appointments Clause." *Id.* at 1982.

Second, the Rule incorporates HRSA's burdensome manufacturer audit guidelines, thereby unduly impeding the ability of manufacturers to file ADR claims. The

guidelines' requirements that manufacturers must demonstrate "reasonable cause" to commence an audit, and must use third-party auditors to conduct one, clearly exceed the agency's limited authority to prescribe "procedures . . . relating to the number, duration, and scope" of audits. 42 U.S.C. § 256b(a)(5)(C). Indeed, even if this grant of statutory authority is considered ambiguous, HRSA's interpretation is unreasonable.

Third, the Rule is arbitrary and capricious. HRSA failed to address numerous comments urging that its one-sided and burdensome audit guidelines be revised because they effectively—and impermissibly—close off the ADR process to manufacturers, rendering any recourse for manufacturers illusory. Defendants' contention that these unfair burdens are a separate and irrelevant concern that HRSA was free to ignore in issuing the ADR Rule is plainly wrong. Indeed, HRSA's own request that parties comment on this very issue belies that argument. It was also arbitrary and capricious for HRSA to fail to consider PhRMA's petition to re-open the record so that HRSA could consider evidence that confirmed the need for changes to the Rule—particularly, the explosive growth in covered entities' use of so-called contract pharmacies, and the corresponding increase in diversion and duplicate discounts.

As PhRMA explains in greater detail below, defendants' motion to dismiss this suit should be denied and PhRMA should be granted summary judgment.

BACKGROUND

A. The 340B Program

In 1992, Congress established the 340B Program to address unintended negative consequences resulting from the enactment of the Medicaid Drug Rebate Program two

years earlier, and to improve access to certain outpatient drugs for certain health care providers serving poor, uninsured, underinsured, and otherwise vulnerable patient groups. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (codified at 42 U.S.C. § 256b). Although highly complex, the creation of the Medicaid Drug Rebate Program had the effect of penalizing manufacturers who were voluntarily providing discounts to safety-net providers, by increasing the rebate amount they were required to pay Medicaid. Congress eliminated that penalty in conjunction with adopting the 340B Program. *See generally* H.R. Rep. No. 102-384, pt. 2, at 10-13 (1992). Pharmaceutical manufacturers participate in this program in order to have their drugs covered under Medicaid and Medicare Part B, 42 U.S.C. § 1396r-8(a)(1), (5), and among other things, they agree not to charge "covered entities" above a deeply discounted "ceiling price" for "covered outpatient drugs," *Id.* § 256b(a)(1).

Manufacturers participate in the program by signing the Pharmaceutical Pricing Agreement with HHS. *Id*. These agreements "contain no negotiable terms" and "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011). The 340B statute enumerates and limits the entities and providers that qualify as "covered entities." *Id.* § 256b(a)(4). This list includes federally qualified health centers, family planning projects, black lung clinics, certain public hospitals, and other specified categories of health care providers, *id.*, that "provide direct clinical care to large numbers of uninsured Americans," H.R. Rep. 102-384, pt. 2, at 12. The Patient Protection and Affordable Care Act (the "Affordable Care Act" or "ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010),

added certain children's hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals. 42 U.S.C. § 256b(a)(4).

Congress placed three critical limitations on covered entities to ensure program integrity. First, the 340B statute prohibits "duplicate discounts," providing that "[a] covered entity shall not request payment" under the Medicaid Drug Rebate Program if it obtains the 340B discounted price. 42 U.S.C. § 256b(a)(5)(A)(i). Second, the statute prohibits diversion of discounted drugs, providing that "[w]ith respect to any covered outpatient drug that is subject to [a 340B] agreement," "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Third, covered entities must allow manufacturers (as well as HHS) to conduct audits of the covered entity's compliance with the 340B Program's requirements. *Id.* § 256b(a)(5)(C).

As part of the ACA, Congress "provide[d] for more rigorous enforcement" of 340B Program requirements by, among other things, requiring HHS to create an administrative dispute resolution process. *Astra,* 563 U.S. at 116; *see* 124 Stat. at 826; 42 U.S.C. § 256b(d)(3)(A). The statute directed the Secretary, "[n]ot later than 180 days after March 23, 2010," to "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they [are] overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits . . . of violations" of the diversion and duplicate discount prohibitions, "including appropriate procedures for the provision of remedies and enforcement of determinations." 42 U.S.C. § 256b(d)(3)(A). The statute further directed that the

regulations "designate or establish a decision-making official or decision-making body within [HHS] responsible for reviewing and finally resolving [these] claims," establish deadlines and procedures "to ensure that the claims [are] resolved fairly," and "require that a manufacturer conduct an audit of a covered entity . . . as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity." *Id.* § 256b(d)(3)(B).

There is no private cause of action to directly enforce the provisions of the 340B statute. *Astra*, 563 U.S. at 121-22. The ADR process is the only means for manufacturers (or covered entities) to file claims seeking relief for diversion, duplicate discounts, or manufacturer overcharges.

B. HRSA's Guidance Has Led To Serious Compliance Issues

HRSA has issued guidance on three relevant aspects of the 340B Program: covered entity use of "contract pharmacies" to dispense 340B drugs; the definition of the "patients" who may receive those drugs; and audit guidelines for manufacturers to monitor covered entity compliance with 340B requirements. Collectively, this guidance has created and exacerbated widespread issues of diversion and duplicate discounts.

Contract Pharmacies. As a recent ruling noted, "throughout the past 25 years, the government has dramatically expanded how covered entities may purchase 340B drugs." *AstraZeneca*, 2021 WL 2458063, at *7. Following passage of the 340B statute, some covered entities sought permission from HRSA to contract with independent pharmacies to dispense 340B covered drugs. In 1996, HRSA issued guidance that permitted covered entities that lack an in-house pharmacy to enter into an agreement with one such

"contract pharmacy," for the purpose of allowing the covered entity to dispense 340B-discounted drugs to the covered entity's patients. HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43549, 43550-52 (Aug. 23, 1996).

In 2001, HRSA started permitting individual covered entities to apply for approval to employ alternative models, including using multiple contract pharmacies. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007). Between 2001 and 2006, HRSA approved 18 alternative models, including 11 covered entities' applications to use multiple contract pharmacies. *Id.*

In 2010, HRSA changed its guidance to permit a covered entity to contract with an unlimited number of contract pharmacies, with no geographical limitations. HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10272 (Mar. 5, 2010). Several stakeholders raised serious concerns that the proposal would lead to diversion and duplicate discounts, in addition to concerns that the guidance unlawfully created new obligations for manufacturers. *See, e.g.*, AR1917-19. HRSA dismissed these concerns, citing advances in inventory management and stating that covered entities were responsible for maintaining title to 340B drugs; ensuring no duplicate discounts were charged and no diversion occurred; for maintaining auditable records; and for entering adequate contracts with each contract pharmacy. *See id*.

Patient Definition. Lack of precision regarding the definition of a "patient" has also led to problems with duplicate discounts and diversion.

In 1996, HRSA stated that an "individual is a 'patient' of a covered entity" if (1) the covered entity "has established a relationship with the individual," (2) "the individual receives health care services from a health care professional . . . employed by the covered entity," and (3) the individual "receives a health care service or range of services from the covered entity . . . consistent with the service or range of services" for which funding has been provided to the entity. HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55156, 55157-58 (Oct. 24, 1996). The definition excludes those who receive no health care from the covered entity other than "the dispensing of a drug or drugs." *Id*. at 55158.

This definition lacks necessary specificity and clarity regarding, among other things, patients who are referred from covered entities to outside providers, patients treated by affiliates of covered entities, and when treatment qualifies as "outpatient" as required under the 340B Program. *See* HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient,"* 72 Fed. Reg. 1543, 1545-46 (Jan. 12, 2007). Indeed, in proposing clarifications to address these issues, HRSA itself recognized that the definition may be leading to 340B Program abuses. It stated that "it is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program." *Id.* at 1544.[2]

[2] HRSA relayed these same concerns several years later to the Government Accountability Office ("GAO"). *See* GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836, at 22-23 (Sept. 2011) ("2011 GAO Rep."), https://bit.ly/3p4brqS ("[a]s a result of the lack of specificity in the

Audit Guidelines. While the foregoing policies have created significant risks of diversion and duplicate discounts, HRSA has also hampered manufacturers' ability to combat such problems through effective audits. Pursuant to a grant of authority to establish "procedures . . . relating to the number, duration, and scope of [manufacturer] audits" of covered entities, 42 U.S.C. § 256b(a)(5)(C), HRSA issued manufacturer audit guidelines in 1996, AR390-97.

Under the guidelines, a manufacturer can conduct an audit "only when it has documentation which indicates that there is reasonable cause" to believe a covered entity has violated the diversion or duplicate discount prohibitions. AR393. Before conducting an audit, a manufacturer must notify the covered entity that it believes the entity violated 340B, and "attempt in good faith to resolve the matter" for "at least 30 days." AR394. If the covered entity contests the allegations, the manufacturer must retain an "independent public accountant," and then "submit a work plan" for the audit to HRSA, "set[ting] forth a clear description of why it has reasonable cause to believe that a violation" of the diversion or duplicate discount prohibitions occurred. AR393-94. The work plan must, among other things, outline the audit objectives and methodology to be used, the qualifications of the independent auditor conducting the audit, and the procedures for protecting patient confidentiality. *Id.* HRSA must then approve the plan for the audit to

---

[Patient Definition] guidance, [HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care").

proceed. "At the completion of the audit, the auditors must prepare an audit report in accordance with reporting standards for performance audits of the [Government Auditing Standards]." AR394. The guidelines direct the covered entity and HRSA to then review the audit report, and the covered entity may provide a response. *Id*. The manufacturer must then engage in another round of "good faith" efforts to resolve the issues with the covered entity. *Id.*

In practice, these requirements are so resource-intensive and demand such burdensome, protracted efforts that they effectively block manufacturer audits. As a result, audits have been exceedingly rare, and have provided manufacturers no meaningful ability to check unlawful activities. *See infra*, at 10-13.

C. The Development of the ADR Rule

1. The Advance Notice. Shortly after passage of the ACA, HRSA issued an Advance Notice of Proposed Rulemaking ("ANPRM" or "advance notice") regarding the 340B administrative dispute resolution process. AR1-3. Among other things, the advance notice invited "comment[] on whether it is appropriate to modify the guidelines concerning audits prior to implementing" the ADR process. AR3. As HRSA itself recognized, this was an important issue, because the ACA required manufacturers to "conduct an audit of a covered entity prior to bringing a claim," yet "over the history of the 340B Program manufacturers have rarely utilized the process in the guidelines to conduct an audit." AR3. PhRMA, its members, and others submitted numerous comments on this topic, explaining that the guidelines were unduly burdensome and costly, inconsistent with the statute, and needed to be substantially revised in order to

ensure that manufacturers would have meaningful access to the ADR process. *See* AR43, AR46, AR64, AR67, AR75-76, AR93-94, AR116, AR119-120, AR124. PhRMA and others also raised concerns about the lack of a clear definition of "patient." *See* AR41-42, AR60-61, AR97, AR103-04. Although these comments were submitted only months after HRSA had permitted covered entities to use multiple contract pharmacies, one commenter presciently noted that this new policy "may increase the risk that 340B-priced drugs are diverted to individuals who are not patients of the covered entity and that Medicaid rebates are sought on 340B discounted drugs." AR61.

2. The Proposed Rule. After receiving comments on the ANPRM, HRSA—in violation of Congress's directive to act within 180 days of March 23, 2010—took no steps to implement a rule for years. In 2016, it finally published a Notice of Proposed Rulemaking. AR4-11. Again PhRMA, its members, and other organizations submitted comments in response to this proposed rule, demonstrating that HRSA's proposal was inadequate, unlawful, and contrary to the statute's requirements. *See* AR180-379.

Commenters stressed that, because an audit of a covered entity is a statutory prerequisite to manufacturers submitting ADR claims, 42 U.S.C. § 256b(d)(3)(A), reliance on the highly burdensome audit guidelines would fundamentally skew the process, preventing manufacturers from obtaining "fair[], efficient[], and expeditious[]" resolution of their claims. 42 U.S.C. § 256b(d)(3)(B)(ii); *see, e.g.*, AR307-309, AR311-313, AR355. Commenters explained that having HRSA's complex and unwieldy audit guidelines act as a "gatekeeper" for manufacturer claims—when covered entities face no such requirement—would create unfair and lopsided administrative barriers to accessing

the dispute resolution process. AR 307. To illustrate this point, one commenter submitted the following side-by-side comparison of the relevant steps that covered entities and manufacturers would need to take to initiate ADR under the proposed rule, AR307-09:

Table 1: Required Steps Necessary to Submit an ADR Claim	
Covered Entity	**Manufacturer**
Identify Possible Overpayment. Review data in Ceiling Price Reporting system maintained by HRSA and populated by manufacturers. Compare reported prices to invoice prices.	**Identify Possible Non-Compliance**. Manufacturers have no readily available automated tools for monitoring duplicate discounts or diversion. The rules and practices employed by covered entities are diverse and opaque, while duplicate discounts in the Managed Medicaid context and the proliferation of Contract Pharmacy arrangements have grown and exacerbated this opacity.
Communicate with Manufacturers	**Communicate with Covered Entity**
Engage in Good Faith Dispute Resolution	**Engage in Good Faith Dispute Resolution (Round 1)**
Submit ADR Claim	**Evaluate Case, Obtain Internal Approvals to Conduct Audit**
	Provide Formal Notice of Audit to Entity. The manufacturer shall notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B.
	Engaged in Formal Good Faith Dispute Resolution (Round 2).The manufacturer and the covered entity shall have at least 30 days from the date of notification to attempt in good faith to resolve the matter.
	Develop and Submit to HRSA Evidence of "Reasonable Cause"
	Await "Reasonable Cause" Review By HRSA. The Department will review the documentation submitted to determine if reasonable cause exists. If the Department finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the Department will not intervene. In cases where the Department determines that the audit shall be performed by the Government, the Department will so advise the manufacturer and the covered entity within 15 days of receipt of the audit work plan.
	Seek, Interview and Engage Independent Auditor
	Submit Audit Work Plan to HRSA. The manufacturer must file an audit work plan with the Department. The manufacturer must set forth a clear description of why it has reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, along with sufficient facts and evidence in support of the belief. In addition, the manufacturer shall provide copies of any documents supporting its claims.
	Await HRSA Review of Audit Workplan. Upon receipt of the manufacturer's audit work plan, the Department, in consultation with an appropriate audit component, will review the manufacturer's proposed workplan. As requested by GAS, the audit workplan shall describe in detail the following: (1). audit objectives (what the audit is to accomplish), scope (type of data to be reviewed, systems and procedures to be examined, officials of the covered entity to be interviewed, and expected time frame for the audit), and methodology (processes used to gather and analyze data and to provide evidence to reach conclusions and recommendations); (2). skill and knowledge of the audit organization's personnel to staff the assignment, their supervision, and the intended use of consultants, experts, and specialists; (3). tests and procedures to be used to assess the covered entity's system of internal controls; (4). procedures to be used to determine the amounts to be questioned should violations of section 340B(a)(5) (A) and (B) be discovered; and (5). procedures to be used to protect patient confidentiality and proprietary information.
	Submit Revision(s) to Audit Workplan
	Await HRSA Review of Revisions to Audit Workplan
	Provide Notice to Covered Entity of Audit. The covered entity will have at least 15 days to prepare for the audit.
	Work with Covered Entity to Find Time for On-Site Audit (Auditor)
	Conduct the Audit (Auditor). This involves at least the following steps:
	1. Review the covered entity's policies and procedures regarding the procurement, inventory, distribution, dispensing, and billing for covered outpatient drugs.
	2. Obtain an understanding of internal controls applicable to the policies and procedures identified above (step a) when necessary to satisfy the audit objectives.
	3. Review the covered entity's policies and procedures to prevent the resale or transfer of drugs to a person or persons who are not patients of the covered entity.
	4. Test compliance with the policies and procedures identified above (step c) when necessary to satisfy the audit objectives.

	5. Review the covered entity's records of drug procurement and distribution and test whether the covered entity obtained a discount only for those programs authorized to receive discounts by section 340B of the PHS Act.
	6. Where the manufacturer's auditors conclude that there has been a violation of the requirements of section 340B(a)(5) (A) or (B), identify (1) the procedures or lack of adherence to existing procedures which caused the violation, (2) the dollar amounts involved, and (3) the time period in which the violation occurred.
	7. Following completion of the audit field work, provide an oral briefing of the audit findings to the covered entity to ensure a full understanding of the facts.
	Draft Audit Report (Auditor). At the completion of the audit, the auditors must prepare an audit report in accordance with reporting standards for performance audits of the GAS. The manufacturer shall submit the audit report to the covered entity.
	Review Audit Report. The manufacturer will review the audit findings.
	Await Covered Entity Review of Audit Report. The covered entity shall provide its response to the manufacturer on the audit report's findings and recommendations within 30 days from the date of receipt of the audit report. When the covered entity agrees with the audit report's findings and recommendations either in full or in part, the covered entity shall include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations. When the covered entity does not agree with the audit report's findings and recommendations, the covered entity shall provide its rationale for the disagreement to the manufacturer.
	Submit Copies to HRSA and HHS OIG. The manufacturer shall also submit copies of the audit report to the Department.
	Good Faith Dispute Resolution (Round 3). Engage in discussions with Covered Entity related to repayment pursuant to Audit findings.
	Submit ADR Claim

Moreover, as a result of the growth of contract pharmacies during the half-decade since HRSA issued the advance notice, commenters expressed numerous concerns about how contract pharmacy arrangements were increasing diversion and duplicate discounts, which in turn heightened the need for revised audit guidelines. One commenter explained that "the proliferation of Contract Pharmacy arrangements have grown and exacerbated" the difficulties of detecting diversion and duplicate discounts. AR307. Another explained that use of contract pharmacies increased the risk of duplicate discounts and that, as a result, "the one-sidedness of the dispute process, and especially the incorporation of the need to show cause as a condition of audit, raises concerns where drugs are dispensed by contract pharmacies." AR233. This commenter argued that, "[a]t a minimum, the necessity to show cause before auditing should not apply to 340B drugs dispensed by contract pharmacies." *Id.*

Others argued that a covered entity's use of a contract pharmacy reasonably believed to have violated Program requirements should satisfy the "reasonable cause" standard as to the covered entity, AR293, and that manufacturers should be permitted to audit "multiple covered entities based on the fact that the covered entities utilize the same contract pharmacy," AR210. Yet another argued that manufacturers should be allowed to bring claims alleging "[u]ses of a contract pharmacy that may be abusing the 340B Program." AR197.[3] Several commenters also noted the role that the ambiguous "patient" definition played in exacerbating the problems of diversion and duplicate discounts. AR204, AR228-29, AR357.

3. Abandonment and Revival of the Proposed Rule. On January 20, 2017, the Trump administration issued a memorandum freezing certain regulatory actions. According to HRSA, this memorandum "had the effect of pausing action on the proposed rule." AR13. HRSA abandoned the proposed rule on August 1, 2017, and took no further action on it for years. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), https://bit.ly/3q1t37o; AR1982 (HHS noting

[3] The HHS Office of the Inspector General (OIG) had previously expressed some of these same concerns in a 2014 report that found that 340B contract pharmacies create "complications" in preventing diversion and duplicate discounts. HHS OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1–2 (Feb. 4, 2014) ("2014 OIG Rep."), https://bit.ly/2Nrink1. HHS OIG also concluded that a number of covered entities "did not report a method to avoid duplicate discounts," and that "most covered entities in [OIG's] study do not conduct all of the oversight activities recommended by HRSA" in connection with their contract pharmacy arrangements. *Id.* Earlier still, GAO had warned that "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program." 2011 GAO Rep. at 28.

abandonment of proposed ADR rule due to "concerns raised by commenters about the policy set forth in the proposed rule and its associated burdens"). On March 12, 2020, a HRSA official told a 340B-focused publication that the agency had no plans to issue an ADR rule. According to the official, "[i]t would be challenging to put forth rulemaking on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance" that defendants understood to be legally unenforceable. Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), https://bit.ly/35kU6lw; *see* AR1999-2000.

HRSA abruptly reversed course, however, after several covered entities sued the agency in October 2020. The suits sought to compel HRSA to promulgate the ADR Rule on the ground that the agency was long past the 2010 statutory deadline for doing so and had unreasonably delayed taking action. *See Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, (D.D.C. Oct. 9, 2020), ECF No. 1; *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar & U.S. Dep't of Health & Hum. Servs.*, No. 20-cv-3032, (D.D.C. Oct. 21, 2020), ECF No. 1. On November 17, 2020, HRSA forwarded a final rule to the Office of Management and Budget ("OMB") for review and approval. *See* OMB/OIRA, Conclusion of EO 12866 Regulatory Review for RIN 0906-AB26 (Dec. 7, 2020), https://bit.ly/3eUujW1.

D. PhRMA's Petition Regarding the ADR Rulemaking

On November 24, 2020, PhRMA filed a petition to express its deep concern with HRSA's plan to rush to finalize the previously-abandoned 2016 proposed rule. *See* PhRMA, Petition for Rulemaking Regarding an Administrative Dispute Resolution Process for the 340B Drug Pricing Program (RIN 0906-AA90 and RIN 0906-AB26) (Nov.

24, 2020) (Compl., Ex. A) ("PhRMA Petn."). PhRMA requested that HRSA issue a new proposed rule and open a new comment period, or at least reopen the record to consider new evidence, arising after the close of the prior comment period, that confirmed the flaws in the proposed rule that PhRMA and others had previously identified. This evidence underscored the need for a clear definition of "patient" and revised audit guidelines to ensure that manufacturers can use the ADR process to check what had become rampant problems of diversion and duplicate discounts.

In its petition, PhRMA cited evidence showing that, since 2016, use of contract pharmacies had skyrocketed. The number of contract pharmacy arrangements between 340B covered entities and vertically-integrated specialty pharmacies increased more than 1000 percent since 2016. *Id.* at 6 (citing Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* (Oct. 2020), https://bit.ly/2KzNFDD). PhRMA also cited evidence showing that the explosive growth of the 340B Program—and in particular the increasingly "widespread use of contract pharmacy arrangements"—is connected to burgeoning "challenges and inconsistencies," with respect to diversion and duplicate discounts. *Id.* (citing HHS OIG Testimony: *Examining Oversight Reports on the 340B Drug Pricing Program, Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions*, at 5 (May 15, 2018)). For example, in 2018, the House Energy and Commerce Committee found that nearly half—and in some years more than half—of covered entities audited by HRSA unlawfully sold or transferred 340B drugs to nonpatients. *Id.* at 7 (citing House Energy and Commerce Committee, *Review of the 340B Drug Pricing Program*, at 38 (Jan. 2018) ("2018 House Report"), https://bit.ly/3eWFL3v).

PhRMA also cited GAO reports from 2018 and 2020 finding that the dramatic growth in contract pharmacy arrangements had increased the risk of both duplicate discounts and unlawful diversion. *Id.* 7 (citing GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement,* GAO-20-212, at 2 (Jan. 2020) ("Jan. 2020 GAO Report"), https://bit.ly/3qWxTmr); *see also* GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480, at 45 (June 2018) ("2018 GAO Rep."), https://bit.ly/3kZYAD7. For example, GAO observed that approximately two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Rep. at 44; *see also* HRSA, *Program Integrity: FY18 Audit Results*, https://bit.ly/3o0g6Zo. Similar results were posted for Fiscal Year 2019, with numerous audits identifying instances of diversion and duplicate discounts as a result of the use of contract pharmacies. PhRMA Petn. 7 (citing HRSA, *Program Integrity: FY19 Audit Results*, https://bit.ly/3nUPqJK).

PhRMA also cited recent evidence that shows that HRSA often does not terminate covered entities from the 340B Program even when there are findings of serious noncompliance with its guidance. For instance, in one case where HRSA initially concluded that a covered entity had violated 340B requirements, the lack of a clear and binding regulatory definition of "patient" hampered its enforcement efforts, and HRSA ultimately withdrew both the enforcement measures and audits. *See* PhRMA Petn. 7.

PhRMA's petition further showed that, while the growth in covered entities and contract pharmacies has coincided with a massive growth in diversion and duplicate discounts, it has not resulted in corresponding benefits to the low income and vulnerable

patients the 340B Program is intended to help. While manufacturers must offer the drugs to covered entities at steep discounts, private insurers (and until 2018, Medicare as well) provide *full* reimbursement when the drugs are dispensed to patients. *See, e.g.*, PhRMA Petn. 8 (citing 2018 GAO Rep. at 30). Moreover, HRSA imposes no requirement on covered entities to share 340B discounts with their patients, nor does the agency require that contract pharmacy arrangements ensure that 340B patients receive any portion of the 340B discounts. PhRMA Petn. 7. Instead, covered entities are permitted to retain the full value of 340B discounts if they choose to do so, and even to share it with contract pharmacies. *Id*.

Pharmacies and covered entities have therefore been able to generate substantial profits from the difference between the low acquisition price mandated by the 340B Program and the higher reimbursement value of the drug. PhRMA Petn. 9. HHS itself estimated that it would save Medicare $1.6 billion in 2018 alone by merely reducing the large gap between 340B hospitals' acquisition costs for 340B-discounted drugs and their Medicare reimbursement amounts for those drugs. Centers for Medicare and Medicaid Services, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 52356, 52509 (Nov. 13, 2017); *see also Am. Hosp. Ass'n v. Azar,* 967 F.3d 818, 822 (D.C. Cir. 2020).

Finally, PhRMA's petition explained that, in light of the widespread and serious issues that had arisen since the promulgation of the proposed rule, it would be arbitrary and capricious for HRSA to simply resurrect its moribund proposal in an attempt to stave off litigation, without considering whether changed circumstances warranted changes to

the Rule. PhRMA Petn. 11-12. Among other things, the growth of abuses relating to contract pharmacy arrangements underscored the need to alter the audit requirements to eliminate the serious restrictions manufacturers would otherwise face in accessing the ADR process at all. *Id*. at 12-18.

E. HHS Issues the ADR Final Rule.

HRSA issued the final ADR Rule on December 14, 2020, without addressing PhRMA's petition. *See* AR12 (codified at 42 C.F.R. §§ 10.3, 10.20-.24). The final Rule provides that manufacturers can bring claims only after completing an audit conducted in accordance with the audit guidelines. 42 C.F.R. § 10.21(c)(2). The final Rule does not substantively respond to comments regarding those audit guidelines' flaws. Nor does it address the changed circumstances that have arisen during the more than four-year delay between the proposed rule and the final Rule.

The final Rule provides that the Secretary will create an ADR Board "consisting of at least six members appointed by the Secretary with equal numbers" from HRSA, the Centers for Medicare and Medicaid Services, and the HHS Office of the General Counsel ("OGC"). 42 C.F.R. § 10.20. From this Board, HRSA will select three-member panels with "relevant expertise and experience" for each dispute. *Id.* Individual members can be removed from a panel, but only "for cause." *Id.* § 10.20(a)(1)(ii) The final Rule lists "a conflict of interest" as the only grounds for a panelist's removal. *Id.* §§ 10.20(a)(2), (b).

In a significant and unexplained departure from the proposed rule, the final Rule provides that ADR panel decisions are both "binding" on the parties and "precedential" for purposes of future adjudications. *Id.* § 10.20. Indeed, the regulation provides that the

ADR panel's decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." *Id.* § 10.24(d). It does not provide for any internal review of ADR panel judgments by a superior (much less Senate-confirmed) Executive Branch official.

F. Subsequent Developments

The day after HRSA published the final Rule, GAO released a report on deficiencies in the 340B Program. *See generally* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 (Dec. 2020) ("Dec. 2020 GAO Rep."), https://bit.ly/3c36FGl. The report revealed that, since 2012, HRSA's auditors have made 1,536 findings of noncompliance in the 1,242 audits of covered entities conducted by the agency (which does not have to follow the procedures set forth in the audit guidelines). *Id.* at 13. But, beginning with its Fiscal Year 2019, HRSA requires corrective action only when the "audit information presents a clear and direct violation," and HRSA officials have stated that they believe they lack "appropriate enforcement capability." *Id.* at 15.

Among other things, GAO found that in numerous instances HRSA "did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility"; "did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies . . . because the 340B statute does not address contract pharmacy use"; "did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements . . . because the agency does not have statutory authority to

enforce state Medicaid requirements"; and concluded, in response to a legal challenge by a covered entity, that "in the absence of binding and enforceable regulations," it would no longer "issue findings based solely on noncompliance with guidance." *Id.* at 15-16 & n.26 (discussing *Genesis Health Care Inc. v. Azar*, 2019 WL 6909572 (D.S.C. Dec. 19, 2019)). In some instances, HRSA did not require corrective action regarding duplicate discounts due to its perceived lack of statutory authority. *Id.* at 17.

HRSA was aware of these findings before it published the ADR Rule. GAO had previously sent a draft of the report to HRSA for review, and HHS provided a comment letter reflecting HRSA's views on November 16, 2020, *see* Dec. 2020 GAO Rep., Appendix II—the day before it forwarded its final rule to OMB.

Shortly after GAO published this report, the HHS OGC issued an Advisory Opinion announcing the agency's definitive position that "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 1 (Dec. 30, 2020), https://bit.ly/3y4FO4J. This action spawned the litigation involving certain PhRMA members that defendants discuss in their brief. *See* Br. 10. In one of these cases, the court held that the HHS opinion was "legally flawed" in its interpretation of the 340B statute, *AstraZeneca*, 2021 WL 2458063, at *8, which in turn

prompted HHS to withdraw the opinion, *see AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27 (D. Del. June 18, 2021), ECF Nos. 81 & 81-1.[4]

PhRMA has raised no claims in this case concerning the HHS opinion or the statutory basis for contract pharmacy arrangements. Instead, it challenges the ADR Rule and HRSA's manufacturer audit guidelines.

LEGAL STANDARD

Federal Rule of Civil Procedure 56 "standards do not apply to a court's review of a final agency action under the APA." *Landmark Hosp. of Salt Lake City v. Azar*, 442 F. Supp. 3d 327, 331 (D.D.C. 2020). Rather, "summary judgment 'serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review,'" including whether the agency action is consistent with the Constitution and governing statute. *Id.*; *see Policy & Rsch., LLC v. U.S. Dep't of Health & Human Servs.*, 313 F. Supp. 3d 62, 74 (D.D.C. 2018) ("[T]he entire case on review is a question of law, and only a question of law.'").

ARGUMENT

I. The ADR Rule Violates The Appointments Clause.

The ADR Rule violates the Appointments Clause of Article II of the Constitution because it provides for officers not appointed by the President to issue final binding

[4] In another one of the cases, a court had earlier issued a preliminary injunction barring HRSA from enforcing the ADR Rule against the plaintiff, Eli Lilly. *Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *12 (S.D. Ind. Mar. 16, 2021). The court held that "the agency's message regarding the ongoing rulemaking related to the ADR Rule was ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA." *Id.* at *10. As a result, it found that the plaintiff was likely to succeed on the claim that HRSA failed to engage in proper notice-and-comment rulemaking. *Id.*

decisions on behalf of the Executive Branch. The Supreme Court's recent decision in *United States v. Arthrex, Inc.*—which held that the Patent and Trademark Office's appointment of administrative judges with final authority to decide patent validity violated Article II—confirms that this is unconstitutional.

The Appointments Clause provides that the principal "Officers of the United States" must be appointed by the President with the Senate's advice and consent, while "inferior Officers" may be appointed by "the Heads of Departments." U.S. Const. Art. II, § 2, cl. 2. This is a "structural safeguard" that "preserves political accountability." *Arthrex*, 141 S. Ct. at 1982. Executive officers "wield executive power on behalf of the President," and the Constitution allows them to do so only "through 'a clear and effective chain of command'" running to the President. *Id.* at 1979. Giving an inferior officer the "power to render a final decision on behalf of the United States without any . . . review by their nominal superior or any other principal officer in the Executive Branch" would allow principal officers to evade "responsibility for the ultimate decision," thus "blur[ring] the lines of accountability demanded by the Appointments Clause." *Id.* at 1981-82. Therefore, *Arthrex* held, vesting such power in an officer who is not presidentially appointed violates the Appointment Clause. *Id*.

The appointment process for ADR Board members is inconsistent with this constitutional mandate. Defendants do not dispute that ADR Board members are "officers" of the United States, rather than "lesser functionaries" who are not subject to the Appointments Clause. Br. 21. Indeed, Board members are clearly officers. They are appointed for a "continuing" term, *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018), and because

they control the proceedings before them and issue final precedential decisions, they "exercise significant authority pursuant to the laws of the United States," *id*. at 2051-53; *see also Free Enter. Fund v. PCAOB*, 561 U.S. 477 (2010); *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868 (1991).

Defendants also do not dispute that the Board members are not appointed by the President and confirmed by the Senate, as the Appointments Clause requires for those exercising the duties of principal officers. Br. 21. Rather, the ADR Board members are appointed as purportedly inferior officers by a head of department, the Secretary of HHS. *See* 42 C.F.R. § 10.20.

As in *Arthrex*, "the nature of their responsibilities" is not "consistent with their method of appointment." *Arthrex*, 141 S. Ct. at 1980. ADR Board rulings may not be reversed, modified, or otherwise reviewed within the Executive Branch. Instead, the Rule provides that the Board members issue a "final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(d); *see also id.* § 10.20(c)(5) (Board members "issue a final agency decision on each claim"). The agency explicitly rejected comments calling for review by superior executive officials, stating "HHS does not believe that an appeals process is necessary given that an aggrieved party has a right to seek judicial review." AR21.

Arthrex addressed officers with highly similar authorities: Administrative Patent Judges ("APJs" or "patent judges"), appointed by the Secretary of Commerce to sit on the Patent Trial and Appeal Board ("PTAB"). That Board is an "executive adjudicatory body"

much like the ADR Board, charged with deciding challenges to patent validity. *Arthrex*, 141 S. Ct. at 1977. The Presidentially-appointed department head controlled which patent judges were assigned to hear a given case, but could not fire them "from federal service entirely" except for cause. *Id.* at 1982. The Board's determinations of validity were appealable to the Federal Circuit, but otherwise final, without the possibility of further review within the Executive Branch. *Id.* at 1977-78.

The Supreme Court held that this binding, "unreviewable authority wielded by APJs . . . is incompatible with their appointment by [a department head]." *Id.* at 1985. It explained that a prior ruling, *Edmond v. United States*, 520 U.S. 651 (1997), "goes a long way towards resolving this dispute." *Id.* at 1981; *see Edmond*, 520 U.S. at 664-65 (Coast Guard administrative judges were inferior officers because they had "no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers."). "What was 'significant' to the outcome [in *Edmond*]—[direct] review by a superior executive officer"—was absent in *Arthrex*, where patent judges could "'render a final decision on behalf of the United States' without any such review by their nominal superior." *Arthrex,* 141 S. Ct. at 1981. Even though they "appear[ed] to be inferior officers" in "*every* [other] respect," patent judges could not be appointed lawfully by a department head so long as their decisions were "insulat[ed] . . . from review within the Executive Branch." *Id.* at 1986 (plurality) (emphasis added); *see also id.* at 1990 (Gorsuch, J., concurring) ("Through some provisions, Congress has authorized executive officers to cancel patents. Through others, it has made their exercise of that power unreviewable within the Executive Branch. It's the combination of these provisions—the exercise of

executive power and unreviewability—that violates the Constitution's separation of powers."); *see also Free Enter. Fund*, 561 U.S. at 486, 510 (Public Company Accounting Oversight Board members were inferior officers because the Securities and Exchange Commission had broad authority to review, approve, and modify the Board's final decisions).

Defendants insist that "numerous persuasive decisions" show that Congress may insulate inferior officers' determinations from Executive Branch review. Br. 22 n.4. But to the extent any prior decisions hold that inferior officers can wield final unreviewable authority on behalf of the Executive Branch, they are no longer good law following *Arthrex*. *See supra*. For example, defendants' heavy reliance on the Third Circuit's pre-*Arthrex* decision in *Pennsylvania Department of Public Welfare v. United States Department of Health & Human Services*, 80 F.3d 796 (3d Cir. 1996) (cited by Br. 22-23, 25, 27), is misplaced in light of *Arthrex's* clear instruction that *Edmond* supplies a very different "governing test." 141 S. Ct. at 1982; *compare Pa. Dep't of Pub. Welfare*, 80 F.3d at 802 (considering the scope of adjudicators' duties, the length of their tenure, and the strength of their removal protections), *with Arthrex*, 141 S. Ct. at 1980 (explaining *Edmond*'s focus on whether and how a principal officer can specifically "direct[] and supervise[]" an adjudicator's "power to issue decisions").

Even on their own terms, however, many of defendants' authorities do not support their position. For instance, defendants rely on the D.C. Circuit's decisions in *Intercollegiate Broadcasting Systems, Inc. v. Copyright Royalty Board*, 684 F.3d 1332 (D.C. Cir. 2012), and *Fleming v. USDA*, 987 F.3d 1093 (D.C. Cir. 2021). But both cases hold that

agency adjudicators were inferior officers in part *because* their decisions were subject to direct review and correction by other officials within the Executive Branch in critical respects. *Intercollegiate*, 684 F.3d at 1338-39 (Copyright Royalty Board judges were inferior officers because the board's conclusions of law were subject to review and correction by the Register of Copyright); *Fleming*, 987 F.3d at 1103 (U.S. Department of Agriculture's Administrative Law Judges were inferior officers because their decisions could be appealed as of right to a superior executive officer, or the Secretary could "at his election, step in and act as final appeals officer in any case."). Here, by contrast, there is no mechanism for further executive review of the ADR Board's decisions—they can only be reviewed by an Article III court. 42 C.F.R. § 10.24(d). But under *Arthrex*, "review outside Article II . . . cannot provide the necessary supervision," because the officers are "exercising executive power and must remain dependent upon the President." *Arthrex*, 141 S. Ct. at 1982.

Defendants also assert that the Secretary has unlimited power to remove members from the ADR Board, and that this is such a "powerful tool for control" that it necessarily renders the members inferior officers. *See* Br. 26-27. But the Rule does not provide any method of removing members from the ADR Board, and states that Board members may be removed from panels only "for cause." *See* 42 C.F.R. § 10.20(a)(1)(ii). Even if defendants were correct in inferring a power for the Secretary to remove members from their assignment to the Board at will, most are protected from removal from their other Executive Branch positions except "for cause." *See* 5 U.S.C. § 7513. Thus, as in *Arthrex*, the

Board members are not "'meaningfully controlled' by the threat of removal from federal service entirely." *Arthrex*, 141 S. Ct. at 1982.

At any rate, even unfettered removal power would not cure the Appointments Clause violation. *Arthrex* makes clear that "insulation of [adjudicators'] decisions from review within the Executive Branch" violates the Appointments Clause even when they appear otherwise to be inferior officers "[i]n *every* respect." 141 S. Ct. at 1986 (plurality) (emphasis added); *see Edmond*, 520 U.S. at 664-65 (availability of Executive-Branch review is "significant" even in cases where the purportedly inferior adjudicating officer may be "remove[d] . . . from his judicial assignment without cause"). Even unlimited removal power "gives the [Secretary] no means of countermanding . . . final decision[s] already on the books." *Arthrex*, 141 S. Ct. at 1982. Further, the Secretary's ability to use "machinations" such as threatening removal to influence rulings is "the problem" "not the solution." *Id*. It would result in "neither an impartial decision by a panel of experts nor a transparent decision for which a politically accountable officer must take responsibility," thus "blur[ring] the lines of accountability" that the Constitution demands. *Id*. PhRMA is entitled to summary judgment that the ADR Rule violates the Appointments Clause.

II. The Manufacturer Audit Guidelines, Incorporated In The ADR Rule, Are Contrary To Law.

A. The Reasonable Cause and Third-Party Auditor Requirements Conflict with the Text, Structure, and Purpose of the 340B Statute.

The ADR Rule incorporates the onerous manufacturer audit guidelines, which create an undue barrier to manufacturer access to the ADR process. These audit

guidelines are invalid because they conflict with the plain text of the 340B statute in two respects. The statute gives the Secretary authority only to establish "procedures . . . relating to the number, duration, and scope of audits." 42 U.S.C. § 256b(a)(5)(C). Far from implementing Congress' "unambiguously expressed intent," Br. 12, the guidelines' "reasonable cause" and third-party auditor requirements do not relate to the number, duration, or scope of audits, and instead exceed the Secretary's limited authority.

1. Reasonable Cause. The audit guidelines state that "[a] manufacturer shall conduct an audit only when it has documentation which indicates that there is reasonable cause" to believe that a covered entity has violated the diversion or duplicate discount prohibitions, and HRSA determines that the manufacturer has made such a showing. AR393-94. Contrary to defendants' contentions, this threshold evidentiary requirement does not fall within the Secretary's limited statutory authority.

Defendants contend that the reasonable cause requirement '"relat[es] to the number of audits that a manufacturer may conduct by limiting the number of audits to instances where the manufacturer 'has documentation which indicates that there is reasonable cause' to 'believe that a covered entity may have violated the statute.'" Br. 13; *see* AR393 (defining "reasonable cause" as a regulation of "Number of Audits"). But the plain meaning of "number" is "numerical quantity." Oxford English Dictionary, www.oed.com; *see* Merriam-Webster Dictionary, www.merriam-webster.com ("a sum of units"). The audit guidelines themselves include regulations of "number," including permitting "[o]nly one audit of a covered entity . . . at any one time." AR393. The reasonable cause standard is not a "numerical quantity." Nor is there any necessary

relationship between that standard and the number of audits: A regulation could provide both that a manufacturer may "conduct no audit without reasonable cause," and that a manufacturer could "conduct no more than one such audit per year/per covered entity."

Defendants' argument to the contrary proves too much. Under their logic, *any* regulation would "relate to the number of audits" by making audits more difficult (or less difficult) to conduct. But that capacious construction is impermissible, because it gives no limiting principle to the phrase "relate to." *See N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (refusing to construe "relate to" in the Employee Retirement Income Security Act "to the furthest stretch of its indeterminacy" because it would have no limiting principle, "for 'really universally, relations stop nowhere.'").

Moreover, the statute authorizes the Secretary to establish "*procedures*" that "relat[e] to the number . . . of audits." 42 U.S.C. § 256b(a)(5)(C) (emphasis added). But reasonable cause is an evidentiary standard, not a procedure, in the same way that probable cause is an evidentiary standard for issuance of a search warrant, not the procedure (i.e., submission of affidavits to a neutral judge) for obtaining one.

Defendants also contend that the reasonable cause requirement relates to "the 'scope of the audits'" in that a review of the audit work plan's "purpose and scope" "necessarily entail[s] a review of whether there is 'reasonable cause' to conduct the audit in the first instance." Br. 13. But support for this construction is found nowhere in the regulation, *see* AR390-93, which cannot be upheld on the basis of a "*post hoc* rationalization devised during litigation," *Am. Trucking Ass'ns v. Fed. High. Admin.*, 51

F.3d 405, 411 (4th Cir. 1995); *see SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (court must "confin[e] our review to a judgment upon the validity of the grounds upon which the [agency] itself based its action"). And it is contrary to the plain meaning of "scope," which concerns the "extent" or "range" of an activity. *See* Merriam-Webster Dictionary, www.merriam-webster.com (the "space . . . for unhampered . . . activity" or the "extent of . . . activity"); Oxford English Dictionary, www.oed.com ("space or range for free movement or activity"). As defendants themselves put it, the "reasonable cause" requirement concerns whether a manufacturer may "conduct the audit in the first instance," Br. 13, not the extent of the audit.

Defendants claim that the reasonable cause standard is justified by the statute's "express limit on the *circumstances* where an audit is appropriate," which they assert flows from the requirement that an audit "'directly pertain to the entity's compliance'" with the statute's prohibitions. Br. 14 (quoting statute) (emphasis added). The portion of the statute defendants quote, however, does *not* identify the "circumstances" where an audit is appropriate. Instead, it identifies the *documents* that may be audited—*i.e.*, "the *records* of the entity that directly pertain to the entity's compliance with the [statute's] requirements." 42 U.S.C. § 256b(a)(5)(C) (emphasis added).

Finally, defendants claim the reasonable cause requirement prevents manufacturer misuse of their audit rights. Br. 13. But the requirement is not tied to any prior misuse of audit rights; it erects a threshold, evidentiary barrier to all audits, whether or not a manufacturer has ever conducted (much less misused) a 340B audit before. Ultimately, defendants' "misuse" theory rests on the implicit assumption that an audit

conducted without "reasonable cause" is, necessarily, an abuse of the right to conduct audits. But there is no basis for such an assumption, which is contradicted by HRSA's own auditing practices and the rights that covered entities have to audit contract pharmacies, which do not require a threshold "reasonable cause" showing. *See infra* Part II.B.

Indeed, the agency's creation of such a threshold requirement confirms the impropriety of its interpretation. Congress knows how to prescribe threshold requirements for statutorily authorized activities. It has done so not only in other statutes,[5] but elsewhere in § 340B, which expressly conditions the right of manufacturers to invoke the ADR process on completion of an audit. 42 U.S.C. § 256b(d)(3)(A). If Congress had intended to limit ADR to manufacturers that completed audits based on "documentation which indicates that there is reasonable cause" to believe a covered entity had violated one or more statutory requirements, it could and would have said so.

Instead, Congress required covered entities to allow manufacturer audits, authorized the Secretary to prescribe *procedures* relating only to "the number, duration, and scope of" such audits, and required that the procedures for the ADR process "ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(ii). That limited authority does not include the power to

[5] *See, e.g.*, 15 U.S.C. § 45(b) (authorizing the Federal Trade Commission to bring proceedings if it has "reason to believe that" a person "has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce"); 47 U.S.C. § 205(a) (authorizing the Federal Communications Commission to prescribe rates if it "shall be of opinion that any charge, classification, regulation, or practice of any carrier or carriers is or will be in violation of any of the provisions of this chapter").

prescribe additional threshold requirements, beyond those set forth in the statute, for manufacturers to be able to invoke the ADR process.

2. Third-Party Auditors. The audit guidelines' requirement that "[t]he manufacturer's auditor shall be an independent public accountant employed by the manufacturer to perform the audit," AR393, is likewise contrary to the statutory text. Indeed, this provision directly conflicts with the statute's express command that "[a] covered entity shall permit . . . *the manufacturer* of a covered outpatient drug . . . to audit" the covered entity. 42 U.S.C. § 256b(a)(5)(C) (emphasis added); *see* AR311-313.

Defendants say this "defies common sense" because a manufacturer "is not one person who can readily conduct an audit." Br. 14. Since "a manufacturer must necessarily employ someone in order to audit a covered entity," they argue that a requirement that "the person employed by the manufacturer [be] an independent accountant" is permissible. *Id*. But while an audit must certainly be conducted by a person, this argument provides no basis for prohibiting manufacturers from using their own auditors. Manufacturers employ internal auditors capable of applying the same scrutiny to covered entities, *see* AR67—an arrangement perfectly compatible with government auditing standards, *see infra*, at 36-37. Defendants make no effort to connect the additional requirement of a third-party auditor to the "number, scope, or duration" of audits. No such connection is possible. The plain text of the statute gives "the manufacturer" the right to ensure covered entities purchasing drugs from it at a steep discount are complying with the diversion and duplicate discount prohibitions, with no requirement that they must employ a third party each time they wish to exercise this right.

B. The Reasonable Cause and Third-Party Auditor Requirements Do Not Constitute A Reasonable Interpretation of the 340B Statute.

Because the audit guidelines conflict with the text, structure, and purpose of the 340B statute, the Court does not need to proceed beyond *Chevron* Step One. However, to the extent the Court concludes the 340B statute is ambiguous, the reasonable cause and third-party auditor requirements reflect an unreasonable interpretation of the statutory text and thus do not merit deference. *See Util. Air. Reg. Grp. v. EPA*, 134 S. Ct. 2427, 2442 (2014) ("Even under *Chevron*'s deferential framework, agencies must operate 'within the bounds of reasonable interpretation'").

The reasonable cause requirement is not necessary to "prevent[] misuse of the manufacturers' audit right[s]." Br. 13. In fact, the requirement is contrary to both defendants' own practices and the rights of covered entities to audit contract pharmacies. Far from requiring documentation supporting a reasonable cause standard, HRSA allows covered entities to audit their contract pharmacies without restriction, *see* 75 Fed. Reg. at 10278 (Mar. 5, 2010), and HRSA's own "audits include covered entities that are randomly selected based on risk-based criteria." Dec. 2020 GAO Rep. at 11 n.22; *See also* 42 U.S.C. § 256b(d)(1)(B)(v) (permitting "selective auditing of manufacturers"). Defendants claim this disparity makes sense, because the manufacturers' interests "are diametrically opposed to those of covered entities." Br. 16. But in auditing their contract pharmacies, covered entities should have the same interest in rooting out diversion and duplicate discounts, since they remain responsible for preventing such violations. 75 Fed. Reg. at 10273 ("[U]se of a contract pharmacy arrangement . . . does not lessen a covered

entity's . . . full responsibility and accountability for compliance with all requirements to prevent [diversion and duplicate discounting].").

The restriction on manufacturer audits thus places manufacturers in a Catch-22: Without access to covered entities' records, manufacturers have limited ability to acquire the evidence to demonstrate reasonable cause—even though HRSA's audits of covered entities show widespread non-compliance. *See* AR309. And the proliferation of contract pharmacies has made it even more difficult for an outside observer to track whether 340B patients are being provided the 340B discounted drugs. *See* AR233, AR307. That information is solely in possession of the covered entities and their contract pharmacies.

Defendants argue that restricting manufacturers' ability to conduct audits is necessary to prevent manufacturers attempting to use "audits where there are 'no valid business concerns.'" Br. 16. But they cite nothing in the administrative record or elsewhere demonstrating that manufacturers have attempted to misuse audits of covered entities. And other provisions of the statute prevent such misuse, including the requirement that all audits must be conducted at "the manufacturer's expense," and can encompass only "records of the entity that directly pertain to the entity's compliance" with 340B Program requirements. 42 U.S.C. § 256b(a)(5)(C). Other provisions of the audit guidelines also prevent any misuse of audits. For example, manufacturers can conduct "only one audit at time," with an "audit period of one year," and audits must be conducted with "minimum intrusion on the covered entity's operations." AR394.

Indeed, far from demonstrating that manufacturers "misuse" audits, the last 25 years demonstrate that the audit guidelines are so burdensome and expensive that

manufacturers rarely conduct audits at all, despite the significant problems of duplicate discounts and diversion. *See supra*, at 10-13; AR46, AR66-67, AR196-97, AR311; *see also* AR3 ("over the history of the 340B Program manufacturers have rarely utilized the process in the guidelines to conduct an audit").

As to the third-party auditor requirement, defendants claim "PhRMA's real concern" is "that independent auditors without a financial stake in the results of the audit may not uncover nonexistent wrongdoing on the part of covered entities." Br. 14-15. Defendants cite no support in the record for this groundless accusation.[6] In reality, covered entity violations are far from "nonexistent," *see* AR309; *supra*, at 16-17, 20-21, and "PhRMA's real concern" is that the requirement to hire third-party auditors sharply increases the expense, rendering audits financially infeasible in most instances, *see* AR355.

Defendants contend that "generally accepted auditing standards" require "independent auditors." Br. 16. But the federal government's own Generally Accepted Government Auditing Standards permit the use of internal "professional staff" to conduct audits so long as "safeguards" are in place. AR312-13. *See also* GAO, *Government Auditing Standards* ¶ 3.58 (2018 rev.) (noting that, with appropriate safeguards, internal auditors "can be considered independent" when "conduct[ing] engagements pertaining to external parties, such as contractors or entities subject to other outside agreements"). And those same standards are also applied outside the federal government itself, "to

[6] This is the same kind of "unfair characterization[]" of an opponent's position that the *AstraZeneca* court deemed objectionable. *AstraZeneca*, 2021 WL 2458063, at *4 n.6.

engagements pertaining to . . . government [programs] administered by contractors, nonprofit entities, and other nongovernmental entities." *Id.* ¶ 1.08. Defendants cite no evidence in the record that manufacturers lack the internal "accounting expertise," Br. 14, necessary to conduct audits, *see* AR67 ("[A] manufacturer's own internal auditors can audit a covered entity at significantly less expense [than external ones].").

By requiring a showing of reasonable cause and use of third-party auditors, the guidelines and the ADR Rule deny manufacturers a "fair[], efficient[], and expeditious[]" resolution of their claims. 42 U.S.C. § 256b(d)(3)(B)(ii). Accordingly, HRSA's interpretation of its authority to prescribe "procedures . . . relating to the number, duration, and scope of audits," *id.* § 256b(a)(5)(C), is unreasonable and should be rejected.

III. Defendants' Adoption of the ADR Rule Was Arbitrary and Capricious.

PhRMA is likewise entitled to summary judgment because defendants "entirely failed to consider" multiple "important aspect[s] of the problem" before them. *Mayor of Baltimore v. Azar*, 973 F.3d 258, 275 (4th Cir. 2020) (en banc) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Defendants concede that HRSA promulgated the ADR Rule without considering either 1) calls by numerous commenters to reform the audit guidelines, which are an integral part of the ADR process; or 2) PhRMA's petition, which identified significant shifts in the 340B Program since the comment period closed in 2016 that underscored the need for changes to the proposed ADR Rule. The agency's failure to consider these serious issues renders the Rule arbitrary and capricious.

A. HRSA Entirely Failed to Address Whether the Audit Guidelines That Control Manufacturers' Access to the ADR Process Should Be Modified.

In the advance notice, HRSA expressly "invite[d] comments on whether it is appropriate or necessary to modify the guidelines concerning audits prior to implementing the [ADR] regulation." AR3. This inquiry reflected the agency's clear recognition that the guidelines were inextricably linked to the efficacy of the ADR process: HRSA noted that a completed audit was a statutory prerequisite to a manufacturer ADR claim and that, "over the history of the 340B Program manufacturers have rarely utilized the process in the guidelines to conduct an audit." *Id.*

In response to both the advance notice and the proposed rule itself, numerous stakeholders submitted comments that identified major problems with the audit guidelines. *See supra*, at 10-13. Many explained that HRSA's "reasonable cause" standard for commencing an audit unfairly requires more information than manufacturers can obtain without access to a covered entity's records. *See, e.g.*, AR75, AR120, AR293. Others explained the legal and practical problems with HRSA's requirement that manufacturers hire expensive third-party auditors rather than rely on qualified in-house personnel, *see, e.g.*, AR67, AR94, AR355-56, and pointed out that the audit guidelines' lack of provision for "joint audits by manufacturers" means that the statutorily-required "ability for manufacturers to consolidate claims is illusory," AR313; *see also* AR294. Commenters also pointed out that the burdensome audit guidelines would became a serious barrier to manufacturers' ability to access the ADR process at all. AR307.

Defendants concede that HRSA did not "substantively respond" to any of these comments. Br. 19. The preamble to the final Rule simply asserts without explanation that "updat[ing] manufacturer audit guidelines" is not "needed to finalize the ADR process." AR13. This "conclusory statement[]" does not demonstrate that the agency "'adequately analyze[d] . . . the consequences' of its actions." *Casa de Md., Inc. v. Wolf*, 486 F. Supp. 3d 928, 961 (D. Md. 2020); *see also S.C. ex rel. Tindal v. Block*, 717 F.2d 874, 886 (4th Cir. 1983) (agency's explanation must be enough to "enable a reviewing court" to understand "why the agency reacted . . . the way it did"); *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977) ("[T]he opportunity to comment is meaningless unless the agency responds to significant points raised by the public."). The agency's failure to "respond to relevant, significant issues raised" by commenters renders the Rule arbitrary and capricious. *N.C. Growers Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 769 (4th Cir. 2012).

Defendants argue that HRSA's failure to respond "makes no difference"; in their view, the audit guidelines are "beyond the scope of the rulemaking" and thus not "relevant." Br. 18. This is incorrect. Because it expressly requested comments on the guidelines, HRSA was obligated to respond to the comments it received. In all events, the audit guidelines are critical to the efficacy of the ADR process itself, and thus plainly relevant to the ADR Rule.

"By inviting comments . . . the [agency] placed these issues on the table. It was therefore 'incumbent upon the agency' to address relevant, substantial comments to this effect." *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256 (D.D.C. 2020); *Ohio Valley Env't Coal. v. U.S. Army Corps of Eng'rs*, 2013 WL 1305732, at *6 (S.D. W. Va. Mar. 28, 2013) (by

"soliciting comments regarding *any and all parts* of the [plan]" the agency suggested it "would consider all pertinent comments . . . [and] could alter any of its mitigation requirements [in response]"). The comments submitted at the agency's own invitation urging reform of the audit guidelines thus raised relevant, significant issues that required a substantive response.

The fact that the comments were solicited in an advance notice, Br. 19-20, does not alter this conclusion. Defendants cite cases addressing whether *proposals* set forth in an advance notice are sufficiently concrete to give rise to justiciable disputes.[7] But here, HRSA identified an *issue*—whether the guidelines that govern a statutory prerequisite for ADR claims by manufacturers should be changed. That issue was significant and germane when HRSA raised it, and it remained so when it issued a final rule that, in fact, required manufacturers to comply with the audit guidelines in order to bring ADR claims. Defendants' lack of any reasoned explanation for HRSA's decision to incorporate the audit guidelines without change renders the Rule arbitrary and capricious. *ALLTEL Corp. v. FCC*, 838 F.2d 551, 558 (D.C. Cir. 1988) ("[T]he Commission must do more than simply ignore comments that challenge its assumptions and must come forward with some explanation that its view is based on some reasonable analysis.").

Second, and more fundamentally, whether a comment raises '"an important aspect of the problem,' . . . turns on what a relevant substantive statute makes

[7] *See, e.g., Roman Cath. Archdiocese of N.Y. v. Sebelius*, 907 F. Supp. 2d 310 (E.D.N.Y. 2012) (holding issuance of advance notice did not deprive plaintiff of standing to challenge current rule); *Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25, 39 (D.D.C. 2012) (holding issuance of advance notice rendered challenge to current rule unripe).

'important.'" *Or. Nat. Res. Council v. Thomas*, 92 F.3d 792, 798 (9th Cir. 1996). When an issue "is evident on the face" of the statute and raised by commenters, "the APA require[s the agency] to acknowledge those concerns and respond to them in a meaningful way, not blithely dismiss them as 'outside the limited scope of this rulemaking.'" *Cath. Legal Immigr. Network, Inc. v. Exec. Off. For Immigr. Rev.*, — F. Supp. 3d —, 2021 WL 184359, at *11-12 (D.D.C. Jan. 18, 2021); *see Mozilla Corp. v. FCC*, 940 F.3d 1, 60 (D.C. Cir. 2019) ("[I]t is for Congress in the first instance to define the appropriate scope of an agency's mission."). Indeed, defendants' own authorities demonstrate that whether comments are "relevant and significant" must be measured by the governing statute. *City of Portland v. EPA*, 507 F.3d 706, 713-14 (D.C. Cir. 2007) (comments regarding cost-benefit analysis were "beside the point" where the governing statute "require[d] EPA to impose the most stringent feasible treatment technique . . . regardless of cost-benefit analysis").

Here, the relevance of the audit guidelines to the ADR process is also evident on the face of the statute. The statute expressly provides that "the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by . . . manufacturers, after the conduct of *audits* as authorized by subsection (a)(5)(C)." 42 U.S.C. § 256b(d)(3)(A) (emphasis added). It requires manufacturers to conduct an audit under HRSA's audit regulations as a "prerequisite" to filing an ADR claim. *Id.* § 256b(d)(3)(B)(iv). And it requires that the Secretary adopt procedures "to ensure that claims shall be resolved fairly, efficiently, and expeditiously." *Id.* § 256b(d)(3)(B)(ii). Whether the audit guidelines incorporated into the ADR Rule unduly burden the ability of manufacturers to bring ADR claims is plainly relevant to whether

that Rule permits manufacturers' claims to "be resolved fairly, efficiently, and expeditiously." *Id.* And if there were any conceivable doubt about the importance of the audit guidelines to the ADR process, the numerous comments discussed above spelled out in detail the ways in which those guidelines significantly frustrate the ability of manufacturers to obtain fair, efficient, and expeditious resolution of their claims.

The audit guidelines are therefore not a "separate matter" from the ADR process. Br. 18. Indeed, the agency's refusal to consider the broken audit guidelines means that it has failed to implement half of the statutory directive: while it created a process "for the resolution of claims by covered entities," it has not created a usable process for "claims by manufacturers."

B. HRSA Entirely Failed to Address PhRMA's Petition Demonstrating that the Record is Stale.

Defendants also acted arbitrarily and capriciously by "ignor[ing]" PhRMA's petition. Br. 20. The petition explained that "the four year-old record before HRSA is stale" because it "does not reflect the explosive growth in contract pharmacies" and "the corresponding increase in diversion and other abuses," requiring at least a new comment period to consider changes to the proposed rule. PhRMA Petn. 1. After years of inaction, it was arbitrary and capricious for defendants to "rush to finalize its deeply flawed proposed rule in order to avoid responding to lawsuits." *Id*. at 2.

As discussed above, *see supra*, at 16-17, the petition detailed the explosive growth in contract pharmacy arrangements and how, with "little change in regulatory oversight to keep pace with this rapidly evolving program," the 340B Program now suffers from

widespread problems of duplicate discounts and diversion, PhRMA Petn. 5. Government findings show "that nearly half—and in some years more than half—of audited covered entities unlawfully sold or transferred 340B drugs to nonpatients." *Id*. at 7. A substantial majority of these diversion findings involved contract pharmacies, which also typically absorb a share of the revenue from discounts intended to help vulnerable patients. *Id*. at 7, 11. In short, new evidence shows that the 340B Program's "good intentions have been overwhelmed by middlemen that pocket discounts while forcing patients, employers, and the Medicare program to pay more for prescription drugs." *Id*. at 8.

This information was plainly material to development of an appropriate ADR Rule. In particular, it "underscore[d] the need to . . . eliminate the restrictions manufacturers face in accessing the ADR process," including the lack of "fair and adequate audit procedures," as well as the lack of a clear definition of "patient," "so that key participants in the program can use the ADR process to resolve claims in a fair, efficient, and timely manner." PhRMA Petn. 10-11. Indeed, just as the advance notice acknowledged the importance of the manufacturer audit guidelines to the ADR process, the preamble to the final ADR Rule acknowledged that the definition of "patient" is also critically important to the ADR process. HRSA recognized that, to resolve ADR disputes, panels "may find it necessary to resolve related issues such as whether someone is a 'patient.'" AR13. HRSA should have addressed that critical issue directly itself, but instead punted it to politically unaccountable panel members.

Defendants do not dispute that they simply "ignore[d]" PhRMA's petition, giving it no consideration. Br. 20. They therefore "entirely failed to consider an important aspect

of the problem" and failed to "articulate a satisfactory explanation for [their] action," rendering the Rule arbitrary and capricious. *Motor Vehicle Mfrs.*, 463 U.S. at 43.

Defendants argue that they were "free to ignore" the petition because it was "submitted well after the close of the comment period." Br. 20. But PhRMA's claim is that defendants erred in failing to consider *new evidence* that *arose after* the comment period and rendered the record stale. "Although the Administrative Procedure Act does not establish a 'useful life' for a notice and comment record, clearly the life of such a record is not infinite." *Mobil Oil Corp. v. EPA*, 35 F.3d 579, 584-85 (D.C. Cir. 1994)). Where "new information relevant to the agency's decisionmaking" has "come to light after the original notice and comment proceedings," the APA requires a new comment period, so that impacted stakeholders can present this new information, and the agency can fairly consider it and alter the proposed rule as needed. *Id.*; *see Sierra Club v. EPA*, 671 F.3d 955, 965 (9th Cir. 2012) (agency acted arbitrarily and capriciously when it "did not analyze this new data or explain why it chose not to analyze the data").

In addition, PhRMA's petition is not an untimely "comment," but rather a petition for rulemaking based on a change in "a significant factual predicate" for the proposed rule. *Am. Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 5 (D.C. Cir. 1987). Such a petition is a proper vehicle to raise arguments that the agency should consider new evidence relevant to a rulemaking. *Geller v. FCC*, 610 F.2d 973, 978 (D.C. Cir. 1979). As the D.C. Circuit has explained, to deny a petition claiming that "new facts . . . merit[] a new rulemaking," an agency must articulate "the factual and policy bases for the decision" in enough detail "to assure a reviewing court that [its] refusal to act was the product of reasoned

decisionmaking." *Am. Horse. Prot. Ass'n*, 812 F.2d at 5-6; *see Massachusetts v. EPA*, 549 U.S. 497, 527-28 (2007) (explaining that agencies must provide a "public explanation" for denying a rulemaking petition); *cf.* 45 C.F.R. § 1.5 (authorizing petitions "to withdraw or modify" agency guidance, requiring HHS to respond in writing and "state whether the Department agrees or disagrees with the petition and the Department's rationale."). "If the original record is still fresh, a new round of notice and comment might be unnecessary. Such a finding, however, must be made by the agency and supported in the record," and HRSA's failure to do so here is arbitrary and capricious. *Mobil Oil*, 35 F.3d at 584. PhRMA's petition was, at the least, entitled to a reasoned response.

CONCLUSION

For these reasons, the Court should grant PhRMA's cross-motion for summary judgment, and deny defendants' cross-motion and motion to dismiss.

Date: July 26, 2021

Respectfully submitted,

/s/ Sujit Raman .

Sujit Raman (Bar No. 28907)
Joseph R. Guerra (*pro hac vice*)
Erika L. Maley (*pro hac vice*)
sujit.raman@sidley.com
jguerra@sidley.com
emaley@sidely.com
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: 202-736-8000
Facsimile: 202-736-8711

Attorneys for Plaintiff Pharmaceutical Research and Manufacturers of America