IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

950 F Street N.W., Suite 300, Washington, D.C., on behalf of itself and its members,

Plaintiff,

vs.

NORRIS COCHRAN,

200 Independence Avenue S.W., Washington, D.C. 20201, in his official capacity as Acting Secretary of the U.S. Department of Health and Human Services;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

200 Independence Avenue S.W., Washington, D.C. 20201;

DIANA ESPINOSA,

5600 Fishers Lane, Rockville (Montgomery County), Maryland 20852, in her official capacity as Acting Administrator of the Health Resources and Services Administration; and

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

5600 Fishers Lane, Rockville (Montgomery County), Maryland 20852,

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) brings this suit on behalf of itself and its members, and alleges as follows:

INTRODUCTION

1. PhRMA challenges a final rule that the U.S. Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) rushed to publish in the final days of the Trump Administration in an effort to moot several recently-filed lawsuits filed against those agencies. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80632 (Dec. 14, 2020) (ADR Final Rule). The ADR Final Rule governs disputes that arise in the 340B Drug Pricing Program (340B Program), which Congress enacted in 1992 to help underserved and vulnerable patients. Under the 340B Program, pharmaceutical manufacturers that participate in the Medicaid and Medicare Part B programs must offer steep discounts on their prescription medications (at or below a statutorily-set ceiling price) to qualifying hospitals and clinics (known as "covered entities") that provide medical care to these patients.

2. PhRMA and its members support the goals of the 340B Program. But, as Congress recognized, the legitimacy of this program depends on enforcement of statutory safeguards that prohibit covered entities from (1) causing "duplicate discounts" on the same drug (one under Medicaid and another under the 340B Program), or (2) diverting drugs to persons not entitled to them under the 340B law, *i.e.*, "resell[ing] or otherwise transfer[ing]" a drug they purchase under the 340B program "to a person who

is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Congress also directed HHS to establish an Administrative Dispute Resolution (ADR) process to resolve disputes over violations of these safeguards, as well as claims by covered entities that they have been denied discounts. *Id.* at § 256b(d)(3)(A).

3. After failing for a decade to establish this process, HRSA suddenly revived and altered a moribund ADR proposal, then published it as a final rule within weeks of being sued for its failure to comply with the statute. In its haste, HRSA issued a rule that is arbitrary and capricious—not the product of reasoned decision-making—and unconstitutional.

4. Overwhelming evidence demonstrates that the 340B Program is now plagued by problems of diversion and duplicate discounts. These problems, moreover, are directly attributable to decisions that HRSA has made in overseeing the program over the course of two decades. HRSA has allowed covered entities to use an unlimited number of third-party commercial pharmacies, or so-called "contract pharmacies," to acquire and distribute drugs under the 340B Program. And it has failed to provide a precise definition of the "patients" of covered entities that are entitled to receive the discounted drugs. Together, these decisions have created an environment in which 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." Letter from Adam J. Fein to the Hon. Lamar Alexander and the Hon. Greg Walden (Oct. 30, 2020) ("Fein Letter").

5. Making matters worse, HRSA has imposed undue burdens on manufacturers' statutory right to audit covered entities to determine whether these entities are complying with the prohibitions on diversion and duplicate discounts. *See* 42 U.S.C. § 256b(a)(5)(C). And HRSA has repeatedly failed to police and remedy these abuses itself, making it all the more critical that manufacturers be able to seek the "fair[], efficient[], and expeditious[]" resolution of claims of diversion and duplicate discounts through the ADR process, 42 U.S.C. § 256b(d)(3)(B), as Congress intended.

6. In a 2010 Advance Notice of Proposed Rulemaking (ANPRM) on ADR, as well as its 2016 ADR proposed rule, HRSA explicitly asked if it should alter its manufacturer audit guidelines, because audits are a prerequisite to a manufacturer's ability to initiate ADR claims under the statute. 42 U.S.C. § 256b(d)(3)(B)(iv). Manufacturers responded by submitting evidence of the then-growing problems of diversion and duplicate discounts, and explaining (among other things) that, because an audit is a statutory pre-condition to manufacturer-initiated ADR, HRSA's burdensome and legally flawed audit guidelines should be revised so manufacturers can meaningfully police such abuses.

7. HRSA failed to take any action on its proposed rule for several years. Late last year, however, several covered entities sued the agency over its inaction. Shortly thereafter, HRSA hurriedly finalized its long-dormant ADR rule for the expedient purpose of mooting those lawsuits.

8. In doing so, HRSA failed to modify the flawed audit guidelines. Moreover, HRSA acted on the basis of a stale record, refusing to consider new evidence that

highlighted the growth in 340B Program abuse and the now even more urgent need for manufacturer-initiated ADR to address statutory violations and seek relief. In addition, HRSA failed to offer any meaningful response to comments explaining the need for revised audit guidelines. Instead, by leaving them in place, HRSA effectively ratified—and gave new legal force to—guidelines that severely restrict manufacturers' ability to audit covered entities for diversion and duplicate discount violations, and thus restrict manufacturers' ability to bring ADR claims (as a manufacturer audit is a precondition to such claims). Further, because the guidelines exceed HRSA's statutory authority to regulate only the "number, duration, and scope of audits," they are themselves contrary to law. 42 U.S.C. § 256b(a)(5)(C). Most significantly, the guidelines improperly require manufacturers to have "reasonable cause" to conduct an audit, when the very purpose of audits is to detect whether a given entity is committing violations.

9. At the same time, HRSA failed to address significant policy questions critical to the fair and efficient operation of the 340B Program, such as defining who is a "patient" of a covered entity entitled to receive drugs subject to the 340B discount. Instead, HRSA punted the resolution of these and other critical policy questions to ADR panels. But these panels are composed of politically unaccountable agency employees who are not appointed by the President and confirmed by the Senate. And HRSA chose, in the ADR Final Rule, to give panel decisions binding and precedential effect, without further review by agency officials who are so appointed and confirmed. In doing so, HRSA violated the Appointments Clause of Article II of the Constitution.

10. As PhRMA explains in greater detail below, these defects render the ADR Final Rule unlawful and unconstitutional. The Court should therefore set aside, vacate, and remand that rule to the agency.

JURISDICTION AND VENUE

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, because this is an action arising under federal law, and pursuant to 28 U.S.C. § 1346(a)(2), because this is a civil action against the United States based on a regulation of an executive department.

12. Venue is proper under 28 U.S.C. § 1391(e)(1)(A), because this is a civil action in which a defendant is an officer or employee of the United States, sued in her official capacity, who performs her official duties in this District. Venue is also proper under 28 U.S.C. § 1391(e)(1)(B), because a substantial part of the events or omissions giving rise to PhRMA's claims occurred in this District.

13. Plaintiff brings this action under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

14. This Court has the power to grant injunctive and declaratory relief pursuant to 5 U.S.C. §§ 701–706 and 28 U.S.C. §§ 2201–2202.

PARTIES

15. Plaintiff PhRMA is a non-profit Delaware corporation, with offices located in Washington, D.C. PhRMA's members are the country's leading research-based pharmaceutical and biotechnology companies, devoted to creating new medications that allow people to live longer, healthier, and more productive lives. (A list of PhRMA members can be found at www.phrma.org.) PhRMA's members develop life-saving and

life-enhancing medicines that are prescribed and sold throughout the nation, including vaccines and therapeutics to prevent, diagnose, and treat COVID-19. *See* PhRMA, *The Biopharmaceutical Industry Is Leading the Way in Developing New Vaccines and Treatments for COVID-19* 1 (Nov. 2, 2020), *available at* https://onphr.ma/35Up8la. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state policymakers, and the courts. This suit seeks to protect interests that are germane to PhRMA's core concerns, including its interest in ensuring that regulations governing the resolution of disputes that concern discounts pharmaceutical manufacturers provide under government benefit programs—and that can lead to potential enforcement actions—are fair, reasonable, and designed to further the proper functioning of that program consistent with applicable law.

16. Numerous PhRMA members have entered into pharmaceutical pricing agreements with HHS under the 340B Program, and will be adversely affected by the ADR Final Rule. Some covered entities have already invoked the ADR process and filed claims against PhRMA members. *See Nat'l Ass'n of Community Health Ctrs. v. Eli Lilly and Co., et al.*, Petition No. 210112-2 (HHS Jan. 13, 2021).

17. Neither the claims asserted nor the relief sought in this Complaint requires the participation of any individual PhRMA members.

18. Defendant Norris Cochran is the Acting Secretary of HHS. He oversees HRSA and the 340B Program, and performs his official duties at 200 Independence Avenue, S.W., Washington, D.C. 20201. He is sued in his official capacity only.

19. Defendant HHS is an executive department of the United States, headquartered in Washington, D.C. and responsible for HRSA and the 340B Program.

20. Defendant Diana Espinosa is the Acting Administrator of HRSA. She administers the 340B Program—including the ADR Rule—and oversees HRSA's other activities. She performs her official duties at 5600 Fishers Lane, Rockville, Maryland 20857. She is sued in her official capacity only.

21. Defendant HRSA is an administrative agency within HHS that is headquartered at 5600 Fishers Lane, Rockville, Maryland 20857, and administers the 340B Program.

BACKGROUND

A. The 340B Program

22. In 1992, Congress established the 340B Program to improve access to certain outpatient drugs for health care providers providing clinical care to 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 (adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b); *see also* H. Rep. No. 102-384 (II), at 11-13 (1992). Under the 340B Program, drug manufacturers must charge no more than a deeply discounted "ceiling price" for covered outpatient drugs purchased by specified "covered entities." 42 U.S.C. § 256b(a)(1). Pharmaceutical manufacturers must participate in the 340B Program as a condition of receiving federal reimbursement for their products under Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1), (5).

23. Manufacturers participate in the 340B Program by signing a form contract, the Pharmaceutical Pricing Agreement, with HHS. The 340B statute directs the Secretary of HHS to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act . . . , reduced by the rebate percentage" set by the statute. 42 U.S.C. § 256b(a)(1). These agreements, composed by HHS, "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 statute and agreements "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

24. The statute specifically limits and enumerates the types of health care providers that qualify as covered entities. 42 U.S.C. § 256b(a)(4) ("Covered entity defined"). The eligible types of "covered entities" include, for example, federally-qualified health centers, family planning projects, black lung clinics, certain public hospitals, and other specified categories of health care providers that "provide direct clinical care to large numbers of uninsured Americans." *See id.*; *see also* H.R. Rep. 102-384(II), at 12 (1992). In subsequent amendments to the 340B statute, Congress has expanded the definition of a "covered entity" to include children's hospitals excluded from the Medicare prospective payment system, free-standing cancer hospitals excluded

from the Medicare prospective payment system, critical access hospitals, rural referral centers, and sole community hospitals. 42 U.S.C. § 256b(a)(4); *see also Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 31-32 (D.D.C. 2014).

25. Congress recognized that this program needed careful limits to ensure that the steep manufacturer discounts on drugs extend only to the covered entities specified in the 340B statute and the patients of those entities. It therefore included three crucial safeguards to protect against abuse and to ensure that the program serves its intended public purpose. First, the 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) ("A covered entity shall not request payment under [Medicaid] . . . with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under the [Medicaid Drug Rebate Program]."). Second, the statute prohibits diversion of the 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 the agency) to conduct audits of the covered entity's compliance with the 340B Program's requirements. *Id.* § 256b(a)(5)(C) ("A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense

the records of the entity that directly pertain to the entity's compliance with the requirements described in [§ 256b(a)(5)(A) & (B)] with respect to drugs of the manufacturer."). Under subsection (d)(3)(B)(iv), the Secretary is directed to promulgate regulations requiring that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) "as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity." *Id.* § 256b(d)(3)(B)(iv).

26. Congress amended the 340B Program in 2010 as part of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. *See* Patient Protection and Affordable Care Act § 7102, Pub. L. No. 111-148, 124 Stat. 119, 826–27 (Mar. 23, 2010); Health Care and Education Reconciliation Act of 2010 § 2302, Pub. L. No. 111-152, 124 Stat. 1029, 1082–83 (Mar. 30, 2010) (collectively, the Affordable Care Act ("ACA")). As part of those 2010 amendments, Congress directed HHS to improve covered entity compliance with the program's diversion and duplicate-discount prohibitions. *See* 42 U.S.C. § 256b(d)(2)(A). Congress also instructed the agency to establish and implement "an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under [the 340B Program], and [of] claims by manufacturers" that covered entities have violated the statutory prohibition on duplicate discounts or diversion. *Id.* § 256b(d)(3)(A). The statute required that this ADR process be established "not later than 180 days after March 23, 2010," the date of enactment of the Patient Protection and Affordable Care Act. *Id.*

B. HRSA Guidances Lead to Serious Compliance Issues

27. As discussed further below, numerous sources (including Congressional and other governmental reports), have shown widespread and pervasive issues with covered entity compliance in the 340B Program. *See* ¶ 52, *infra*. These compliance issues have increased at an alarming rate in recent years. *See* ¶ 51, *infra*. HRSA guidance on three key issues—the use of "contract pharmacies," the definition of "patient," and auditing guidelines for manufacturers—created or exacerbated these widespread issues with duplicate discounts and diversion in the 340B Program.

28. Shortly after the creation of the 340B Program in 1992, some covered entities that lacked an in-house pharmacy sought permission from HRSA to contract with independent pharmacies to dispense 340B covered drugs. *See* 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996). HRSA issued guidance stating that the agency would permit covered entities that lack an in-house pharmacy to enter into an agreement with one contract pharmacy, for the purpose of allowing the covered entity to dispense 340B-discounted drugs to the covered entity's patients. *See id.* at 43551-52. The agency stressed that "the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing" and that "[t]he mechanism does not in any way extend this pricing to entities which do not meet program eligibility." *Id.* at 43550 (emphasis added).

29. Starting in 2001, covered entities could apply to the Office of Pharmacy Affairs for an Alternative Methods Demonstration Project (AMDP) to contract with multiple pharmacies. HRSA approved eighteen AMDPs over the next nine years.

30. In 2010, HRSA revised its contract pharmacy guidance to permit any covered entity to contract with an unlimited number of contract pharmacies, with no geographical limitations. 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). When HRSA had proposed this sweeping expansion of its contract pharmacy guidance in 2007, 72 Fed. Reg. 1540 (Jan. 12, 2007), several stakeholders raised serious concerns that the proposal, if finalized, would lead to rampant issues with diversion and duplicate discounts, in addition to concerns that the proposal was unlawful. *See, e.g.*, 75 Fed. Reg. at 10273-75. HRSA dismissed these concerns, opining that advances in inventory management would permit more covered entities to utilize multiple contract pharmacies without an increase in duplicate discounts and diversion. *Id.* HRSA stated that covered entities were responsible for 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*. at 10272-74.

31. HRSA's 2010 guidance unleashed an explosive growth of contract pharmacies, from 1,256 in 2010 to more than 27,928 in 2020. Adam. J. Fein, *A Primer on 340B Contract Pharmacies and Medicaid Duplicate Discounts (video)*, Drug Channels (Oct. 22, 2020), *available at* https://bit.ly/3iy0Qlj. This explosive growth outran HRSA's capacity to properly oversee the 340B Program and greatly increased the risk of duplicate discounts and diversion, without corresponding benefit to patients. *See* ¶¶ 54-57, *infra.*

32. While the extent of these problems has expanded dramatically in recent years, *see* ¶¶ 50-52, *infra,* government reports warned from the outset that the rapid expansion spurred by HRSA's 2010 guidance could lead to diversion and duplicate

discounts. *See* GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011) ("2011 GAO Rep."), *available at* https://bit.ly/3p4brqS. In 2011, for example, a report by the U.S. Government Accountability Office (GAO) concluded that "[o]perating the 340B Program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." *Id.* GAO further warned that the "[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." *Id.*

33. HHS itself reached similar conclusions. In 2014, the HHS Office of the Inspector General (OIG) found that 340B contract pharmacies create "complications" in preventing diversion and duplicate discounts. HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1–2 (Feb. 2014) ("2014 OIG Rep."), *available at* 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.* at 2.

34. Lack of precision regarding the definition of a "patient," and lack of oversight of contract pharmacy arrangements, has also led to problems with duplicate discounts and diversion. *See, e.g.*, 2011 GAO Rep., at 22–23 ("patient" definition); GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-

480, at 35, 43–44 (June 2018) ("2018 GAO Rep.") (oversight guidance), *available at* https://bit.ly/39WY3yd. As noted above, the statute prohibits a covered entity from "resell[ing] or otherwise transfer[ring]" a 340B-discounted drug "to a person who is not *a patient* of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). 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, such that the covered entity maintains records of the individual's health care;
>
> 2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

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 anyone who receives no health care from the covered entity other than "the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." *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. Despite GAO's specific recommendation that HRSA issue a revised and clearer "patient" definition, 2011 GAO Rep. at 34, and despite

repeated requests from manufacturers and other stakeholders for a more precise definition, HRSA has not updated this definition since 1996.

35. HRSA's failure to issue a revised "patient" definition is all the more troubling in light of HRSA's own recognition that the definition may be leading to 340B Program abuses. For example, HRSA has 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." HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient,"* 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) (providing examples of specific ways that covered entities "may have interpreted the definition too broadly"). Similarly, GAO has recognized that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for purposes of 340B" and that this has "raised concerns that the guidance will be interpreted too broadly." 2011 GAO Rep. at 22. GAO further noted that, "[a]s a result of the lack of specificity in the 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." *Id*. at 23.

36. On two separate occasions, HRSA has proposed revisions to its definition of "patient" to add clarity. *See* 72 Fed. Reg. at 1544; 80 Fed. Reg. 52300, 52306 (Aug. 28, 2015). Yet the agency did not finalize either proposal, and the 340B Program abuses

resulting from the vague and imprecise existing definition not only continue to occur, but have dramatically accelerated in recent years. *See* ¶¶ 50-52, *infra*. Meanwhile, HRSA is not enforcing the existing definition, *see* ¶ 53, *infra*, further exacerbating these unchecked program abuses.

37. In 1996, HRSA also issued guidelines that established procedures for manufacturer audits of covered entities. 61 Fed. Reg. 65406 (Dec. 12, 1996). Under the 340B statute, covered entities are required to permit manufacturers to audit the entity's compliance with the statutory prohibitions on duplicate discounts and diversion with respect to the manufacturer's covered outpatient drugs. 42 U.S.C. § 256b(a)(5)(C). The guidelines issued by HRSA create significant hurdles that impede manufacturers' statutory right to address diversion and duplicate discount violations by covered entities.

38. Among other things, the guidelines require a manufacturer, before initiating an audit, to "notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B" and to direct the parties to "attempt in good faith to resolve the matter" for "at least 30 days." 61 Fed. Reg. at 65410. If those attempts fail and a manufacturer seeks to proceed with the audit, the guidelines require the manufacturer to first "file an audit work plan" with HRSA setting forth "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." *Id.* According to the guidelines, HRSA will then "review the documentation submitted to determine if reasonable cause exists," permitting a manufacturer to proceed with the audit only if this threshold is satisfied. *Id.* HRSA has stated that "utilization of more than one contract

pharmacy" does not "create[] automatic cause to suspect diversion." 75 Fed. Reg. *at* 10274.

39. If HRSA authorizes an audit, a manufacturer must hire an independent third-party auditor, rather than being able to conduct an audit itself, and must submit a detailed work plan. *Id.* HRSA then reviews the work plan, which also must be approved before the audit can begin. *Id.* And once the audit is complete, the manufacturer (or its third-party auditor) must complete a report in accordance with the Generally Accepted Government Auditing Standards. *Id.* The covered entity and HRSA 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. 61 Fed. Reg. at 65408, 65412 ("[W]hen a covered entity disagrees with the audit report[] . . . the manufacturer and the covered entity must make a good faith effort to resolve the issue before requesting review using the dispute resolution process.").

40. In practice, these guidelines have proved to be so resource-intensive and burdensome that they serve as an unfair obstacle to legitimate manufacturer audits. Despite the well-documented and widespread problems with duplicate discounts and diversion, *see* ¶ 52, *infra*, audits have been exceedingly rare, and have provided little ability to check such unlawful activities.[1]

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[1] In 2017, President Trump issued Executive Order 13891, which instructed each federal agency to perform a substantive review of its guidance to determine whether it was and should still remain in effect, and to post such guidance to a Guidance Portal; any guidance not posted to the portal was rescinded. As of June 29, 2020, HHS completed its

C. The Development of the ADR Rule

41. Shortly after passage of the Affordable Care Act, HRSA issued an Advance Notice of Proposed Rulemaking regarding the 340B administrative dispute resolution process. 75 Fed. Reg. 57233 (Sept. 20, 2010). Among other things, the advance notice recognized that "over the history of the 340B program manufacturers have rarely utilized the process in the guidelines to conduct an audit." *Id.* at 57235. The advance notice invited "comment[] on whether it is appropriate to modify the guidelines concerning audits prior to implementing" the ADR process, *id.*, given that manufacturers would be required to complete an audit before they could access the dispute resolution process, 42 U.S.C. § 256b(d)(3)(A).

42. PhRMA, a number of its members, and others submitted comments to the advance notice, including comments—as invited by HRSA—regarding the need to revise the audit guidelines. *See* Comments Received, *340B Drug Pricing Program Administrative Dispute Resolution Process*, Document ID HRSA-2010-0005-0001, *available at* https://bit.ly/3sLqgk6. Despite the statutory deadline to issue the rule by September 2010, HRSA took no action on the advance notice for years. Eventually, in 2016, HRSA published a Notice of Proposed Rulemaking, 81 Fed. Reg. 53381, 53382 (Aug. 12, 2016).

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comprehensive review of its guidance documents related to the 340B Program, determined which of them have continued effect, and made them available on HHS's website. In doing so, HHS renewed and readopted the 1996 manufacturer audit guidelines. *See* https://www.hhs.gov/guidance/.

43. PhRMA, a number of its members, and other organizations likewise submitted comments in response to this proposed rule, demonstrating that HRSA's proposal was inadequate, unlawful, and contrary to the statute's requirements. *See* Comments Received, *340B Drug Pricing Program: Administrative Dispute Resolution*, Docket HRSA-2016-0002, OMB RIN 0906-AA90, *available at* https://bit.ly/2HBbCJK.

44. Commenters explained that, because a manufacturer audit of a covered entity is a statutory prerequisite to manufacturer-initiated ADR, 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 id.* § 256b(d)(3)(B)(iv); 85 Fed. Reg. at 80633, 80636. Commenters explained that having HRSA's complex and unduly burdensome 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. One commenter illustrated its understanding of the lopsided and unreasonably burdensome nature of the audit guidelines with the following side-by-side comparison—based on the commenter's direct experience with this extensive, resource-intensive, and unduly cumbersome process:[2]

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.

[2] Excerpt from Comment of Eli Lilly and Co. on Proposed 340B Drug Pricing Program: Administrative Dispute Resolution (ADR) Process, OMB RIN 0906-AA90 (Oct. 11, 2016), *available at* https://bit.ly/3qEYaoU.

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

45. Commenters also explained, among other things, that the proposal to have ADR panels composed of HHS employees rather than Administrative Law Judges would increase the risk of bias, given that HHS employees would also be involved in initiating enforcement actions and in issuing guidances regarding the 340B Program, including on key interpretive issues that could arise in the course of ADR proceedings or subsequent enforcement actions (such as potential civil monetary penalties).

46. 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." 85 Fed. Reg. at 80633. The proposed rule was then abandoned on August 1, 2017. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), *available at* https://bit.ly/3q1t37o.

47. HRSA took no action regarding the ADR rulemaking for more than four years. In fact, on March 12, 2020, a HRSA official told *The 340B Report*, a 340B-focused news 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), *available at* https://bit.ly/35kU6lw; *see also id.* (quoting HRSA official as stating, "While HRSA believes that its program policies are sound, guidance does not provide HRSA appropriate enforcement capability.").

48. HRSA reversed course almost immediately after several covered entities filed suit against the agency in October 2020. The suits sought a writ of mandamus ordering 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, ECF No. 1 (D.D.C. Oct. 9, 2020); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar & U.S. Dep't of Health & Hum. Servs.*, No. 20-cv-3032, ECF No. 1 (D.D.C. Oct. 21, 2020). On November 17, 2020, HRSA forwarded a final rule to the Office of Management and Budget's Office of Information and Regulatory Affairs for review and approval.

D. PhRMA's Petition Regarding the ADR Rulemaking

49. On November 24, 2020, PhRMA filed a petition to express its deep concern with HRSA's apparent plan to finalize the previously-abandoned 2016 proposed rule without considering both the changes in circumstances in the years since the prior comment period, and the numerous deficiencies with the proposed rule outlined in the prior comments. *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), *attached as* Ex. A. PhRMA requested that HRSA instead reopen the record so that HRSA could consider these issues in light of new evidence,

arising after the close of the prior comment period, of increased diversion and duplicate discounts.

50. PhRMA cited evidence showing that since 2016 the number of covered entities and the use of contract pharmacies had skyrocketed. According to GAO, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 20,000 in 2017. 2018 GAO Rep. at 2. As of October 2020, there were approximately 25,000 unique contract pharmacy locations across the country and more than 170,000 arrangements between contract pharmacies and 340B covered entities. *See* HRSA, *340B Contract Pharmacy Database*, *available at* https://bit.ly/39qpNNp (last visited Nov. 22, 2020). And the number of contract pharmacy arrangements between 340B and vertically-integrated specialty pharmacies increased more than 1000 percent between 2016 and 2020 alone. *See* Aaron Vandervelde et al., Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* (Oct. 2020), *available at* https://bit.ly/2KzNFDD;. By 2019, discounted drugs purchased through the 340B Program accounted for at least 8% of the total U.S. drug market, amassing $29.9 billion in sales that year, an "astonishing" 23% increase over sales in 2018. Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), *available at* https://bit.ly/39P3z6f.

51. In its petition, 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," specifically in ensuring that uninsured patients benefit from the

program. PhRMA Petition, Ex. A at 6 (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)).

52. 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. *See* House Energy and Commerce Committee, *Review of the 340B Drug Pricing Program*, at 38 (Jan. 2018) ("2018 House Report"). In 2018 and 2020, GAO likewise observed that the dramatic growth in contract pharmacy arrangements had increased the risk of both duplicate discounts and unlawful diversion. *See* 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"), *available at* https://bit.ly/3qWxTmr; *see also* 2018 GAO Rep. at 45. For example, GAO observed that approximately two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." *Id*. at 44; *see also* HHS, HRSA, *Program Integrity: FY18 Audit Results*, *available at* 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. HHS, HRSA, *Program Integrity: FY19 Audit Results*, *available at* https://bit.ly/3nUPqJK.

53. Equally troubling, recent evidence shows that HRSA often does not terminate covered entities from the 340B Program even when there are findings of serious noncompliance. For instance, in one case where HRSA initially concluded that a covered

entity had violated 340B requirements, the lack of a clear definition of "patient" hampered its enforcement efforts, and HRSA ultimately withdrew both the enforcement measures and audits. *See Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements,* GAO-21-107 (Dec. 2020) ("Dec. 2020 GAO Rep.") (discussing *Genesis Health Care Inc. v. Azar*, 2019 WL 6909572 (D.S.C. Dec. 19, 2019)), *available at* https://bit.ly/3c36FGl.

54. PhRMA's petition further stated 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.*, 2018 GAO Rep. at 1; GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), *available at* https://bit.ly/3bZ3e3E; *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (describing the "large gap between the amount a 340B hospital would spend to acquire a [prescription drug] and the higher amount Medicare would reimburse that hospital. The gap ranged from 25% to 55% of the cost of the drug."). Moreover, HRSA imposes no requirement on covered entities to share 340B discounts with their patients, nor does the agency require contract pharmacy arrangements to ensure that 340B patients receive any portion of the 340B discounts. Instead, covered entities are permitted to keep all of the

revenue for 340B discounts if they choose to do so, or even to share it with contract pharmacies.

55. 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. As Senator Chuck Grassley has stated, "hospitals are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, Senate Comm. on the Judiciary, to Mary K. Wakefield, Administrator, Health Res. and Servs. Admin. (March 27, 2013), *available at* https://bit.ly/3kFquVS. Indeed, according to HHS in its own rulemaking for the Medicare Part B program, this hospital outpatient reimbursement gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs," 82 Fed. Reg. 52356, 52494 (Nov. 13, 2017)—at the expense of the Medicare program and seniors exposed to higher cost-sharing.

56. One study estimated that, due to the steep discounts mandated under Section 340B, "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines"—more than triple the average margin. Vandervelde, *For-Profit Pharmacy Participation in the 340B Program* 7. The study found that "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018." *Id*. 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. 82 Fed. Reg. at 52509; *see also Am. Hosp. Ass'n*, 967 F.3d at 822.

57. These huge profits are frequently not passed on or used to benefit patients. Instead, covered entities are charging patients—including uninsured patients—full price for the drugs that the entities themselves receive at a deep discount. *See* Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs (Oct. 2014), *available at* https://bit.ly/2J5qvok; *see also* Sunita Desai & J. Michael Williams, *Consequences of the 340B Drug Pricing Program*, 378 N. Engl. J. Med. 539, 546-47 (Feb. 8, 2018) (finding "no evidence of hospitals using the surplus . . . generated from [the 340B Program] to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups," and suggesting that "hospital responses [have been] contrary to the goals of the program"), *available at* https://bit.ly/362pcz5. Indeed, 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies. 2018 GAO Report at 30. And many of the remaining 55% reported that they provide discounts to patients obtaining medicines through contract pharmacies only in limited cases. *Id*. In 2014, HHS OIG similarly found that a number of contract pharmacies failed to offer 340B-discounted prices to uninsured patients at all. 2014 OIG Rep. at 2. Rather, "uninsured patients pa[id] the full non-340B price for their prescription drugs at contract pharmacies." *Id.*

58. In short, 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." Fein Letter; *see also* PhRMA, Press Release, *New Analysis Shows Contract Pharmacies Financially Gain from 340B Program with No Clear Benefit to Patients* (Oct. 8, 2020), *available at* https://onphr.ma/3itN57s.

59. The unchecked expansion of the 340B Program has also resulted in increased treatment costs. Covered entities have acquired distant child sites in affluent communities to turn previously independent physician offices and clinics into 340B sites, thereby expanding their opportunities to dispense discounted 340B drugs to commercially insured patients (and non-eligible individuals). This expansion drives care away from less expensive physician office settings into more expensive hospital settings. Aaron Vandervelde & Eleanor Blalock, Berkeley Research Group, *Site-of-Care Shift for Physician-Administered Drug Therapies* 3 (Oct. 16, 2017), *available at* https://bit.ly/2NpEeYR. The 2018 House Report provided an illustrative example, noting that after one Atlanta oncology practice was acquired by a major hospital network in 2013, "the out of pocket cost of treatment for one patient rose from $20 to $212, a more than 1000 percent increase." 2018 House Report at 68.

60. Several government entities have raised concerns about market distortions caused by the program's expansion. The 2018 House Report noted that the 340B Program appears to be affecting "market dynamics" in ways that "should be concerning to everyone focused on improving patient care":

> The committee has been unable to determine at this time how frequent or widespread such dynamics may be. However, the sincere concerns expressed by numerous health care providers who have witnessed these challenges suggest there may be at least some negative consequences of market dynamics associated with the 340B Program. Given the widespread agreement between all covered entities that the aim of the 340B Program is to assist these entities in providing care to patients, first-person reports of negative patient impacts or patient harm should be concerning to everyone focused on improving patient care.

2018 House Report at 70. Likewise, the GAO has identified rapid program growth as an area of significant concern. *See, e.g.*, GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight*, at Highlights (July 18, 2017), *available at* https://bit.ly/3612ZRD.

61. 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 a transparent attempt to stave off litigation, without considering whether changed circumstances warranted changes to the rule. Among other things, the growth of unchecked 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.

62. HRSA proceeded to issue the final rule on December 14, 2020, without addressing PhRMA's petition. *See* 85 Fed. Reg. 80632. The same day that the final rule was published, the government moved to dismiss as moot one of the two suits seeking promulgation of an ADR process. *See* Defs.' Mem. in Support of Motion to Dismiss at 10-11, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, ECF No. 41-1 (Dec. 14, 2020).

Both suits were subsequently stayed on the ground that the ADR Rule the plaintiffs sought had been issued. *See* Joint Motion to Stay, *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 20-cv-3032, ECF No. 12 (D.D.C. Dec. 17, 2020) (motion granted Jan. 7, 2021); Joint Motion to Stay, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, ECF No. 58 (D.D.C. Jan. 13, 2021) (motion granted Jan. 13, 2021).

E. HHS Issues the ADR Final Rule Without Responding to Significant Comments or PhRMA's Petition to Reopen

63. HRSA's final rule creates an unfair and fundamentally skewed process that, while nominally available for both manufacturers and covered entities to resolve issues, in actuality is inaccessible and unworkable for manufacturers.

64. The final rule reiterates that manufacturers can bring claims only after completing an audit in accordance with the 1996 audit guidelines. 85 Fed. Reg. at 80635, 80638. Notably, the final rule does not substantively respond to comments regarding those audit guidelines' flaws. Neither does it meaningfully address the changes in circumstances arising during the more than four-year delay between the proposed rule and the final rule.

65. Furthermore, 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 (CMS), and the HHS Office of the General Counsel (OGC). *Id.* at 80634. From this Board, HRSA will select three-member panels with "relevant expertise and experience" for each dispute. *Id.* The rule provides that individual members can be removed from a panel, but only "for

cause." *Id.* The final rule lists "a conflict of interest" as the only grounds for a panelist's removal. *Id.*

66. 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. 42 C.F.R. § 10.20. Specifically, 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).

67. The ADR Rule does not provide for any internal review of ADR panel judgments by a superior (much less Senate-confirmed) Executive Branch official.

68. The final rule went into effect on January 13, 2021. On that same date, a covered entity trade association filed an ADR complaint against PhRMA members Eli Lilly and Company, Sanofi-Aventis U.S. LLC, and Astrazeneca PLC, seeking declaratory and injunctive relief. *Nat'l Ass'n of Cmty. Health Ctrs. v. Eli Lilly and Co.*, Petition No. 210112-2 (HHS Jan. 13, 2021).

F. After the Issuance of the Rule, a GAO Report Finds HRSA is Not Enforcing Program Requirements for Covered Entities, and HRSA Issues an Advisory Opinion Regarding Contract Pharmacies

69. The day after HRSA published the final rule, GAO released a report on deficiencies in the 340B Program. *See generally* Dec. 2020 GAO Rep. The report found that HRSA has hired an outside organization to conduct 200 audits per year. *Id.* at 11. It revealed that, since 2012, HRSA's auditors have made 1,536 findings of noncompliance in the 1,242 audits conducted. *Id.* at 13. But, beginning with its Fiscal Year 2019 audits of

covered entities, HRSA requires corrective action only when the "audit information presents a clear and direct violation" of the statute, and HRSA officials stated that they believed they lacked "appropriate enforcement capability." *Id.* at 15.

70. Among other things, GAO found that in numerous instances HRSA officials "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"; and "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." *Id.* at 15-16. There were instances where the agency did not require corrective action regarding duplicate discounts due to its perceived lack of statutory authority. *Id.* at 17. GAO stated that it "remain[ed] concerned" that HRSA was not taking adequate steps to ensure that covered entities complied with 340B Program requirements. *Id.* at 21. Indeed, the GAO report makes clear that HRSA is fundamentally failing to take enforcement actions adequate to deter violations by covered entities.

71. HRSA was aware of these findings before it finalized the ADR Rule. GAO had previously sent a draft of the report to HRSA for review, and HRSA provided a comment letter on November 16, 2020. *See* Dec. 2020 GAO Rep., Appendix II.

72. In marked contrast to its lax stance regarding covered entity compliance, the HHS Office of General Counsel in December 2020 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). Under the ADR Final Rule, employees of this same office will be appointed as members of ADR panels to resolve disputes between covered entities and manufacturers, and will presumably rely on this Advisory Opinion rather than impartially weighing the legal arguments without pre-judgment.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(Declaratory/Injunctive Relief—The ADR Rule is Arbitrary and Capricious, an Abuse of Discretion and Otherwise Not in Accordance with Law)

73. The prior paragraphs of the Complaint are incorporated by reference.

74. Under the APA, a "reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). To satisfy the APA, agency action must at a minimum be the product of "reasoned decisionmaking." *Tradeways Ltd. v. U.S. Dep't of the Treasury*, 2020 WL 3447767, at *15 (D. Md. June 24, 2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)).

75. The ADR Rule should be vacated and remanded to HHS to correct at least two interrelated shortcomings. These shortcomings create a one-sided process that improperly hampers the ability of manufacturers to address violations of program

requirements by covered entities, while imposing no such burdens on the ability of covered entities to bring claims against manufacturers.

76. First, HRSA failed to adequately address comments regarding the audit guidelines, which, under the ADR Rule, govern the audit prerequisite for manufacturers to initiate ADR claims.

77. The 2010 ANPRM specifically requested comment on whether the audit guidelines were appropriate, given that they would serve as a gatekeeper to manufacturers' ability to initiate claims in the ADR process. *See* 75 Fed. Reg. 57233, 57234 (requesting comments regarding "Manufacturer Audits"); *see also id.* at 57235. In response to both the 2010 Advance Notice of Proposed Rulemaking and the 2016 Notice of Proposed Rulemaking, a number of commenters raised concerns about those audit guidelines, explaining in considerable detail that they create an unduly cumbersome precondition to commencing ADR for manufacturers.

78. In issuing the 2020 ADR Final Rule, HRSA failed to adequately address these comments. Indeed, HRSA acknowledges that many commenters discussed this question, but in response cites only the inapposite 340B Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) regulation and states, in a conclusory manner, that "updated manufacturer audit guidelines" are not "needed to finalize the ADR process," and that the ADR panels can "determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts." 85 Fed. Reg. at 80633.

79. This response reflects a complete failure to engage in reasoned decisionmaking. At the threshold, the fact that ADR panels can determine violations

during a proceeding is plainly irrelevant to the question of whether the audit guidelines unduly and unreasonably burden the ability of manufacturers to *initiate* a proceeding in the first place. And the agency's peremptory assertion that updated guidelines are not "needed" is pure—and impermissible—*ipse dixit*. Insofar as this assertion is meant to express HRSA's conclusion that the audit guidelines do not unduly and unreasonably burden the ability of manufacturers to initiate ADR, HRSA wholly failed to explain the basis for any such conclusion.

80. "An agency establishing a rule need not address every comment," but it must "reasonably respond to those comments that raise significant problems." *North Carolina v. FAA*, 957 F.2d 1125, 1135 (4th Cir. 1992); *see also Casa de Maryland, Inc. v. Wolf*, — F. Supp. 3d —, 2020 WL 5500165, at *23 (D. Md. Sept. 11, 2020) (explaining that the agency "must actually give meaningful consideration to these concerns," and "cannot 'brush aside' important facts, or [merely] offer 'conclusory statements.'") (citations and modifications omitted); *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n. 58 (D.C. Cir. 1977) (Significant comments are those "which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule."). Here, the agency itself acknowledged that, as a result of its audit guidelines, manufacturers had rarely engaged in audits, and it therefore explicitly invited comment "on whether it is appropriate or necessary to modify the guidelines concerning audits prior to implementing" the ADR process. 75 Fed. Reg. at 57235. PhRMA and numerous other organizations responded to this invitation by providing detailed, reasoned explanations of the significant problems the audit guidelines pose to manufacturer-

initiated ADR. HRSA's total failure to provide any substantive response to these comments violates the APA. For this same reason, HRSA acted arbitrarily and capriciously, because it "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

81. Second, HRSA's complete failure to justify the cumbersome requirements for manufacturer audits is compounded by its failure to refresh the record and to consider the evidence submitted in PhRMA's petition.

82. After issuing the 2010 advance notice and the 2016 proposed rule, HRSA abandoned the proposed rule and for more than four years took no action towards creating an ADR process. Yet, when faced with litigation in late 2020 regarding its decade-long delay in undertaking its statutory obligation to promulgate an ADR rule, the agency hastily issued a final rule on December 14, 2020. Because this was hurriedly done in response to litigation, the agency blatantly disregarded PhRMA's request in its petition to consider evidence showing that the existing record was not adequate given the lapse of time and changed circumstances.

83. Indeed, HRSA entirely failed to respond to PhRMA's petition to reopen the record so that PhRMA could submit new, material evidence of how circumstances have changed. That petition set out numerous *government* findings, issued after the comment period on the 2016 proposed rule had closed, showing that the 340B Program is increasingly plagued by significant compliance issues associated with the recent explosive growth of contract pharmacies, as well as the lack of a clear "patient" definition. That evidence shows that manufacturer-initiated ADR claims are essential to identifying

and preventing diversion and duplicate discounts, particularly in light of HRSA's general failure to enforce these requirements, and that it is all the more unreasonable to require manufacturers to comply with burdensome audit guidelines in order to bring such claims. HRSA's decision to turn a blind eye to that evidence, and to press forward based on a stale record, was arbitrary and capricious. *See Mobil Oil Corp. v. U.S. EPA*, 35 F.3d 579, 585 (D.C. Cir. 1994).

SECOND CAUSE OF ACTION

(Declaratory/Injunctive Relief—The Manufacturer Audit Guidelines, Which HRSA Effectively Incorporated in the ADR Rule, are Contrary to Law)

84. The prior paragraphs of the Complaint are incorporated by reference.

85. Section 340B authorizes HHS to create "procedures . . . relating to the number, duration, and scope of audits" conducted by manufacturers. 42 U.S.C. § 256b(a)(5)(C). The 1996 audit guidelines, as re-adopted by HHS on June 29, 2020, *see* note 1, and as further reiterated and readopted in the ADR Final Rule as a required precondition to manufacturer-initiated ADR, exceed this limited grant of authority and are therefore unlawful in at least two ways.

86. First, the audit guidelines impermissibly require manufacturers to establish "reasonable cause" to believe that a covered entity has violated the prohibitions on diversion or duplicate discounts before they can even commence an audit. *See* 61 Fed. Reg. at 65409. That requirement is not a "procedure[] . . . relating to the number, duration, [or] scope" of audits. It is an extra-statutory substantive restriction on manufacturers' ability to institute audits. Indeed, HRSA's authority to prescribe audit guideline

"procedures" appears in a part of the statute that imposes requirements on covered entities, not on manufacturers, *see* 42 U.S.C. § 256b(a)(5). This provision immediately follows the prohibitions on duplicate discounts and diversion, *id.* § 256b(a)(5)(A)&(B), and it is set forth in a subsection that requires covered entities to permit audits by HRSA and manufacturers.

87. The statutory context makes clear that HRSA's authority is limited to preventing misuse of the manufacturers' audit right—*i.e.*, to ensure that a manufacturer does not engage in too many audits, or audits that are overbroad and unduly long. The reference to the "number" of audits is not a grant of authority to limit the circumstances in which a manufacturer can commence any audit at all. Indeed, it is valid and reasonable for manufacturers to conduct audits based on general risk factors, just as HRSA recognizes that covered entities may conduct "spot audits" of their contract pharmacies, 75 Fed. Reg. at 10278, and just as HRSA itself—pursuant to its audit authority under the 340B statute—conducts both "targeted" and "risk-based" audits of covered entities, Dec. 2020 GAO Rep. at 11 n.22 ("HRSA's audits include covered entities that are randomly selected based on risk-based criteria . . . and those that are targeted based on information from stakeholders such as drug manufacturers about potential noncompliance."); *see also* HRSA, *Program Integrity: Audits of Covered Entities*, *available at* https://bit.ly/39NXQxt (Date Last Reviewed: April 2020). The ADR Final Rule thus establishes a Catch 22 for manufacturers who cannot institute an ADR proceeding without completing an audit first: Manufacturers may not initiate the required audit without "reasonable cause," but they may not use a risk-based audit to uncover potential violations in the first place.

88. Second, the guidelines' requirement that manufacturers employ third parties to conduct audits, *see* 61 Fed. Reg. at 65409, conflicts with the plain language of Section 340B, which directs covered entities to "permit the Secretary and *the manufacturer* . . . to audit at the . . . manufacturer's expense the records of the entity that directly pertain to the entity's compliance." 42 U.S.C. § 256b(a)(5)(C) (emphasis added).

THIRD CAUSE OF ACTION

(Declaratory/Injunctive Relief—Selecting ADR Board Members Without Senate Confirmation Violates the Appointments Clause)

89. The prior paragraphs of the Complaint are incorporated by reference.

90. The Appointments Clause, Article II, Section 2, Clause 2 of the U.S. Constitution, provides that executive branch officers shall be appointed by the President "by and with the advice and consent of the Senate," except that "Congress may by law vest the appointment of such inferior officers, as they think proper, in the President alone, in the courts of law, or in the heads of departments." "The Appointments Clause prescribes the exclusive means of appointing 'Officers.'" *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018).

91. The Appointments Clause "is among the significant structural safeguards of the constitutional scheme." *Edmond v. United States*, 520 U.S. 651, 659 (1997). "By vesting the President with the exclusive power to select the principal (noninferior) officers of the United States, the Appointments Clause prevents congressional encroachment upon the Executive and Judicial Branches." *Id.* Although it may be administratively convenient for other persons to appoint officers, "that convenience was

deemed to outweigh the benefits of the more cumbersome procedure only with respect to the appointment of 'inferior Officers.'" *Id*. at 660.

92. ADR Board members are "officers" of the United States. They are appointed for a "continuing" term, *Lucia*, 138 S. Ct. at 2051, 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). Indeed, under the ADR rule, HHS has directed them to make critical legislative policy judgments. Further, they can "take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders." *Id*. (quoting *Freytag*, 501 U.S. at 881-82); *see also* 42 C.F.R. §§ 10.23, .22(b)-(c); 85 Fed. Reg. at 80641.

93. Moreover, ADR Board members are "principal officers" of the United States. They independently determine how to conduct proceedings, and make final precedential determinations for HHS that are not subject to any further executive branch review, much less by agency officials who are appointed by the President and confirmed by the Senate. By statute, the decision under the ADR process is "a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

94. ADR Board members are "principal officers" because they may be removed from panels only "for cause." 85 Fed. Reg. at 80634. Thus, in their conduct of ADR panels, they are not supervised or directed by any superior officer. *See Edmond*, 520 U.S. at 662 ("Generally speaking, the term 'inferior officer' connotes a relationship with some higher

ranking officer or officers below the President: Whether one is an 'inferior' officer depends on whether he has a superior.").

95. Because ADR Board members are principal officers, they must be appointed by the President with the Senate's advice and consent. The ADR Rule therefore violates the Appointments Clause by vesting the power to appoint Board members in the Secretary alone.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests judgment against Defendants as follows:

- A declaration that the ADR Rule is arbitrary, capricious, an abuse of discretion, and otherwise contrary to law, that the 1996 manufacturer audit guidelines are contrary to law, and that the mode of appointment for ADR Board members violates the Appointments Clause of the Constitution;
- A permanent injunction prohibiting Defendants from implementing or enforcing the ADR Rule, and vacating and setting the ADR Rule aside;
- Award of PhRMA's attorney fees and costs; and
- Such other relief as this Court may deem just and proper.

Date: January 22, 2021

By: _____/s/ *Sujit Raman*_____

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Exhibit A

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PETITION FOR RULEMAKING REGARDING AN ADMINISTRATIVE DISPUTE RESOLUTION PROCESS FOR THE 340B DRUG PRICING PROGRAM

(RIN 0906–AA90 and RIN 0906–AB26)

Pursuant to 5 U.S.C. §§ 553(e), 555(b), and 555(e), submitted to:

THE HEALTH RESOURCES AND SERVICES ADMINISTRATION
THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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November 24, 2020

Pharmaceutical Research and Manufacturers of America, Petitioner

TABLE OF CONTENTS

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STATEMENT OF PETITIONER

The Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby petitions the Secretary of the Department of Health and Human Services "HHS"), and the Administrator of the Health Resources and Services Administration ("HRSA"), as well as the Director of HRSA's Office of Pharmacy Affairs ("OPA"), to issue a new proposed rule establishing an administrative dispute-resolution ("ADR") procedure for participants in the 340B Drug Pricing Program. PhRMA supports the goal of the 340B program, which is to make prescription drugs more accessible to uninsured or vulnerable patients. But, as PhRMA explains in detail below, there is significant new evidence that the 340B program is plagued by abuses that are undermining that goal and HRSA has been unwilling to hold covered entities accountable for those abuses. *Genesis Health Care v. Azar*, No. 4;19-cv-1531-RBH (D. S.C. Dec. 18, 2019). Accordingly, as part of this petition, PhRMA reiterates its prior requests that HRSA include a precise definition of "patient" as well as practical audit procedures. Both elements are essential to an efficient ADR process, which is in turn critical to maintaining the integrity of the 340B program and ensuring that the program achieves its intended purpose.

It has been more than four years since HRSA previously proposed an ADR rule in 2016, only to abandon it in 2017. As a result of recent litigation against HHS for failing to issue an ADR rule, an ADR final rule has been sent to the White House Office of Management and Budget ("OMB") Office of Information and Regulatory Affairs ("OIRA") for review, https://www.reginfo.gov/public/do/eoReviewSearch (last visited Nov. 22, 2020), and it appears HRSA plans to complete its rulemaking without affording affected parties adequate opportunity to comment on the material changes that have occurred in the 340B program's operation since the close of the 2016 comment period. Rushing to publish an abandoned ADR rule based on dated comments is plainly inconsistent with the Administrative Procedure Act ("APA"). The four year-old record before HRSA is stale, and does not reflect the explosive growth in contract pharmacies, which are not mentioned in the 340B statute and stem from non-binding guidance, and the corresponding increase in diversion and other abuses that have occurred since 2016, as documented by the HHS Inspector General, Congress and the Government Accountability Office, among others. HRSA cannot engage in the reasoned and non-arbitrary decisionmaking that the APA requires based on a record that is plainly past its useful life. HRSA must therefore open a new comment period to ensure that the ADR rule it promulgates will promote the purposes of the 340B program as it currently exists, not as reflected in the now-stale record it assembled in 2016.

It is of course indisputable that an ADR rule is required by law. See 42 U.S.C. § 256b(d)(3). But the agency also has an obligation to ensure that the ADR rule protects the 340B program's integrity, which in turn ensures that the program

benefits the patients Congress intended it to serve. To achieve these goals, the ADR rule must rest upon a more precise definition of "patient" under the 340B program. It must also be based on practical audit procedures, so manufacturers can meaningfully access the ADR process, which Congress designed to help HRSA resolve claims of unlawful diversion and duplicate discounts left unresolved after good faith negotiations between the parties. PhRMA and others provided comments on these and other issues in the 2016 ADR rulemaking. In addition, PhRMA has sought clarity and precision in the patient definition for many years in repeated comments to HHS and in response to Congress. *See, e.g.*, PhRMA, Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA) (Oct. 27, 2015), https://bit.ly/3nXZq55; PhRMA, Comment Letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018), https://bit.ly/366NRTr; PhRMA, Comment Letter in Response to Senator Lamar Alexander and Congressman Greg Walden's Request for Input on Modernizing 340B Drug Pricing Program (Oct. 30, 2020), https://onphr.ma/2VbZ12Z. But the need and justifications for PhRMA's earlier requests and proposals have become much clearer in light of significant events and trends reflecting how the 340B program now functions in the real world.

Specifically, significant new evidence has emerged since 2016 reflecting serious problems in the 340B program, including diversion of drugs, duplicate discounts, and other abuses by covered entities that exploit the lack of a "patient" definition. The increase in these abuses has occurred in tandem with an explosive growth in arrangements between covered entities and contract pharmacies—arrangements that create market-distorting incentives, to the detriment of both the 340B program and patient care. HRSA cannot simply rush ahead with its previous 2016 proposal without reopening the record in order to consider those changes.

Accordingly, HRSA should instead issue a new proposed rule and open a new comment period pursuant to 5 U.S.C. § 552(e) so stakeholders have the opportunity to comment on the proposed rule and provide fresh evidence on critical program issues. At the very least, HRSA should re-open the comment period on its prior proposed rule for 60 days, to allow stakeholders to submit comments regarding the new evidence and issues that have arisen since that rule was abandoned, and HRSA should revise the proposed rule in response to these issues. After years of inaction, HRSA should not rush to finalize its deeply flawed proposed rule in order to avoid responding to lawsuits. Doing so will simply compound the legal deficiencies in the 2016 proposed rule and make it more vulnerable to legal challenges under the APA.

STATEMENT OF INTEREST

PhRMA is a voluntary, non-profit organization representing the nation's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to lead longer, healthier, and more productive lives. PhRMA is committed to advancing public policies that

support innovative medical research, yield progress for patients today, and provide hope for new treatments and cures in the future. To advance these goals, PhRMA serves as the pharmaceutical industry's principal public policy advocate before Congress, regulatory agencies, and the courts.

PhRMA supports the goals of the 340B program, which Congress enacted to help make prescription drugs more accessible to uninsured or otherwise vulnerable patients. PhRMA submits this petition to ensure that HRSA appropriately addresses the serious issues with the current operation of the program, so that in future years the program can be strong, sustainable, and administered fairly and consistently with the 340B statute. This petition incorporates by reference the comments previously submitted by PhRMA in response to the agency's 2016 proposed ADR rule, see PhRMA, Comment Letter on Proposed Rule for Administrative Dispute published by the Health Resources and Services Administration (HRSA) (Oct. 11, 2016), https://bit.ly/3pVnrvA, and 2015 proposed omnibus guidance, see PhRMA, Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA) (Oct. 27, 2015), https://bit.ly/3nXZq55.

BACKGROUND

Congress established the 340B program in 1992 to improve access to essential medications for certain poor, uninsured, and otherwise vulnerable patient groups. *See* H. Rep. No. 102-384 (II), at 11-13 (1992); *see also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act). Under the program, drug manufacturers as a condition of participating in Medicaid must charge no more than a deeply discounted "ceiling price" to specified "covered entities" on certain outpatient prescription drugs. 42 U.S.C. § 256b(a)(4).

Congress recognized that this program needed limits to ensure that the typically steep manufacturer discounts on drugs reached the covered entities listed in the 340B statute. It therefore wrote two crucial safeguards into the 340B statute to protect against abuse and to ensure that the program serves its intended public purpose. Among other things, the statute prohibits "duplicate-discounts," sales on which a manufacturer is charged both a 340B discount and a Medicaid Drug Rebate Program rebate. *See* 42 U.S.C. § 256b(a)(5)(A). In addition, the statute's "anti-diversion" provision prohibits covered entities from "resell[ing] or otherwise transfer[ing]" 340B drugs to anyone "who is not a patient of the [covered] entity." *Id.* § 256b(a)(5)(B).

Congress amended the 340B program in 2010 as part of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. *See* Patient Protection and Affordable Care Act of 2010 § 7102, Pub. L. No. 111-148, 124 Stat. 119, 826–27 (Mar. 23, 2010); Health Care and Education Reconciliation Act of

2010 § 2302, Pub. L. No. 111-152, 124 Stat. 1029, 1082–83 (Mar. 30, 2010) (collectively, the Affordable Care Act ("ACA")). As part of those 2010 amendments, Congress directed the agency to improve covered entity compliance with the program's anti-diversion and duplicate-discount prohibitions. *See* 42 U.S.C. § 256b(d)(2)(A). Congress also instructed the agency to establish and implement "an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under [the 340B program], and [of] claims by manufacturers" that covered entities have generated duplicate discounts or allowed 340B covered drugs to be transferred to non-patients. 42 U.S.C. § 256b(d)(3)(A). HRSA was to establish this ADR process "not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act [March 23, 2010]." *Id.*

On September 20, 2010, HRSA published an advance notice of proposed rulemaking regarding the ADR process. *See 340B Drug Pricing Program Administrative Dispute Resolution*, 75 Fed. Reg. 57,233, 57,233 (Sept. 20, 2010). On August 12, 2016, HRSA issued a notice of proposed rulemaking, *340B Drug Pricing Program; Administrative Dispute Resolution Process*, 81 Fed. Reg. 53,381 (Aug. 12, 2016). In October 2016, PhRMA and other organizations submitted comments demonstrating that the rule HRSA proposed was inadequate, unlawful, and contrary to the statute's requirements. *See* OMB, 340B Drug Pricing Program; *Administrative Dispute Resolution Process*, RIN 0906-AA90, https://bit.ly/2HBbCJK. Not surprisingly, the flawed proposed rule was abandoned on August 1, 2017. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), https://bit.ly/3q1t37o (reflecting that the ADR proposed rule was abandoned on August 1, 2017).

Recently, two lawsuits were filed against the agency in federal district court for the District of Columbia. *Ryan White Clinics for 340B Access, et al. v. Azar, et al.*, No. 20-cv-2906, ECF No. 1 (D.D.C. Oct. 9, 2020); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar & U.S. Dep't of Health & Hum. Servs.*, No. 20-cv-3032, ECF No. 1 (D.D.C. Oct. 21, 2020). Each lawsuit seeks, among other things, a writ of mandamus ordering the agency to promulgate an ADR rule, on the ground that the statutory deadline has passed, and the agency has unreasonably delayed taking action. Apparently in response to these lawsuits, HRSA has sent a 340B ADR final rule to OMB for review and approval.

REASONS FOR NEW ADR RULEMAKING AND COMMENT PERIOD

PhRMA files this petition to express its deep concern with HRSA's apparent plan to finalize the abandoned 2016 proposed rule without considering both the changes in circumstances in the years since the prior comment period, and the numerous deficiencies with the proposed rule outlined in the prior comments. Among other things, the proposed rule cannot be issued without a clear and adequate definition of "patient" and appropriate audit guidelines in place. HRSA should instead develop a new proposed rule, or at least re-open the comment period for the

ADR proposed rule, to account for material new developments relevant to any ADR process.

A. Changed Circumstances and New Evidence Since 2016 Require a New Comment Period.

As a threshold matter, finalizing the 2016 proposed rule rather than undertaking a new notice-and-comment rulemaking proceeding would not satisfy the requirements of the APA. There is no good cause to dispense with the APA's notice-and-comment requirements; the agency's apparent desire to avoid litigating the recently-filed suits does not justify a last-minute rush to finalize a flawed proposal after years of inaction. *See, e.g., Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93-95 (D.C. Cir. 2012) (holding agency lacked "good cause" for promulgating emergency interim rule because notice and comment was not impracticable or unnecessary); *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754-55 (D.C. Cir. 2001) (similar).

Nor does the 2016 comment period on the proposed rule obviate the need for a notice-and-comment proceeding here. "[T]he life of [a notice and comment] record is not infinite." *Mobil Oil Corp. v. U.S. EPA*, 35 F.3d 579, 585 (D.C. Cir. 1994). Rather, 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.* That is particularly the case here, given the new evidence of problems that has come to light in the years since the close of the comment period in 2016 and abandonment of the ADR rule in 2017.

Here, changes in circumstances and new evidence demonstrate that the prior 2016 comment period is past its "useful life." *Id.* Since 2016, Congress, independent agencies, and even HRSA have compiled evidence that the 340B program is rife with compliance abuses. The most significant change in the 340B program since 2016 has been the dramatic increase in the number of covered entities and the use of contract pharmacies, which has corresponded with a dramatic increase in unlawful drug diversion and duplicate discounts, as well as other new for-profit entities.

- The 340B program continues to experience explosive growth, tripling in size since 2014, with little change in regulatory oversight to keep pace with this rapidly evolving program. According to a 2018 GAO Report, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 20,000 in 2017. GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (June 2018), https://bit.ly/3kZYAD7.

- As of October 2020, there apparently are approximately 25,000 unique contract pharmacy locations across the country and more than 170,000 arrangements between contract pharmacies and 340B covered entities. *See* HRSA, 340B

Contract Pharmacy Database, https://bit.ly/39qpNNp (last visited Nov. 22, 2020).

- Starting in 2016, a new pattern of vertically integrated specialty pharmacy enrollments emerged. In January 2016, there were 1,473 contract pharmacy arrangements between 340B covered entities and these vertically integrated specialty pharmacies. By April 2020, this count had grown to 16,293—a 1,006 percent increase in four years. *See* Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* (October 2020), https://bit.ly/2KzNFDD; *see also* Sunita Desai & J. Michael Williams, *Consequences of the 340B Drug Pricing Program*, N. Engl. J. Med. (Feb. 8, 2018), https://bit.ly/362pcz5.

This unchecked program growth has been reported in the years that followed the close of the comment period to the ADR proposed rule. For example, the House Energy and Commerce Committee has found that "the number of participating unique covered entities has grown from 3,200 in 2011…to 12,722 in October 2017." H. Comm. on Energy & Commerce, Review of the 340B Drug Pricing Program, 114th Cong., at 44 (Jan. 10, 2018) ["2018 House Report"]. The 2018 House Report went on to state that: "As of October 1, 2017, 42,029 registered covered entity sites were participating in the 340B program, including 12,722 covered entity (parent) sites and 29,307 associated (child) sites." *Id.* at 13. As a result, the sale of discounted 340B drugs has exploded beyond any measure that Congress contemplated. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug* Sales, Drug Channels (June 9, 2020) ["2020 Drug Channels Report"]. By 2019, discounted drugs purchased through the 340B program accounted for at least 8% of the total U.S. drug market, amassing $29.9 billion in sales that year, an "astonishing" 23% increase over sales in 2018. *See* 2020 Drug Channels Report (noting that "the 340B program is now almost as large as the Medicaid program's outpatient drug sales").

Similarly, the rapid growth in the number of commercial contract pharmacies participating in the 340B program—from 1,256 in 2010 to more than 27,928 in 2020—has occurred since the 2016 comment period closed. *See* Adam. J. Fein *A Primer on 340B Contract Pharmacies and Medicaid Duplicate Discounts (video)*, Drug Channels (Oct. 22, 2020); *see also* Adam J. Fein, *Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?*, Drug Channels (July 14, 2020). OIG flagged this problematic unchecked growth in 2018 congressional testimony, where OIG noted that it had "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." 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 (May 15, 2018), at 5.

The explosive growth in the number of covered entities and contract pharmacies has not resulted in any guaranteed benefit to patients but instead has coincided with significant increases in diversion of 340B drugs. In 2018, the House Energy and Commerce Committee found that nearly half—and in some years more than half—of audited covered entities unlawfully sold or transferred 340B drugs to nonpatients. *See* 2018 House Report at 38 (noting that audit information from 2012 through 2016 shows that nearly half of audited covered entities were involved in unlawful diversions to non-patients). Likewise, in 2020 and 2018, the GAO concluded that the sharp growth in contract pharmacy arrangements sharply increased the risk of both duplicate discounts and unlawful diversion. *See* GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020) ["2020 GAO Report"]; *see also* GAO, GAO-18-480, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) ["2018 GAO Report"]. For example, GAO found that approximately two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." *Id.*; *see* HHS, HRSA, *Program Integrity: FY18 Audit Results*. 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. Equally troubling, HRSA does not terminate covered entities when there are findings of noncompliance. For instance, in one case where HRSA initially concluded that a covered entity had violated 340B requirements, the lack of a clear definition of "patient" hampered its enforcement efforts, and ultimately both the enforcement measures and audits were withdrawn. *Genesis Health Care v. Azar*, No. 4;19-cv-1531-RBH (D. S.C. Dec. 18, 2019).

Unlike in-house pharmacies, contract pharmacies do not possess and do not have access to the records of the covered entity's patients. *See* Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions, 115th Cong. 6 (May 15, 2018) (statement of Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, HHS OIG) ("Retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores."); *see also* Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of H. Comm on Energy and Commerce, 115th Cong. (July 18, 2017) (Statement of Erin Bliss, Assistant Inspector General, Office of Evaluation and Inspections, HHS OIG).

While the growth in covered entities and contract pharmacies has coincided with growth in diversion and duplicate discounts, it has not resulted in benefits to the low income and vulnerable patients the program is intended to help. Indeed, HRSA imposes no requirement on covered entities to share 340B discounts with their patients, nor does the agency require contract pharmacy arrangements to ensure that 340B patients receive any portion of the 340B discounts. Instead, covered entities are permitted to keep all of the revenue for 340B discounts if they choose to do so, or even to share it with contract pharmacies.

Troublingly, government reports have found that many covered entities do, in fact, fail to pass on any portion of the 340B discount to their patients, even as they share a portion of the discounts with their commercial entity, for-profit contract pharmacies. *See, e.g.,* 2018 GAO Report at 30, https://bit.ly/3kZYAD7 (finding that, of 55 covered entities that responded to a questionnaire, only 30 stated that they provide low-income, uninsured patients with discounts on 340B drugs dispensed at some or all of their contract pharmacies, and that 25 said they do not offer 340B discounts to patients at their contract pharmacies); 2018 House Report, at 32–34 (finding that contract pharmacies typically not only charge a dispensing fee for their role in distributing covered outpatient drugs, but also ensure that they receive a share of the revenue that the covered entity receives through the 340B-discounted price).

To the contrary, 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." Ltr. from Adam J. Fein to the Hon. Lamar Alexander and the Hon. Greg Walden (Oct. 30, 2020). And among other things, contract pharmacies often fail to extend 340B pricing to the low income or uninsured patients to whom they dispense, instead siphoning manufacturer discounts from covered entities in the form of "spread-splitting" and service fees. *See* Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall St. J. (Sept. 10, 2020); *see also* PhRMA, *New Analysis Shows Contract Pharmacies Financially Gain from 340B Program with No Clear Benefit to Patients*, Press Release (Oct. 8, 2020). *See, e.g.*, 2018 GAO Report at 30, https://bit.ly/3kZYAD7; HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014), https://bit.ly/2UZSCaM.

In addition, new studies show that the amount of charitable care provided by covered entities has *decreased*. Evidence published in 2019 shows that, between 2013 and 2017, the total value of uncompensated care (as a proxy for charity care) is estimated to have declined from $46.8 billion to $38.4 billion. *See* Adam. J. Fein, *340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019) ["2019 Drug Channels Report"] (noting that uncompensated care as a percentage of total expenses has hit a historic low, declining from 5.9% in 2013 to 4.0% in 2017).

Covered entities are also directing more resources to wealthier and better insured individuals—specifically, they are charging full price for the drugs that the entities themselves receive at a deep discount. *See* Rena M. Conti, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs (Oct. 2014), https://bit.ly/2J5qvok. Many covered entities have acquired distant child sites in affluent communities to turn previously independent physician offices and clinics into 340B sites, expanding their opportunities to dispense discounted 340B drugs to commercially insured patients

(and non-eligible individuals). In addition, and ironically, this shift often causes government and private payors to pay *more* in reimbursement (hardly "stretching scarce federal resources"). *See* Peter B. Bach & Raina H. Jain, *Physician's Office and Hospital Outpatient Setting in Oncology: It's About Prices, Not Use*, J. of Oncol. Pract. Volume 13 Issue, 1 (Jan. 2017). These increased costs are also borne by patients with coinsurance obligations when based off a non-discounted price, not the deeply discounted 340B price.

Further, in the Medicare Part B context, government reports—and rulemaking from HHS/CMS itself—have found and emphasized the extent to which 340B program discounts result in significant financial losses for the Medicare program. For example, government reports and rulemaking from HHS/CMS have demonstrated that hospitals participating in the 340B Program typically paid between 20 percent and 50 percent *below* the average sales price (ASP) that is used as a metric for Medicare Part B reimbursement of most prescription drugs when they acquired Part B drugs—but, they received the full reimbursement from Medicare. *See* GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), https://bit.ly/3fx8Npu; *see also* CMS, Hospital Outpatient Prospective Payment System Proposed Rule Calendar Year 2021, 85 Fed. Reg. 48,772, 48,886 (Aug. 12, 2020) ("We estimate that the typical acquisition cost for 340B drugs for hospitals paid under the [Medicare Hospital Outpatient Prospective Payment System] is ASP minus 34.7 percent"). *See also Am. Hosp. Ass'n v. Azar* (D.C. Cir. July 31, 2020), slip op. at 6 (noting the "large gap between the amount a 340B hospital would spend to acquire a [prescription drug] and the higher amount Medicare would reimburse that hospital. The gap ranged from 25% to 55% of the cost of the drug"). Indeed, HHS and CMS acknowledged, in the rulemaking for the Medicare Part B program, that this hospital outpatient reimbursement gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs," 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017)—at the expense of the Medicare program. The government prevailed earlier this year in the D.C. Circuit in litigation that hospitals brought to challenge cuts the agency made in these 340B hospital reimbursement rates. *See Am. Hosp. Ass'n v. Azar*, *supra*. And, further reflecting the agency's efforts to address the 340B program's negative impact on Medicare, CMS has proposed to continue and potentially even increase these 340B hospital reimbursement cuts under Part B going forward. *See* 85 Fed. Reg. at 48,886.

The unchecked expansion of the 340B program has also resulted in increased treatment costs. Indeed, the 340B program drives care away from less expensive physician office settings into more expensive hospital settings:

> [M]edical-benefit drug costs for these patients in the hospital outpatient setting cost more than twice as much as in the physician office setting. Due to these types of price differences,

> the hospital outpatient setting is typically the highest-cost setting for administration of medical benefit drugs.

Aaron Vandervelde & Eleanor Blalock, *Site of Care Shift for Physician-Administered Drug Therapies*, Berkeley Research Group, 3 (Oct. 2017). Likewise, the 2018 House Report provided another illustrative example, noting that in Atlanta, "after Northside acquired Atlanta Cancer Care in 2013, the out of pocket cost of treatment for one patient rose from $20 to $212, a more than 1000 percent increase." 2018 House Report, at 68.

Several government entities have raised concerns about market distortions caused by the program's expansion. The 2018 House Report noted that the 340B program is affecting "market dynamics" in ways that "should be concerning to everyone focused on improving patient care":

> The committee has been unable to determine at this time how frequent or widespread such dynamics may be. However, the sincere concerns expressed by numerous health care providers who have witnessed these challenges suggest there may be at least some negative consequences of market dynamics associated with the 340B program. Given the widespread agreement between all covered entities that the aim of the 340B program is to assist these entities in providing care to patients, first-person reports of negative patient impacts or patient harm should be concerning to everyone focused on improving patient care.

2018 House Report, at 68. HHS, OIG, and GAO have identified unchecked program growth as an area of significant concern because of the unknown consequences in the shifts in behavior. *See* GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight, Testimony Before H. Comm. on Energy & Commerce*, 113th Cong., 1–3 (July 18, 2017) (statement of Debra A. Draper, Director, Health Care, GAO).

The foregoing is not an exhaustive recitation of the problems and new evidence that has arisen in the 340B program since 2016. These examples, however, are more than sufficient to show that stakeholders should be afforded the opportunity to supplement the record to ensure that any final ADR rule can take account of, and address, these material developments in the 340B program. Due to the changed circumstances since the 2016 comment period, it would violate the APA for HRSA to finalize the abandoned proposed rule without taking into proper consideration the new evidence, and making the necessary alterations to the proposed ADR process to address these problems.

B. The Abandoned 2016 Proposed Rule Cannot Be Finalized.

To survive review under the APA's arbitrary and capricious standard, the agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). An agency determination is arbitrary and capricious if it is not "based on a consideration of the relevant factors," "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or "there has been a clear error of judgment." *Id.*; *see also, e.g., Whitaker v. Thompson*, 248 F. Supp. 2d 1, 13 (D.D.C. 2002) ("[T]he basic finding upon which the [agency] rests its decision . . . is unreasonable because it is not supported by an overall review of the available evidence . . . .").

Here, the agency's 2016 proposed rule was invalid at the outset because it did not include "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii). That directive reinforces the agency's obligation to "provide for improvements in compliance by covered entities . . . in order to prevent diversion and violations" of the statutory prohibition on duplicate discounts. *Id.* § 256b(2)(A). To satisfy those obligations, the agency needs to adopt a precise patient definition and audit procedures. The impacts of these deficiencies have only become more pronounced, as unchecked abuses in the program have grown. The agency cannot continue to turn a blind eye to evidence of the explosive growth in the 340B program and the abuses that growth has spawned since the close of the 2016 comment period. This new evidence underscores the need to implement a patient definition that has undergone adequate notice-and-comment rulemaking and to eliminate the restrictions manufacturers face in accessing the ADR process, so that key participants in the program can use the ADR process to resolve claims in a fair, efficient, and timely manner.

To be effective, all participants in a dispute resolution process—including those who administer it—must understand the governing standards, including the definition of patient and appropriate audit procedures. Leaving the development of key elements of these standards to case-by-case decision-making is the antithesis of an efficient system. It is also inconsistent with the statutory requirement that the agency "*shall*" establish "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii) (emphasis added). In many cases, a dispute between a covered entity and a manufacturer turns on whether the recipient of the 340B drug is a patient entitled to receive that drug under the statute. Accordingly, the ADR process cannot possibly be efficient and expeditious until the agency has adopted a clear and adequate definition of the statutory term "patient."

Likewise, the 2016 proposed rule was promulgated without the fair and adequate audit procedures necessary to investigate diversion and duplicate discount

violations. These audit procedures are critically important for manufacturers because an audit is the gateway to the ADR process, as it is a required prerequisite under the statute and provides a basis for asserting that the covered entity has violated the diversion or duplicate-discount prohibitions. *See* 42 U.S.C. § 256b(d)(3)(A), (B)(iv). Limitations in the current audit guidelines prevent manufacturers from availing themselves of a process HRSA has said should be "fair, efficient, and [facilitate] timely resolution of claims." 81 Fed. Reg. 53381, 53385 (Aug. 12, 2016).

For these reasons, the agency must take into account new evidence as part of a new notice and comment rulemaking process to protect the program's integrity and stakeholder rights under the APA.

PROPOSED PATIENT DEFINITION AND AUDIT PROCEDURES

Before finalizing an ADR rule, consistent with our prior comments, and in light of the new evidence, the agency should provide a notice and comment period that (i) allows stakeholders to comment on the definition of "patient" and key policies and terms necessary to ensure a meaningful, fair, and effective dispute-resolution process, and (ii) provides clear manufacturer audit procedures for investigating and adjudicating disputes, including claims that a covered entity has diverted discounted drugs to nonpatients.

A. The Agency Should Adopt a Definition of "Patient" to Ensure That the Dispute-Resolution Process is Meaningful and Promotes the Integrity of the 340B Program.

Nearly 30 years ago, HRSA issued a "patient" definition. HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55,156 (October 24, 1996). According to that notice, an "individual is a 'patient' of a covered entity . . . if:

> " 1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
>
> 2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center

> look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement."

61 Fed. Reg. at 55,157. The definition excludes anyone who receives no other health care from the covered entity other than "the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." *Id*. at 55,158.

The 1996 notice was inadequate to ensure program integrity because the definition lacked needed clarity and specificity. HRSA and other government agencies such as GAO have recognized some of these problems. For example, GAO has stated that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for purposes of 340B" and that this has "raised concerns that the guidance will be interpreted too broadly." GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 22 (Sept. 2011); *see also* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient," 72 Fed. Reg. 1543, 1544 (reflecting HRSA's own statement that "it is possible that some 340B covered entities may have interpreted the definition [under the 1996 'patient' definition guidance] too broadly, resulting in the potential for diversion of medications purchased under the 340B Program"). GAO further noted that, "[a]s a result of the lack of specificity in the 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." GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011). Since putting forward the 1996 guidance, the agency has on two separate occasions proposed a new patient definition. *See* 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007); 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015). Yet the agency did not finalize either proposal, and they are no longer being actively considered.

The agency should therefore adopt a definition for when an individual is a patient of a covered entity, on a prescription-by-prescription and order-by-order basis. The following six requirements were largely proposed by HRSA in 2015 and are necessary to protect the 340B program's integrity and to ensure that the program serves its lawful public purposes. Below each of these we offer additional improvements to bring needed clarity to the definition.

(1) *The individual receives a health care service at a covered entity site that is registered for the 340B Program and listed on the public 340B database.*

An individual must receive a health care service from a covered entity, and the covered entity must be medically responsible for the care provided to the individual. An individual who sees a physician in a private practice that is not listed on the public 340B database or at any other non-340B site of the covered entity, even as follow-up to care provided at a covered entity, would not be eligible to receive drugs obtained under the 340B Program for the services provided at these non-340B sites or for prescriptions that originate from the services provided at these non-340B sites.

An individual is not considered a patient of the covered entity if the individual's health care that results in the administration or prescription of a covered outpatient drug is provided by another health care organization that has an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization's records, unless the organization with the affiliation arrangement is itself registered under the 340B Program and listed on the public 340B database. Access to an individual's records by a covered entity, by itself, does not make the individual a patient of the covered entity. Merely having a drug dispensed from a contract pharmacy of a covered entity is also not sufficient to establish or renew a patient relationship between an individual and a covered entity.

(2) *The individual receives an in-person*[1] *health care service from a health care provider who is either employed by the covered entity or who is an independent contractor of the covered entity, and in either case the covered entity is authorized to bill for services on behalf of the provider, the provider is listed on the covered entity's Medicare cost report, the provider has direct oversight of the individual's care as it relates to any covered outpatient drug, and the covered entity has responsibility for the care provided.*

Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered-entity-provider relationships that could meet this standard, provided all other requirements of those arrangements are also met. The fact that a provider has privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that provider is a patient of the covered entity for purposes of the

[1] PhRMA supports an appropriately tailored exception to the "in-person" requirement for public health emergencies such as the COVID-19 pandemic.

340B Program. Instead, when an employee or independent contractor provides health care services to an individual on behalf of the covered entity, the covered entity must be responsible for the care provided in order for the individual to qualify as a patient of the covered entity. For the covered entity to be responsible for the care provided, the employee or individual contractor must assign their right to bill and collect payment for services to the covered entity.

If a patient is referred from a covered entity for care at an outside provider that is unaffiliated with the covered entity within the meaning of this section, and receives a prescription from that outside provider, the prescribed drug would not be eligible for a 340B discount at the covered entity. When an individual receives care at several entities, for the individual to be considered a patient of the covered entity with respect to a particular prescription, the prescription must originate during the healthcare service provided at the covered entity, and not at another entity, and should be written by a provider employed by (or as an independent contractor to) the covered entity or by a provider appropriately affiliated with the covered entity, within the meaning and restrictions of this section.

There may be narrow circumstances where a non-hospital entity is 340B-eligible as a result of a HRSA grant that requires it to operate a medical home model of care or otherwise coordinate the care of certain patient populations. In those circumstances, ensuring that patients served by the grantee are referred to other providers as appropriate and closely coordinating with those providers are central to the grantee's ability to fulfill its grant obligations. In those limited circumstances, an individual may qualify as a patient of the covered entity if the grantee refers its patient to a provider for medical services or treatment and the prescription is written by the provider, as long as the grantee takes steps to ensure that only one covered entity seeks a 340B discount on any given prescription.

(3) The individual receives a drug that is directly related to, and is ordered or prescribed by the covered entity provider as a result of, the service described in (2). An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.

An individual qualifies as a patient of a covered entity if the health care service received at the covered entity results in a drug order or prescription for the individual being written by a provider employed by (or as an independent contractor to) the covered entity. An individual

does not qualify as a patient of the covered entity if the covered entity's only relationship to the individual is the dispensing or infusion of a drug. The dispensing of or infusion of a drug alone, without a covered entity provider-to-patient encounter involving the provision of a health care service, does not qualify an individual as a patient for purposes of the 340B Program.

(4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract.

Individuals qualify as patients of a covered entity only if they are receiving health care at a covered entity site from a covered entity provider that is consistent with the health care service or range of services for which the covered entity is 340B-eligible. In the case of a covered entity with 340B eligibility based on receipt of a Federal grant, project, designation or contract, the services provided to the individual must be consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract. In the case of a hospital that is 340B-eligible because it has a contract with a state or local government to care for low-income individuals ineligible for Medicare or Medicaid, the services provided to the individual must be provided within the scope of that contract.

If an individual is receiving services from a child site of a covered entity and the child site's scope of grant, project, or contract is more limited than that of the parent site, the individual will qualify as a patient of the covered entity only if he or she is receiving health care at the child site that is consistent with the health care service or range of services properly delegated to the child site.

(5) The individual is classified as an outpatient when the covered outpatient drug is ordered, prescribed, and dispensed, with the patient's classification status determined by how the services for the patient are billed to and paid by the insurer or third-party payor.

An individual cannot qualify as a patient of the covered entity if his or her care is not properly classified as outpatient. An individual is considered an outpatient for purposes of the 340B Program if his or her health care service is billed as "outpatient" to the individual's insurance or third-party payor (e.g., Medicare or private insurance), and his or her health care service is paid by the individual's insurance or a third-party payor as an outpatient service. Covered entities should maintain auditable records documenting any changes in patient status due to insurer or third-party payor determinations.

A covered entity may not fill "discharge prescriptions" with 340B drugs. A "discharge prescription" does not, however, include prescriptions filled by non-hospital grantees that are responsible for managing the care of the individual both before admission and after discharge.

The outpatient status of individuals who are self-pay, uninsured, or whose care is provided by the hospital covered entity's charity care program, would be determined by the covered entity's documented, auditable policies and procedures. Covered entities would therefore be expected to have clearly defined policies and procedures that they follow to classify individuals consistently as either inpatient or outpatient. Most policies and procedures of covered entities should classify an individual as inpatient or outpatient based on how the services have been billed to Medicare or another third-party payor.

(6) The individual has an ongoing relationship with the covered entity such that the covered entity maintains, owns, controls, and possesses auditable health care records sufficient to demonstrate that the covered entity has an ongoing provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition is met for each 340B drug.

An individual qualifies as a patient of the covered entity if he or she has an established, ongoing relationship with the covered entity such that the covered entity maintains, owns, controls, and possesses auditable health care records that demonstrate that the covered entity has a provider-to-patient relationship with the individual for the health care service that results in the order or prescription and that the covered entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to the individual.

HRSA's 2007 proposed clarification also provided that the covered entity must have "ongoing responsibility" for "the outpatient health care service that results in the use of (or prescription for) 340B drugs," and that "[t]o demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the [340B hospital] or the qualified provider-based facility of the [hospital] within 12 months after the time of the referral." This 12-month standard is reasonable and appropriate. Thus, we recommend that HRSA specify that the 340B provider/patient relationship may begin with an individual's first visit to a covered entity (provided all other elements of the patient definition are met), but that this relationship will end if the individual does not visit the covered entity within 12 months following the visit that resulted in the 340B prescription.

B. The Agency Should Adopt Improved Audit Procedures Necessary to Ensure that the Dispute-Resolution Process is Meaningful and Promotes the Integrity of the 340B Program.

The agency should also adopt improved audit procedures so that manufacturers can reasonably and fairly complete the audits of covered entities that are required in order for manufacturers to access the ADR process. Unfortunately, the existing audit guidelines make manufacturer audits costly and difficult. The result is an arbitrary, one-sided system that drastically exceeds the Agency's authority and unduly limits manufacturers from auditing the abuses that are undermining the integrity of the 340B program and fueling market distortions.

HRSA recognized these unfair barriers to manufacturer audits when it issued an advanced notice of proposed rulemaking in 2010. At that time, the agency requested comments on how make its audit procedures more useful to manufacturers, given that they rarely utilize it. *See* 75 Fed. Reg. at 57,235. In line with that request, PhRMA has provided comments on an audit process that would revise and improve HRSA's existing audit procedures in several respects. *See* PhRMA, Comment Letter on Proposed Rule for Administrative Dispute published by the Health Resources and Services Administration (HRSA) (Oct. 11, 2016), https://bit.ly/3pVnrvA; *see* PhRMA, Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA) (Oct. 27, 2015), https://bit.ly/3nXZq55. Implemented together, PhRMA's proposed improvements will promote manufacturers' use of the audit process to redress program violations. That should help curb the abuses and harmful effects of the program discussed above.

CONCLUSION

For the foregoing reasons, HRSA should issue a new proposed rule and then, after receiving and considering comments, promulgate a final rule establishing an ADR procedure for participants in the 340B Drug Pricing Program. *See* 5 U.S.C. § 552(e). In the alternative and at a minimum, HRSA should re-open the comment period of the ADR rulemaking for at least 60 days.

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

(b) County of Residence of First Listed Plaintiff Washington, D.C.
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Sidley Austin LLP, 1501 K Street, NW, Washington, DC 20005; (202) 736-8000

DEFENDANTS

NORRIS COCHRAN (Acting Secretary of Health and Human Services); U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DIANA ESPINOSA (Acting Administrator of Health Resources and Services Administration); U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION

County of Residence of First Listed Defendant Washington, D.C.
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability			❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		PROPERTY RIGHTS	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability			❒ 820 Copyrights	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 790 Other Labor Litigation	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise			❒ 791 Employee Retirement Income Security Act	❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	IMMIGRATION	FEDERAL TAX SUITS	❒ 893 Environmental Matters
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 895 Freedom of Information Act
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 896 Arbitration
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Administrative Procedure Act, 5 USC 701 et seq.

Brief description of cause:
Challenges Health Resources and Services Administration's issuance of 340B Administrative Dispute Resolution rule

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ❒ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 01/22/2021

SIGNATURE OF ATTORNEY OF RECORD /s/ Sujit Raman

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff(s)

v.

NORRIS COCHRAN, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Norris Cochran, Acting Secretary
c/o General Counsel
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sujit Raman
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff(s)

v.

NORRIS COCHRAN, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Health & Human Services
c/o General Counsel
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sujit Raman
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

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Printed name and title

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Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff(s)

v.

NORRIS COCHRAN, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Diana Espinosa, Acting Administrator
U.S. Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sujit Raman
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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I declare under penalty of perjury that this information is true.

Date: _____

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Server's signature

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Printed name and title

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Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff(s)

v.

NORRIS COCHRAN, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sujit Raman
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

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Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff(s)

v.

NORRIS COCHRAN, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Robert K. Hur
U.S. Attorney for the District of Maryland
c/o Civil Process Clerk
36 S. Charles Street, 4th Floor
Baltimore, MD 21201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sujit Raman
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

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Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff(s)

v.

NORRIS COCHRAN, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Robert M. Wilkinson
Acting U.S. Attorney General
Attn: Civil Process
U.S. Department of Justice 950
Pennsylvania Avenue, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sujit Raman
Sidley Austin LLP
1501 K Street, NW
Washington, DC 20005

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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Date: _____

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Server's signature

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Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: