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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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Pharmaceutical Research and Manufacturers of America, Petitioner

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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.