

EXACERBATING AMBIGUITY: WHY THE FINAL 340B ADMINISTRATIVE DISPUTE RESOLUTION RULE IS A DISTRACTION FROM NEEDED REFORM

*Caryn Levite Marshall**

I. INTRODUCTION

The United States' health care system is one of the most expensive in the world, yet it fails to provide affordable care for millions of patients.¹ Much of this expense results from the high administrative costs of a haphazard system of government agencies, public facilities, and private corporations.² This system treats the exact same provision of care differently based on who the patient is, who provides the care, where the care is provided (both geographically and the type of facility), and what insurance, if any, the patient carries.³

It is against this complex background that Congress enacted the 340B drug pricing law (hereinafter 340B) to enable certain hospitals and health care facilities that serve low-income patients to buy medicines at a steep discount.⁴ It was a well-intentioned federal statute

*J.D. Candidate, 2023, Seton Hall University School of Law; M.B.A. Marylhurst University; M.Phil. Trinity College Dublin; B.A. Cornell University. I would like to express my sincere thanks to my faculty advisor, Professor Jennifer Oliva for her support and guidance, and to Matthew Gallagher, Jane Marshall, and my children for their unwavering support.

¹ ERIC C. SCHNEIDER ET AL., COMMONWEALTH FUND, MIRROR, MIRROR 2021: REFLECTING POORLY 1–4 (2021), <https://www.commonwealthfund.org/publications/fund-reports/2021/aug/mirror-mirror-2021-reflecting-poorly>. In an analysis of the eleven richest countries, the Commonwealth Fund found that despite spending the greatest percentage of its gross domestic product on health care, the United States came last in four out of five categories, including access to care, administrative efficiency, equity, and outcomes. *Id.* at 2.

² *See id.* at 12, 15.

³ *See generally* ROOSA TIKKANEN ET AL., COMMONWEALTH FUND, INTERNATIONAL HEALTH CARE SYSTEM PROFILES: UNITED STATES (June 5, 2020), <https://www.commonwealthfund.org/international-health-policy-center/countries/united-states>.

⁴ Veterans' Health Care Act of 1992, Pub. L. No. 102-585 §§ 601–603, 106 Stat. 4943, 4962–75 (1992) (codified as amended at 42 U.S.C. § 256b).

designed to help vulnerable patients afford vital drugs.⁵ Unfortunately, due to poor drafting language and lack of clear oversight mechanisms, the 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."⁶

In December 2020, the U.S. Department of Health & Human Services (HHS) released a final administrative dispute resolution (ADR) rule designed to adjudicate some of the key areas of contention around the statute.⁷ The ADR process, however, is incapable of addressing 340B's shortcomings without congressional clarification of program goals, mechanisms, and oversight. Promulgation of this rule is thus little more than a distraction from meaningful reform.

This Comment argues that several key reforms are needed for the 340B program to achieve its original promise while mitigating its unintended consequences. Part II provides an overview of the 340B program. Part III examines the statute's unintended consequences. Part IV describes the process that went into the adoption of the final ADR rule, as well as its procedural and substantive deficiencies. Part V places the ADR rule in the context of the current litigation between the pharmaceutical industry and the federal government over contract pharmacy 340B discounts. This Comment concludes by outlining needed reforms to the 340B program, such as clarifying the statute's definitions to enable uniform administration of the program and ensuring that discounts are used to reduce patient costs or improve patient care. This Comment also proposes limiting the amount of money that for-profit pharmacies can skim off the system, and dramatically strengthening oversight of the program. These reforms would help realize the program's goals and make the ADR process both easier to administer and less likely to be invoked.

⁵ CONG. RSCH. SERV., OVERVIEW OF THE 340B DRUG DISCOUNT PROGRAM (2022), <https://crsreports.congress.gov/product/pdf/IF/IF12232>.

⁶ Letter from Adam J. Fein, CEO, Drug Channels Inst., to the Hon. Lamar Alexander and the Hon. Greg Walden (Oct. 30, 2020), <http://www.drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf>.

⁷ 42 C.F.R. § 10.20 (2020).

II. A BRIEF HISTORY OF THE 340B PROGRAM

The 340B drug pricing program is an extension of the Medicaid Drug Rebate Program (MDRP), which was created in 1990 to contain the government's costs for drugs used by Medicaid patients.⁸ MDRP's intent was to restrain prices for Medicaid drugs by requiring drug manufacturers to enter into a rebate agreement with the HSS Secretary in exchange for Medicaid coverage of their products.⁹ MDRP set rebates by a formula based on the drug's Average Manufacturer Price (AMP)¹⁰ and the "best price"¹¹ at which the drug was offered on the market.¹²

Like many significant pieces of legislation, the MDRP had unintended consequences. Since the program did not exempt discounts to government agencies (e.g., the Veterans' Administration Health System) from the calculation of AMP or "best price" calculations, discounts to these agencies lowered the prices manufacturers could charge to the Medicaid program. Thus, the MDRP disincentivized manufacturers from providing rebates they had routinely offered prior to 1990.¹³ This perversely led to an increase in drug costs for the government and prompted Congress to create the 340B program.¹⁴

⁸ Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (codified as amended at 42 U.S.C. § 1396r-8).

⁹ S. REP. NO. 102-259, at 6 (1992); 42 U.S.C. § 1396r-8; *Medicaid Drug Rebate Program (MDRP)*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last visited Feb. 28, 2021).

¹⁰ "Average manufacturer price" is the average price paid by wholesalers purchasing drugs for distribution to retail pharmacies and by retail pharmacies that purchase directly. 42 U.S.C. § 1396r-8(k)(1)(A).

¹¹ "Best price" is the lowest price at which the manufacturer offers the drug during the rebate period to any entity (including wholesalers, retailers, nonprofits and government agencies), with the exception of a few specific government programs. § 1396r-8(c)(1)(C).

¹² § 1396r-8(c)(1)(A)(ii).

¹³ *The Best Price Requirement of the Medicaid Rebate Program*, ACAD. OF MANAGED CARE PHARMACY (Oct. 28, 2021), <http://amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/best-price-requirement-medicaid-rebate-program>; Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. HEALTH CARE L. & POL'Y 25, 30 (2019).

¹⁴ U.S. GOV'T ACCOUNTABILITY OFF., HRD-91-139, MEDICAID: CHANGES IN DRUG PRICES PAID BY VA AND DOD SINCE ENACTMENT OF REBATE PROVISIONS 1-2 (1991), <http://www.gao.gov/assets/hrd-91-139.pdf>.

A. *Creation of the 340B Program*

Congress enacted the 340B program under the Veterans' Health Care Act of 1992 and named it after its authorizing provision in the Public Health Service Act.¹⁵ The program's intent was to help ease financial strain on safety-net hospitals, ensure access to medications for uninsured and underinsured patients, and "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive service."¹⁶ The Health Resources and Services Administration (HRSA) within HHS oversees administration of the program.¹⁷

1. *How the 340B Program Works*

The 340B Program enables covered entities—primarily hospitals that disproportionately serve low-income populations—to purchase drugs from manufacturers at or below the deeply discounted "340B ceiling price" to dispense to their patients.¹⁸ Manufacturers that do not provide 340B discounts for their drugs are ineligible for Medicaid reimbursement for those products.¹⁹ Program participation is nearly universal because Medicaid reimbursement is a major source of revenue for many drug manufacturers.²⁰ A statutory formula determines the 340B discount and results in discounts ranging from a minimum of a 23.1 percent discount for most branded drugs (with a smaller discount for a few very specific types of drugs)²¹ to more than 100 percent (in which case, manufacturers are required to sell medicines for \$0.01 per pill).²²

340B discounts are not limited to prescriptions for low-income or uninsured patients.²³ In fact, covered entities are able to generate

¹⁵ 42 U.S.C. § 256b.

¹⁶ U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-836, DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT 2 (2011) [hereinafter 2011 GAO REPORT].

¹⁷ *Id.*

¹⁸ § 256b(a).

¹⁹ *See id.*

²⁰ 2011 GAO REPORT, *supra* note 16, at 2–3.

²¹ 340B Drug Pricing Program Ceiling Price and Manufacture Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1217 (Jan. 5, 2017).

²² 2011 GAO REPORT, *supra* note 16, at 11 (in some circumstances, the formula can result in a "negative price," but manufacturers are entitled to at least \$0.01 per pill in this circumstance).

²³ *Id.* at 2.

revenue when prescribing drugs to patients whose insurance reimbursement exceeds the 340B ceiling price paid by the covered entity.²⁴ The statute anticipated this scenario, and the drafters appeared to view this form of arbitrage as a way of supporting cash-strapped hospitals serving low-income communities.²⁵ The statute, however, does not specify how 340B-derived revenue must be used.²⁶ As a result, there is no mandate that discounts be passed on to patients or directed toward providing or improving patient care.²⁷

2. What Covered Entities Are and How They Benefit from the Program

There are currently six types of hospitals that can qualify as 340B covered entities, including disproportionate share hospitals and sole community hospitals.²⁸ The general requirements for covered entity eligibility relate to facility ownership, whether the hospital is located in a rural area, and the percentage of Medicare and Medicaid patients the hospital serves.²⁹ The “disproportionate share hospital adjustment percentage” required to achieve covered entity status varies based on the type of hospital and is used as a stand-in measure to identify low-income communities.³⁰ This calculation does not include uninsured patients who are not on Medicaid.³¹ Although this exclusion could

²⁴ *Id.*

²⁵ *Id.* at 1–2.

²⁶ U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-480, DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT 2 (2018) [hereinafter 2018 GAO REPORT].

²⁷ *Id.*

²⁸ The six types of hospitals that can be covered entities are disproportionate share hospitals (those that serve a disproportionate number of Medicare and Medicaid patients), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals. 42 U.S.C. § 256b(a)(4). In addition, there are eleven non-hospital categories, including Tribal/Urban Indian Health Centers and Black Lung Clinics. *Id.*

²⁹ *See id.*

³⁰ *Disproportionate Share Hospitals*, HEALTH RES. & SERVS. ADMIN., <http://hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html> (last visited Mar. 4, 2023).

³¹ Karyn Schwartz, *340B Paradox: As the Uninsured Rate Drops, 340B Program Continues to Grow*, PHRMA (Apr. 2, 2015), <http://catalyst.phrma.org/340b-paradox-as-the-uninsured-rate-drops-340b-program-continues-to-grow>; MEDICARE LEARNING NETWORK, MLN FACT SHEET, MEDICARE DISPROPORTIONATE SHARE HOSPITAL 4 (2023),

incentivize hospitals to help low-income patients enroll in Medicaid (to increase the likelihood that the hospital will qualify for 340B discounts), this potential benefit is likely outweighed by the significant burden on hospitals with high uninsured populations—particularly in states with limited Medicaid programs.³²

In exchange for 340B discounts, covered entities are required to prohibit duplicate discounts or rebates (such as discounts under both the 340B program and the Medicare Drug Rebate Program) as well as the “diversion” of discounted drugs.³³ Diversion occurs when a drug purchased at the 340B discounted price is dispensed to any patient who does not meet the criteria for the program.³⁴ HRSA has stated that “[t]o the extent that any internal compliance activity or audit performed by a covered entity indicates that there has been a violation of 340B program requirements, it is HRSA’s expectation that such finding be disclosed to HRSA along with the covered entity’s plan to address the violation.”³⁵

HRSA provides some guidance about the components of good compliance programs. For example, the agency has explained that “[a]nnual audits performed by an independent outside auditor with experience auditing pharmacies are expected, although the exact method of ensuring compliance is left up to the covered entity.”³⁶ HRSA, however, neither prescribes any particular oversight mechanisms, nor requires that compliance policies be submitted to the agency for review.³⁷

As a result, the U.S. Government Accountability Office (GAO) has repeatedly criticized the program’s lack of oversight, contending that HRSA “cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk,” “[b]ecause of [its] reliance on self-policing to oversee the 340B program as well as

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Disproportionate_Share_Hospital.pdf.

³² Schwartz, *supra* note 31.

³³ 42 U.S.C. § 256b(a)(5).

³⁴ 2018 GAO REPORT, *supra* note 26, at 9; for a description of patient eligibility, see *infra* Part II.A.3.

³⁵ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,274 (Mar. 5, 2010).

³⁶ *Id.* at 10,278.

³⁷ *See id.* at 10,276.

nonspecific guidance.”³⁸ The GAO also found that the rapid expansion of the program under weak oversight instigated significant noncompliance.³⁹ It specifically concluded that “participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance.”⁴⁰

3. Who Qualifies as a “Patient”

Under the 340B program, covered entities may only dispense drugs purchased at the 340B price to its “patients,” a term of art that is far less clear than it sounds.⁴¹ First, the entity must have a relationship with such “patients” and maintain their health care records.⁴² Second, a “patient” must receive health care services from a health care professional directly employed by the covered entity, or under a contractual or “other arrangement.”⁴³ “Other arrangements” are left undefined, but the statute points to a “referral for consultation” as an example.⁴⁴ Finally, the care the “patient” receives at the covered entity must be consistent with the reason the covered entity was granted 340B status.⁴⁵ For instance, if a patient receives care at a federal grantee, such as a Title XXVI clinic (also called Ryan White HIV/AIDS Clinics), such care must be within the scope of the applicable federal grant.⁴⁶ The statute does not include a timeframe for how long the relationship between the patient and covered entity endures or set any geographic limitations. It is unclear under the plain reading of the statute, therefore, whether a covered entity can continue to dispense 340B drugs to an individual across the country who has not been seen by that hospital for years.

³⁸ 2011 GAO REPORT, *supra* note 16, at 26; *see also* 2018 GAO REPORT, *supra* note 26, at 35.

³⁹ U.S. GOV’T ACCOUNTABILITY OFF., GAO-20-108, 340B DRUG DISCOUNT PROGRAM: INCREASED OVERSIGHT NEEDED TO ENSURE NONGOVERNMENTAL HOSPITALS MEET ELIGIBILITY REQUIREMENTS 23 (2019), <http://gao.gov/assets/gao-20-108.pdf>.

⁴⁰ 2011 GAO REPORT, *supra* note 16, at 33.

⁴¹ Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157–58 (Oct. 24, 1996).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.* at 55,157.

⁴⁵ *Id.* at 55,157–58.

⁴⁶ *Id.* at 55,158; HEALTH RES. & SERVS. ADMIN., *Ryan White HIV/AIDS Program Grantees*, <https://www.hrsa.gov/opa/eligibility-and-registration/ryan-white> (last visited Apr. 4, 2023).

4. The Role of Manufacturers

Manufacturers are required to offer drugs to a covered entity at or below the statutorily calculated “ceiling price.”⁴⁷ The ceiling price is the Average Manufacturer Price for the preceding quarter (QAMP) minus the Unit Rebate Amount (URA) as calculated under the Medicare Drug Rebate Program statute multiplied by the drug package size.⁴⁸ The URA is the sum of the Basic Rebate Amount (BRA) and additional rebate amounts.⁴⁹ Both the BRA formula and the availability of additional rebates depend on the type of drug.⁵⁰

The BRA is the greater of (a) the QAMP times the statutory factor for that type of drug (ranging from 17.1 percent to 23.1 percent), or (b) the QAMP minus the best price offered by the manufacturer in the previous quarter.⁵¹ Additional rebates involve calculations that take into account changes to the consumer price index.⁵² A sample calculation for Drug X—an innovative drug with a list price of \$100, a QAMP of \$75, and a best price of \$65—could look like this:

BRA Option 1: QAMP x statutory factor = \$75 x 0.231 = \$17.325

BRA Option 2: QAMP – Best Price = \$75 – \$65 = \$10

URA = Greater BRA Option + Additional Rebates (keeping at \$0 for simplicity)⁵³

340B Ceiling Price = (QAMP – URA) = (\$75 – \$17.325) = \$57.675

⁴⁷ 42 U.S.C. § 256b(a)(1).

⁴⁸ *340B Ceiling Price Calculation*, HEALTH RES. & SERVS. ADMIN. (May 2015), <https://www.hrsa.gov/opa/updates/2015/may.html> [<https://web.archive.org/web/20211025013625/https://www.hrsa.gov/opa/updates/2015/may.html>].

⁴⁹ CTRS. FOR MEDICARE & MEDICAID SERVS., *Unit Rebate Amount (URA) Calculation for Line Extension Drugs with Example*, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/unit-rebate-amount-calculation-for-line-extension-drugs-with-example/index.html> (last visited Apr. 4, 2023).

⁵⁰ CTRS. FOR MEDICARE & MEDICAID SERVS., *Unit Rebate Amount Information*, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-amount-calculation/index.html> (last visited Apr. 4, 2023). Drug classifications affecting Unit Rebate Amount calculations are single source, innovator multiple source, non-innovator multiple source, clotting factor drug, and exclusively pediatric drug. *Id.*

⁵¹ *Unit Rebate Amount (URA) Calculation*, *supra* note 49.

⁵² *Id.*

⁵³ *See id.*

In many cases, the 340B ceiling price will be less than zero, which means that the manufacturer must sell the drug for a penny per pill.⁵⁴ If manufacturers refuse to sell at or below the 340B ceiling price, Medicaid will not cover that drug.⁵⁵ As a result, manufacturers are strongly incentivized to participate in the program, and most do.⁵⁶

As previously noted, HRSA has taken a mostly hands-off approach to monitoring covered entity program compliance. Though manufacturers are permitted to police program compliance, it can be expensive, onerous, and time-consuming.⁵⁷ If a manufacturer suspects diversion or double discounting, for example, it must conduct an audit of the covered entity and try to resolve the issue directly before reaching out to HRSA for relief.⁵⁸ This audit is also a mandatory prerequisite to initiating an ADR proceeding under the statute.⁵⁹

While the 340B statute grants manufacturers the right to audit covered entities by the 340B statute, the 1996 HRSA final notice outlines procedures governing audits.⁶⁰ If a manufacturer suspects a covered entity of engaging in diversion or duplicate discounting, it has to notify the covered entity of its concern first.⁶¹ The parties then must take at least thirty days to attempt to reach a resolution in good faith.⁶² If they are unable to do so, the manufacturer must submit an audit workplan to HRSA demonstrating reasonable cause to suspect noncompliance by the covered entity.⁶³

HRSA must review the audit workplan within fifteen days.⁶⁴ If the agency agrees that there is reasonable cause to suspect diversion or duplicate discounting, the covered entity must allow an audit by an independent public accountant hired by the manufacturer.⁶⁵ The

⁵⁴ 2011 GAO REPORT, *supra* note 16, at 11.

⁵⁵ See 42 U.S.C. § 256b(a); *id.* § 1396r-8(a)(5)(A).

⁵⁶ 2011 GAO REPORT, *supra* note 16, at 2–3.

⁵⁷ Agency Information Collection Activities: Proposed Collection: Public Comment Request, 80 Fed. Reg. 79,915, 79916–17 (Dec. 23, 2015) (noting that the audit process burden is 1,272 hours per year).

⁵⁸ See *infra* Part IV.C.

⁵⁹ § 256b(d)(3)(B)(iv).

⁶⁰ § 256b(a)(5)(C); Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19, 61 Fed. Reg. 65,406, 65,409–11 (Dec. 12, 1996).

⁶¹ *Id.* at 65,410.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 65,409, 65,410.

manufacturer must submit the completed audit report to both the covered entity, which has thirty days to respond, and HRSA.⁶⁶ If the covered entity agrees with the findings, the parties resolve the matter.⁶⁷ If it disagrees, the parties can move to an informal dispute resolution process or a full ADR.⁶⁸ Covered entities need only submit to one audit at a time, so if multiple manufacturers have concerns, they must wait their turn.⁶⁹

B. *Checks and Balances in the Program*

The different players in the 340B system have different goals and incentives. Patients want effective treatments at an affordable cost. Covered entities want to serve their patients but also benefit from the tremendous revenue they generate from the “spread” between the 340B-discounted price they pay and the amount they charge to insurance companies. Manufacturers want their medications to reach patients, but also want to realize the revenue to which they are entitled under the program. These competing interests can provide a system of checks and balances that facilitates oversight of the 340B program, but that is only possible if there is an efficient and effective mechanism for raising and adjudicating suspected misconduct. As we will see, the ADR process, as currently designed, does not fulfill that function.

III. UNEXPECTED RESULTS OF THE STATUTE

Any large and complex government program that involves as much money as the 340B Drug Discount Program is likely to produce unintended consequences. In this case, the size and scope of the 340B program has far outstripped the wildest expectations for the scheme. The widespread use of contract pharmacies by covered entities, also unforeseen at the time the program was enacted, has led to a new constituency in the 340B discussion—one with its own incentives and profit motives.⁷⁰ 340B has become a significant revenue stream for national, for-profit pharmacies that have the lobbying power to become a significant voice in the 340B debate.⁷¹ All these developments have highlighted statutory gaps and deficiencies in the

⁶⁶ See Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. at 65,410.

⁶⁷ *Id.*

⁶⁸ *Id.* at 65,410–11.

⁶⁹ *Id.* at 65,409.

⁷⁰ See *supra* Part II.B.

⁷¹ *Supra* Part II.B.

original 340B law and the way it has been enacted and enforced by HRSA.

A. *340B Program Growth Continues to Accelerate*

In 2020, 340B-discounted drugs accounted for 16 percent of gross brand name drug sales when adjusted for price, but 19 percent of all drug manufacturer gross-to-net discounts on brand name drugs.⁷² That is, of the \$217 billion difference between manufacturers' list prices and what pharmacies and health care institutions actually paid for drugs, more than \$41 billion of that reduction was due to the 340B program.⁷³

The 340B program is vast and continues to grow at an incredible rate. Health care economist Adam Fein noted that “[d]iscounted purchases under the program reached at least \$38 billion in 2020. That figure is an astonishing 27 [percent] higher than its 2019 counterpart—and more than quadruple the value of discounted purchases in 2014.”⁷⁴ Program growth is not in itself a bad thing. Covered entities are realizing significant revenue through the program, which can help them provide improved access and better care to low-income populations.

The size of the program nonetheless raises three main concerns. First, large movements of money in a system can invite profit-seeking actors to take advantage of the system in ways that were not originally intended. Second, the sheer size of the program can amplify the impact of statutory deficiencies and gaps that may be less problematic in a scheme of smaller scope. Finally, the growth of the program presents considerable oversight challenges, both for the responsible agency and for the dispute resolution process. Since 2017, HRSA audited no more than 200 covered entities a year, which is actually an increase from the 51 that were audited in 2012.⁷⁵ The GAO noted that the 200 audits in 2017 amounted to just 1.6 percent of covered

⁷² Adam Fein, *The 340B Program Soared to \$38 Billion in 2020—Up 27% vs. 2019*, DRUG CHANNELS (June 16, 2021) [hereinafter *340B Program Soared to \$38 Billion*], <https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html> (data based on a Freedom of Information Act request filed by the Drug Channels Institute).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Program Integrity*, HEALTH RES. & SERVS. ADMIN, <https://www.hrsa.gov/opa/program-integrity> (last visited Apr. 4, 2023).

entities.⁷⁶ If the program were smaller, those 200 audits would constitute much more meaningful program oversight.

B. *Use of Contract Pharmacies Has Become Widespread*

Many covered entities dispense 340B drugs to patients through use of both their own in-house pharmacies and third-party contract pharmacies.⁷⁷ Under this framework, the patient of a covered entity takes a prescription to the contract pharmacy, which fills the prescription.⁷⁸ If the patient has insurance, the contract pharmacy submits a claim and receives reimbursement at the insurance company-negotiated rate for the drug.⁷⁹ The contract pharmacy then submits the patient and prescription information to the covered entity or a third-party administrator employed by the covered entity to determine if the transaction is eligible for a 340B discount (i.e., to decide whether the individual is a qualified patient receiving qualified care from the covered entity).⁸⁰ If the prescription is 340B-eligible, the contract pharmacy deducts a previously negotiated fee from the insurance company reimbursement and sends the remainder to the covered entity.⁸¹

The 340B statute does not mention contract pharmacies, but HRSA has stated that “[c]overed entities are free to choose how they will provide 340B pharmacy services to their patients, subject to federal and state laws.”⁸² At the outset of the program, less than 5 percent of covered entities had in-house pharmacies, so drafters likely foresaw, on some level, the use of contract pharmacies.⁸³ In 2010, HRSA rescinded previous guidance that limited covered entities to contracting with one pharmacy.⁸⁴ Since then, contract pharmacy locations ballooned from

⁷⁶ 2018 GAO REPORT, *supra* note 26, at 15.

⁷⁷ *Id.* at 2.

⁷⁸ *Id.* at 14.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*; for a discussion of contract pharmacy fee structures, see *infra* Part III.C.

⁸² *340B Drug Pricing Program Frequently Asked Questions*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions> (last visited Apr. 3, 2023).

⁸³ Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

⁸⁴ 2018 GAO REPORT, *supra* note 26, at 2; Adam J. Fein, *340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, DRUG CHANNELS (June 15, 2021) [hereinafter *340B Continues Unbridled Takeover*], <https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html>.

fewer than 3,000 in 2010 to approximately 30,000 in 2021, and contract pharmacies constitute half of U.S. pharmacies.⁸⁵ Research shows that “multi-billion-dollar, for-profit, publicly traded pharmacy chains and PBMs [pharmacy benefits managers]—Walgreens, CVS Health, Express Scripts, OptumRx, and Walmart—dominate 340B contract pharmacy relationships with covered entities.”⁸⁶ Drugs dispensed through contract pharmacies accounted for approximately 30 percent of the 340B program in 2020.⁸⁷

In theory, the 340B process outlined above ensures that only eligible patients receive 340B-discounted drugs. In practice, however, the Department of Health & Human Services (HHS) Office of the Inspector General “found that contract pharmacy arrangements create complications in preventing diversion” and “in preventing duplicate discounts.”⁸⁸ The GAO expressed similar concerns, stating that “[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA’s reliance on participants’ self-policing to oversee the program.”⁸⁹

Since opening the floodgates for contract pharmacy arrangements in 2010, HRSA has denied that this model increases the risk of noncompliance, emphasizing that the covered entity “has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid Rebate claim.”⁹⁰ In a since-retracted December 2020 advisory opinion, HHS went so far as to opine that contract pharmacies never “own” discounted 340B medicines, but are instead mere agents for the covered entity.⁹¹ HHS further noted that duplicate discounting

⁸⁵ *340B Continues Its Unbridled Takeover*, *supra* note 84.

⁸⁶ *Id.*

⁸⁷ *The 340B Program Soared to \$38 Billion*, *supra* note 72.

⁸⁸ Memorandum from Stuart Wright, Deputy Inspector Gen., Off. of the Inspector Gen., to Mark K. Wakefield, Adm’r, Health Res. & Servs. Admin. (Feb. 4, 2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

⁸⁹ 2011 GAO REPORT, *supra* note 16, at 28.

⁹⁰ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

⁹¹ ROBERT P. CHARROW, U.S. DEP’T OF HEALTH & HUM. SERVS., ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM 1, 6 (2020); DANIEL J. BARRY, U.S. DEP’T OF HEALTH & HUM. SERVS., WITHDRAWING ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM (JUNE 18, 2021).

and diversion are already violations of the statute, so no additional guidance is needed with respect to contract pharmacies.⁹² The agency maintains that any covered entity or manufacturer that suspects violations should conduct an audit and file an ADR claim.⁹³ This view ignores the rampant findings of noncompliance by GAO and the HHS Office of Inspector General with regard to duplicate discounts and diversion.⁹⁴ HRSA's position also ignores the heavy burden of conducting an audit and the lack of a formal ADR process in the 340B scheme.⁹⁵

C. *340B Has Become a Significant Revenue Stream for For-Profit Pharmacy Chains*

Contract pharmacies can earn money from 340B prescriptions in two ways. The pharmacy can negotiate a per-prescription fee and/or charge a percentage of the drug price to the covered entity.⁹⁶ Approximately 45 percent of the contracts that GAO evaluated for a 2018 report contained both flat fees and percentages.⁹⁷ Flat fees generally ranged from six dollars to fifteen dollars per prescription, and percentages for patients with insurance ranged from 12 to 20 percent of prescription revenue.⁹⁸ Fees were often higher for brand-name drugs, specialty drugs, and insured patients (with flat fees for insured patients up to sixteen dollars higher per prescription than for uninsured patients).⁹⁹ 340B contracts can be especially lucrative for specialty pharmacies, which “can earn profits from the 340B program that are three to four times larger than a specialty pharmacy’s typical gross profit from a commercial or [Medicare] Part D plan.”¹⁰⁰ There

⁹² CHARROW, *supra* note 91, at 5.

⁹³ *Id.*

⁹⁴ See 2011 GAO REPORT, *supra* note 16, at 26; 2018 GAO REPORT, *supra* note 26, at 35.

⁹⁵ See *supra* Part II.B.4.

⁹⁶ 2018 GAO REPORT, *supra* note 26, at 25.

⁹⁷ *Id.*

⁹⁸ *Id.* at 26–27.

⁹⁹ *Id.*

¹⁰⁰ Adam J. Fein, *PBM-Owned Specialty Pharmacies Expand Their Role In—and Profits From—the 340B Program*, DRUG CHANNELS (July 21, 2020), <http://drugchannels.net/pbm-owned-specialty-pharmacies-expand.html>.

is no statutory or regulatory guidance when it comes to contract pharmacy fees in 340B and no limit on what pharmacies can charge.¹⁰¹

340B contract arrangements are more than a sideline business for retail pharmacies, including major, national chains. CVS Health, a company that earned nearly \$269 billion in revenue in 2020,¹⁰² announced that its third quarter 2021 adjusted operating income increase of 9.5 percent was “primarily driven by improved purchasing economics . . . including pharmacy and/or administrative services for providers and 340B covered entities.”¹⁰³

What was once a modest program aimed at assisting hospitals in low-income communities to supplement their revenue and improve patient care has morphed into a juggernaut. 340B covered entities purchase at least \$38 billion of medication a year at a \$42 billion discount off wholesale acquisition cost list prices.¹⁰⁴ The dramatic increase in the number of covered entities and contract pharmacy arrangements has diluted HRSA’s ability to effectively oversee the program and overwhelmed the mechanisms it has in place. This lack of oversight means that covered entities have little to fear if they—intentionally or simply carelessly—engage in diversion or duplicate discounting. In addition, the tremendous amount of money in the system has attracted the attention of national, for-profit pharmacies, which have begun to skim money out of the 340B program by charging covered entities increasing flat fees and percentages of filled prescriptions—money that could otherwise be used to reduce costs or improve access for patients. Tremendous amounts of money also lead to inevitable conflicts about who is entitled to that money.

IV. ADMINISTRATIVE DISPUTE RESOLUTION RULE

There must be a mechanism for resolving inevitable disputes in any program that involves multiple stakeholders with potentially adverse goals and incentives. The 340B statute requires that HRSA

¹⁰¹ See Adam J. Fein, *How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies*, DRUG CHANNELS (July 23, 2020), <https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html>.

¹⁰² Press Release, CVS Health, CVS Health Reports Fourth Quarter and Full Year 2020 Results and Provides 2021 Full Year Guidance (Feb. 16, 2021), <https://cvshealth.com/news-and-insights/press-releases/cvs-health-reports-results-2020-q4>.

¹⁰³ Press Release, CVS Health, CVS Health Reports Strong Third Quarter Results (Nov. 3, 2021), <https://cvshealth.com/news-and-insights/press-releases/cvs-health-reports-results-2021-q3>.

¹⁰⁴ *340B Program Soared to \$38 Billion*, *supra* note 72.

develop an administrative dispute resolution (ADR) process to resolve such conflicts. The long-delayed ADR rule, however, suffers both procedural and substantive problems that undermine its efficacy, further hamstringing effective 340B program oversight.

A. *History*

In order to resolve claims either by covered entities contending that manufacturers overcharged them, or by manufacturers alleging that covered entities are engaging in duplicate discounts or diversion, the 340B statute mandated that the HHS Secretary “promulgate regulations to establish and implement an administrative process for the resolution of claims . . . including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process” within 180 days of the statute’s enactment.¹⁰⁵ Despite this explicit statutory requirement, HRSA did not even propose an ADR rule until 2016.¹⁰⁶ The proposed rule provided criteria for creating ADR Panels to hear individual cases.¹⁰⁷ It also set forth procedures for filing and adjudicating complaints.¹⁰⁸

HHS sought and received comments on the proposed rule but withdrew the rule in 2017.¹⁰⁹ In March 2020, a HRSA official told a reporter:

It 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. . . . HRSA does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance.¹¹⁰

Despite HRSA’s statement of intention and admission that any ADR process is likely to be hampered by the fact that unclear aspects of the 340B statute are elucidated only by non-binding agency guidance, the

¹⁰⁵ 42 U.S.C. § 256b(d)(3)(A).

¹⁰⁶ Summary of Regulatory Action for RIN-0906-AA90, REGINFO.GOV (Spring 2017), <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90>.

¹⁰⁷ See 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,382 (proposed Aug. 12, 2016). This proposed rule was withdrawn on August 1, 2017. Summary of Regulatory Action for RIN-0906-AA90, *supra* note 106.

¹⁰⁸ 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. at 53,383.

¹⁰⁹ *Id.*

¹¹⁰ Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B REPORT (Mar. 12, 2020), <https://340breport.com/your-340b-report-for-thursday-march-eae>.

agency finalized the rule proposed in 2016 under a new regulation identifier number (RIN) in December 2020, without reopening the comment period.¹¹¹ This action was likely provoked by mandamus actions filed against HRSA by covered entities, which sought to force the agency to finalize an ADR rule more than ten years after the statute was initially enacted (and a far cry from the 180-day time limit).¹¹² The final 2020 HRSA rule included some significant differences from the agency's 2016 proposed rule, including a new provision that makes ADR panel decisions not only binding on the parties but also precedential.¹¹³

B. Procedural Issues with the Adoption of the Final ADR Rule

There are several reasons to believe that the process that HRSA used to adopt the final ADR rule runs afoul of the Administrative Procedure Act (APA). An agency action fails the APA's arbitrary and capricious standard if it: (1) is not "based on a consideration of the relevant factors,"¹¹⁴ (2) "failed to consider an important aspect of the problem,"¹¹⁵ or (3) "is not supported by an overall review of the available evidence."¹¹⁶ An agency must show good cause for failing to follow the notice and comment procedures outlined in the APA where such procedures are neither impracticable nor unnecessary.¹¹⁷

Four years after the original proposed rule's notice and comment period, it was both practicable and necessary for HRSA to open the 2020 ADR proposed rule to new comments. As the D.C. Circuit has explained, the "life of . . . a [notice and comment] record is not

¹¹¹ See *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 406 (S.D. Ind. 2021).

¹¹² See *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-02906 (D.D.C. Oct. 9, 2020); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 20-cv-03032 (D.D.C. Oct. 21, 2020).

¹¹³ *Eli Lilly & Co.*, 526 F. Supp. 3d at 401–03; 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,385 (Aug. 12, 2016); 42 C.F.R. § 10.20 (2020).

¹¹⁴ *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Bowman Transp. Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)).

¹¹⁵ *Id.*

¹¹⁶ *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 13 (D.D.C. 2002).

¹¹⁷ 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 where notice and comment was not impracticable or unnecessary).

infinite.”¹¹⁸ Where “[n]ew information relevant to the agency’s decisionmaking . . . ha[s] come to light after the original notice and comment proceedings,” the APA requires that the agency open a new comment period to fairly consider the new information and change the proposed rule as appropriate.¹¹⁹

In this case, much had changed in the intervening four years, including an increase in 340B covered entities from 9,700 in 2010 to 12,700 in 2020,¹²⁰ and an explosion of 340B contract pharmacy sites from fewer than 1,300 in 2010 to nearly 30,000 in 2020.¹²¹ The HHS Office of the Inspector General raised the issue of rapid 340B contract pharmacy growth in 2018 congressional testimony, saying that it “identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements.”¹²² Contract pharmacy use was not nearly as widespread in 2016 when the initial proposed rule was open for comment, so the full impact of this growth may not have been captured in the responses to the proposed rule.

In addition, after the close of the 2016 comment period, government oversight bodies highlighted extensive evidence of diversion and duplicate discounting in the 340B program. In 2018, the House Energy and Commerce Committee found that nearly half of audited covered entities had unlawfully resold or transferred 340B drugs to nonpatients.¹²³ That same year, GAO concluded that 66 percent of covered entity diversion findings were related to contract pharmacy arrangements, and approximately 63 percent of covered entities that were reaudited had similar noncompliance findings in their second audit.¹²⁴ As of September 2020, HRSA had issued 1,536

¹¹⁸ *Mobil Oil Corp. v. U.S. EPA*, 35 F.3d 579, 584 (D.C. Cir. 1994) (quoting *Action on Smoking & Health v. Civ. Aeronautics Bd.*, 713 F.2d 795, 800 (1983)).

¹¹⁹ *Id.* at 585.

¹²⁰ U.S. GOV’T ACCOUNTABILITY OFF., *DRUG PRICING PROGRAM: HHS USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH 340B REQUIREMENTS 2* (2020) [hereinafter 2020 GAO REPORT]; see *supra* Part III.C.

¹²¹ Adam J. Fein, *A Primer on 340B Contract Pharmacies and Medicaid Duplicate Discounts*, YOUTUBE (Oct. 22, 2020), <https://youtu.be/cAPiy0TRILg>.

¹²² *Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the Comm. on Health, Educ., Lab. & Pensions*, 115th Cong. 5 (2018) (statement of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, U.S. Department of Health & Human Services), <https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-115shrg30195.pdf>.

¹²³ STAFF OF H. R. ENERGY AND COM., 115TH CONG., *REVIEW OF THE 340B DRUG PRICING PROGRAM* 38 (2018).

¹²⁴ 2018 GAO REPORT, *supra* note 26, at 38, 42.

findings of noncompliance—with approximately 36 percent of those for diversion and approximately 28 percent for duplicate discounts—across the 1,242 covered entity audits it finalized between 2012 and 2019.¹²⁵

Beyond the challenges that the program growth posed, there was increased awareness about the problematic nature of the vague definition of “patient” after 2016. The HHS Office of Inspector General also found that covered entities’ “different methods [of defining a patient] lead to differing determinations of 340B eligibility.”¹²⁶ There was also tension between covered entities and manufacturers, with more than one court case turning on how broadly the definition should be interpreted.¹²⁷ The final ADR rule failed to address this issue, and HRSA’s refusal to open that new rule to a comment period prevented parties from flagging the problem and its potential impact on the fairness, consistency, and validity of the ADR adjudication process.

Perhaps in anticipation of criticisms about violating the APA, HRSA claimed that it did not have to restart the notice and comment process because it never formally withdrew the 2016 proposed rule.¹²⁸ The proposed rule, however, had ceased to appear in the Unified Agenda, and the rule adopted in 2020 was listed in the Federal Register under a different RIN.¹²⁹ This led at least one court to conclude that the 2016 proposed rule had likely been withdrawn and that the 2020 rule likely could not be enforced.¹³⁰

This view, however, has not been universal. The Third Circuit recently held that even if HRSA did withdraw the rule from consideration, the APA and the Supreme Court are silent on withdrawal and what, if any, legal significance it has.¹³¹ In light of that silence, the Third Circuit reasoned that HRSA’s observance of the APA requirements with the 2016 comment period was sufficient.¹³² The

¹²⁵ 2020 GAO REPORT, *supra* note 120, at 13.

¹²⁶ Memorandum from Stuart Wright, *supra* note 88, at 1.

¹²⁷ See *Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253 (4th Cir. 2022); *Sanofi-Aventis U.S., LLC v. U.S. Dep’t of Health & Hum. Servs.*, 570 F. Supp. 3d 129 (D.N.J. 2021), *rev’d* 58 F.4th 696 (3d Cir. 2023).

¹²⁸ *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 406 (S.D. Ind. 2021).

¹²⁹ *Id.* at 402, 406.

¹³⁰ *Id.* at 407.

¹³¹ *Sanofi Aventis U.S., LLC*, 58 F.4th at 707.

¹³² See *id.* This decision was not unanimous. In his dissent, Judge Thomas Ambro articulated a test whereby “[s]ome agency actions short of formal notice in the Federal

D.C. and Seventh Circuits are expected to rule on this issue shortly, potentially leading to a circuit split.¹³³

After at least one court ruled that the rulemaking process was likely insufficient,¹³⁴ HRSA issued a notice of proposed rulemaking (NPRM) on November 30, 2022.¹³⁵ This notice does not reoffer the 2020 rule for notice and comment, but HHS seeks “comment on its proposal to revise the current ADR process by modifying the regulations issued under the 2020 final rule.”¹³⁶ Thus, HRSA takes for granted that the 2020 final rule was valid while potentially blunting criticism that it did not properly seek comment.

C. *Substantive Issues with the ADR Rule*

The final 2020 ADR rule does not adopt “procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously” as required by the statute.¹³⁷ Without a clear definition of “patient”—an issue on which many 340B disputes turn—ADR proceedings could suffer from inconsistent outcomes. The HHS Office of Inspector General notes that there are several scenarios that may result in covered entities treating the same prescription differently.¹³⁸

For instance, if a physician sees a patient first at a covered entity hospital and then at his private practice, some covered entities would consider any prescriptions the physician writes for the patient at the second visit eligible for the 340B discount, while others would not.¹³⁹ In another scenario, a physician sees a patient at a covered entity for chest pain but, in addition to blood pressure medication, she prescribes the patient sleep medication for previously diagnosed insomnia.¹⁴⁰ Covered entities that look at clinical data when evaluating

Register should constitute withdrawal because they make any reasonable person believe the proposed rule would not take effect.” *Id.*

¹³³ Avalon Zoppo, *SCOTUS Bound? After Appellate Ruling, What’s Next in 340B Drug Discount Cases?*, NAT’L L. REV. (Feb. 10, 2023), <https://www.law.com/nationallawjournal/2023/02/10/scotus-bound-after-appellate-ruling-whats-next-in-340b-cases/?slreturn=20230306154654>.

¹³⁴ *Eli Lilly*, 526 F. Supp. 3d at 407.

¹³⁵ 340B Drug Pricing Program; Administrative Dispute Resolution, 87 Fed. Reg. 73,516 (proposed Nov. 30, 2022) (to be codified at 42 C.F.R. pt. 10).

¹³⁶ *Id.* at 73,517.

¹³⁷ 42 U.S.C. § 256b(d)(3)(B)(ii).

¹³⁸ Memorandum from Stuart Wright, *supra* note 88, at 10.

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 12.

340B eligibility would not consider the sleep medication prescription to be eligible, while those that look only at prescriber and patient lists would.¹⁴¹

In the absence of clear guidelines, covered entities must make judgment calls that can result in penalties under the ADR rule. HRSA has said,¹⁴² and courts have agreed,¹⁴³ that the agency does not have the rulemaking authority it would need to clarify the definition of “patient,” which leaves two options. HRSA can (1) have ADR panels look at complaints on a case-by-case basis, which is likely to lead to inconsistent and unfair outcomes (as proposed in the 2016 rule),¹⁴⁴ or (2) create a rule that is precedential rather than merely binding on the parties (as in the 2020 final rule).¹⁴⁵

While giving ADR adjudications binding authority would alleviate concerns of inconsistency or capriciousness, HRSA is attempting to accomplish through the ADR process what it admits it does not have the authority to do via rulemaking.¹⁴⁶ A series of binding and precedential ADR decisions on 340B eligibility would have the effect of a HRSA rule clarifying those same issues. HHS highlights this problem in the commentary to the final rule: “Commenters express concern that HRSA should not use its enforcement authority to transform a 340B ADR Panel decision into a broad 340B policy decision.”¹⁴⁷ Yet, HHS proceeded to reiterate that ADR judgments would constitute final agency decisions with precedential authority without any further comment or elaboration.¹⁴⁸

Regardless of the precedential nature of the decisions, ADR panels need to make decisions based on vague definitions about which reasonable people disagree. HRSA has considered revising the

¹⁴¹ *Id.*

¹⁴² U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-556T, DRUG DISCOUNT PROGRAM: STATUS OF AGENCY EFFORTS TO IMPROVE 340B PROGRAM OVERSIGHT 12–13 (2018).

¹⁴³ *Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 30 (D.D.C. 2014).

¹⁴⁴ 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,385 (Aug. 12, 2016).

¹⁴⁵ 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,634 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10).

¹⁴⁶ *See Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 401–02 (S.D. Ind. 2021).

¹⁴⁷ 340B Drug Pricing Program, 85 Fed. Reg. at 80,642.

¹⁴⁸ *Id.*

definition of “patient” in the past but failed to do so.¹⁴⁹ Moreover, and as already explained, courts have made it clear that the agency lacks the statutory authority to create such a rule.¹⁵⁰ This is problematic because, as the GAO points out, “HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough,” and as a result, “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 a responsibility for care.”¹⁵¹ HRSA, in fact, concedes that “it is possible that some 340B covered entities may have interpreted the definition [of patient] too broadly, resulting in the potential for diversion of medications purchased under the 340B program.”¹⁵² In sum, the lack of a clear definition of “patient” makes it impossible for covered entities and manufacturers to predict how ADR panels will treat eligibility determinations.

The final 2020 ADR rule also does nothing to address high barriers for manufacturers to access the ADR process. The 340B statute requires that manufacturers demonstrate reasonable cause for suspecting diversion or duplicate discounting before they are permitted to audit a covered entity.¹⁵³ It is unclear, however, how

¹⁴⁹ In 2007, HHS issued an NPRM to revise the definition of “patient”—a clarification it said was necessary “to protect the integrity of the 340B Program” because “some 340B covered entities may have interpreted the definition too broadly.” Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient”, 72 Fed. Reg. 1543, 1543–44 (Jan. 12, 2007). However, this NPRM was withdrawn after the D.C. Circuit challenged HRSA’s rulemaking authority with respect to 340B. Fisher, *supra* note 13, at 44–45. The agency tried again in 2015 through proposed guidance instead of an NPRM but withdrew the proposal in 2017. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,306–07; *Summary of Regulatory Action for RIN-0906-AB08*, REGINFO.GOV (Spring 2017), <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AB08>.

¹⁵⁰ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient,” 72 Fed. Reg. at 1544; 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,306 (proposed Aug. 28, 2015); see also Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep’t of Health & Hum. Servs., 43 F. Supp. 3d 28, 42 (D.D.C. 2014) (“The rulemaking authority granted HHS by Congress under the 340B program has thus been specifically limited, and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program.”).

¹⁵¹ 2011 GAO REPORT, *supra* note 16, at 22–23.

¹⁵² Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient,” 72 Fed. Reg. at 1544.

¹⁵³ 42 U.S.C. § 256b(d)(3)(iv).

manufacturers are supposed to collect the information needed to demonstrate such cause without access to the very records they seek.¹⁵⁴ Manufacturers report that, while they “suspect[] covered entities of diverting 340B drugs, it is difficult to prove diversion took place.”¹⁵⁵ The GAO found that “although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.”¹⁵⁶

The burden on manufacturers is particularly troublesome given HRSA’s own lax oversight of covered entities. As previously discussed, HRSA audits just 200 covered entities a year—1.6 percent of the covered entities in the program in 2017. Seventy-two percent of the audited programs were found to be noncompliant in the years 2012–2017.¹⁵⁷

D. *Current Status of the ADR Rule*

Almost immediately after it was promulgated, pharmaceutical companies challenged the final 2020 ADR rule.¹⁵⁸ In March 2021, a federal district court granted pharmaceutical manufacturer Eli Lilly a preliminary injunction that enjoined HRSA from implementing the ADR rule.¹⁵⁹ The court ruled that Eli Lilly was likely to succeed on its claim that HRSA violated the APA by failing to reopen the notice and comment period for the 2020 ADR rule.¹⁶⁰ The court concluded that the Agency had likely withdrawn the 2016 proposed rule based on the long period of time that had passed, the rule’s removal from the Unified Agenda, and various comments made by HRSA officials to the media.¹⁶¹ The court held that the Agency’s attempt to present the 2020 rule as a mere finalization of the 2016 rule was “ambiguous, confusing,

¹⁵⁴ Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,406 (Dec. 12, 1996).

¹⁵⁵ 2011 GAO REPORT, *supra* note 16, at 22.

¹⁵⁶ *Id.*

¹⁵⁷ 2018 GAO REPORT, *supra* note 26, at 15–16; *see supra* Part IV.B.

¹⁵⁸ *See generally* Eli Lilly & Co. v. Cochran, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Mar. 16, 2021).

¹⁵⁹ *Id.* at 37.

¹⁶⁰ *Id.* at 24.

¹⁶¹ *Id.* at 15–16.

duplicitous, and misleading—the antithesis of fair notice under the APA.”¹⁶²

Although Eli Lilly also made claims regarding the substantive shortcomings of the final rule, the court did not address them.¹⁶³ HRSA has continued to collect complaints to adjudicate under the ADR process.¹⁶⁴ Moreover, despite the injunction, HHS named the six-member ADR Board and began assigning three-person ADR Panels in October 2021.¹⁶⁵

The 2022 NPRM does make certain substantive changes to the ADR process, including changing who is eligible to serve on an ADR Panel (favoring experts in the 340B program over government administrators)¹⁶⁶ and making the adjudication process less formal and costly,¹⁶⁷ but it does not address the concerns raised above.¹⁶⁸

V. RECOMMENDATIONS FOR REFORM

There is no question that the 340B Drug Pricing Program was a well-intentioned attempt to support covered entities and the low-income populations it serves. Ambitious programs, however, often have unintended consequences or gaps in statutory language that require legislative revision or clarification.¹⁶⁹ That is clearly the case here, where the 340B program has expanded beyond all expectations, revealing several key statutory shortcomings.¹⁷⁰ Under the current

¹⁶² *Id.* at 29–30.

¹⁶³ *Id.* at 30.

¹⁶⁴ 340B Administrative Dispute Resolution, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/340b-administrative-dispute-resolution> (last visited Nov. 7, 2021).

¹⁶⁵ Tom Mirga, *In Significant Development, HRSA Assigns Panels to Review 340B Dispute Resolution Claims Against Drug Companies*, 340B REPORT (Oct. 7, 2021), <https://340breport.com/in-significant-development-hrsa-assigns-panels-to-review-340b-dispute-resolution-claims-against-drug-companies>; 42 C.F.R. § 10.20 (2020).

¹⁶⁶ See 340B Drug Pricing Program; Administrative Dispute Resolution, 87 Fed. Reg. 73,517 (proposed Nov. 30, 2022) (to be codified at 42 C.F.R. pt. 10).

¹⁶⁷ *Id.*

¹⁶⁸ See *supra* Part IV.B.

¹⁶⁹ For example, conflicting statutory language in the CARES Act resulted in domestic violence victims being denied their share of COVID-19 relief funds. The IRS claimed it could not fix the issue with guidance and that Congress would have pass clarifying legislation. Mollie M. Wagoner, *Technically Important: The Essential Role of Technical Corrections and How Congress Can Revive Them*, 106 MINN. L. REV. 2543, 2543–2444 (2022).

¹⁷⁰ See generally Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. HEALTH CARE L. & POL'Y

scheme, covered entities are neither required to pass on savings to patients nor use the revenue the program generates to improve care.¹⁷¹ In fact, they can—and often do—share that revenue with for-profit contract pharmacies above and beyond a set dispensing fee.¹⁷² The vague definition of a 340B-eligible patient also generates significant confusion and will continue to spawn litigation.¹⁷³

Even if HRSA addresses (or is deemed to have addressed) the procedural problems concerning its promulgation of the ADR rule, that will merely delay implementation of the same flawed rule. Until Congress acts to reform the statute, the agency will remain unable to address certain issues and unwilling to address others. There are several statutory changes that could help the 340B program fulfill its original promise while addressing the unintended consequences of its implementation.

A. *Adopt a Workable Definition of “Patient”*

Congress should amend the statutory definition of “patient” to provide the specificity necessary for consistent interpretation. Legislative clarity, however, is only the first step. Congress ought to devise a “patient” definition that facilitates easier oversight and reduces the chances of diversion and duplicate discounting. Specifically, Congress should amend the statute to determine patient eligibility on a prescription-level basis and not just based on patient and provider names. Prescription-level determinations are more precise than patient and provider lists and are less likely to result in 340B-discounted drug diversion to patients who should not be eligible.¹⁷⁴ Requiring covered entities to use this method to determine eligibility not only reduces inconsistencies between covered entities, but addresses concerns that patient eligibility is being interpreted too broadly.¹⁷⁵

25 (2019); Alaa Ziad Haidar, *Recent 340B Contract Pharmacy Troubles and the Necessary Solutions*, 33 HEALTH LAWYER 34 (2020); Lowell M. Zeta, *Comprehensive Legislative Reform to Protect the Integrity of the 340B Drug Discount Program*, 70 FOOD DRUG L.J. 481 (2015); Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY L. REV. 637 (2015).

¹⁷¹ 2018 GAO REPORT, *supra* note 26, at 2.

¹⁷² *Id.* at 27.

¹⁷³ See *supra* Part IV.B.

¹⁷⁴ See *supra* Part IV.C.

¹⁷⁵ U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-455-T DRUG DISCOUNT PROGRAM: STATUS OF GAO RECOMMENDATIONS TO IMPROVE 340B DRUG PRICING OVERSIGHT 8 (2015).

Congress should further amend the statute to require a direct relationship between 340B-eligible prescriptions care received at the covered entity or by a provider on whose behalf the covered entity bills for services (referral, privileges, or credentials are simply not sufficient).¹⁷⁶ In addition, the amendment should mandate that eligible-patient care relate to the facility's reason for receiving covered-entity status (e.g., the scope of the grant or federal contract).¹⁷⁷ Finally, Congress should require covered entities to have ongoing provider-patient care relationships, with those relationships rebuttably presumed to have ended after twelve months without a visit or provision of care beyond prescription renewal.

B. *Pass Discounts on to Patients or Demonstrate How Revenue Is Being Used to Benefit Patient Care or Access*

Congress should expressly mandate that covered entities either pass the bulk of 340B-generated revenue on to patients or demonstrate that they are using the revenue to provide improved care and/or access to low-income patients. There is currently no requirement to pass on discounts to patients, and 45 percent of covered entities that responded to a GAO survey said that they do not offer any discounts to low-income, uninsured patients who receive their 340B prescription through a contract pharmacy.¹⁷⁸ In addition, "because the 340B program has no requirements on how 340B revenue can be used, stakeholders . . . have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program."¹⁷⁹ Even if the entities do not pass savings on to patients, they should use that revenue to provide charitable care or run programs that benefit low-income patients, by, for example, providing free screenings or opening satellite clinics in underserved areas. A showing of direct benefit to low-income or uninsured patients ought to be a program requirement.

C. *Ban Revenue Sharing with Contract Pharmacies and Limit Dispensing Fees*

Contract pharmacies do provide a service in the 340B scheme and should be compensated for that work. Congress ought to amend the

¹⁷⁶ See 2020 GAO REPORT, *supra* note 120, at 8.

¹⁷⁷ See *id.*

¹⁷⁸ Memorandum from Stuart Wright, *supra* note 88, at 14; 2018 GAO REPORT, *supra* note 26, at 30.

¹⁷⁹ 2011 GAO REPORT, *supra* note 16, at 3.

340B statute, however, to require HRSA to develop limits on the fees contract pharmacies can charge to covered entities. Fees should be in line with the service offered and not influenced by the price of the drug or size of the discount.¹⁸⁰ Thus, contract pharmacies could charge limited per-prescription fees based on the complexity of the transaction. Filing a claim with the patient's insurance, working with a specialty pharmacy to dispense a single-source drug, and other scenarios that add steps for the contract pharmacy could result in higher fees, but not above a reasonable ceiling that reflects the actual service.

Congress needs to close the loopholes that currently permit contract pharmacies to use the 340B program as a smokescreen for revenue sharing with the covered entity. In addition, Congress needs to make its intent to limit contract pharmacy fees explicit since HRSA has publicly stated that it “agrees that the intent of the 340B program was to permit the covered entities to stretch scarce [f]ederal resources, and that the benefit of the program was intended to accrue to the covered entities.”¹⁸¹ The agency noted that covered entities are “free to choose to use those dollars to pay contract pharmacies for their services”¹⁸²

D. Determine Prescription Eligibility Prior to Dispensing and Require Covered Entities to Share Claims Data with Manufacturers

Congress should amend the 340B statute to require covered entities to determine 340B eligibility at the prescription level because that would make it easier to prevent duplicate discounts and facilitate compliance and oversight, whether by HRSA or manufacturers.¹⁸³ By requiring covered entities to determine eligibility prior to dispensing the drug or sending the patient to a contract pharmacy, covered entities would be able to prevent duplicate discounting by flagging the prescription as one that has already been discounted. This process also creates clear records that HRSA and manufacturers can audit more easily.

In addition, to address the difficulty of auditing covered entities prior to initiating an ADR proceeding, Congress should mandate that

¹⁸⁰ See 2018 GAO REPORT, *supra* note 26, at 25–27 (describing flat and percentage fee structures).

¹⁸¹ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010).

¹⁸² *Id.*

¹⁸³ Memorandum from Stuart Wright, *supra* note 88, at 6.

covered entities share claims information for 340B-discounted prescriptions. This would enable manufacturers to monitor compliance and easily conduct audits.

Manufacturers could then raise concerns to HRSA and request the agency conduct its own compliance investigation independent of the ADR process. Providing this information to all parties should streamline both ADR processes and HRSA oversight because all parties would be working from a shared set of facts. This proposed reform should not be onerous for the covered entity if it is already determining eligibility at the prescription level. Under such a scheme, the covered entity has claims information for all prescriptions it fills. If the covered entity works with a contract pharmacy, the pharmacy should share this data as part of the service agreement.

E. Require HRSA to Develop a Strong Oversight Process

HRSA can and should do much more both in terms of monitoring manufacturer and covered-entity compliance and strengthening the 340B procedural requirements covered entities must satisfy. Given the rapid growth of the 340B program, Congress should require (and appropriately fund) HRSA to audit a meaningful percentage of contract pharmacy arrangements each year, as opposed to the mere 200 audits per year (out of more than 12,000 covered entities) that it currently conducts.¹⁸⁴

In addition to conducting more proactive oversight, HRSA should require covered entities to follow the agency's existing recommended oversight activities (including the recommendation to conduct independent audits).¹⁸⁵ For instance, six out of twenty recently audited covered entities had no documented process for overseeing contract pharmacies.¹⁸⁶ HRSA should also define a uniform methodology for conducting audits and ensuring compliance. The GAO found that one hospital serving approximately 21,000 patients a year reviewed just five claims in its annual audit.¹⁸⁷

Worse yet, even where covered entities conduct thorough audits, there is no requirement that they share the results with HRSA.¹⁸⁸ HRSA should enact clear regulations that require covered entities to

¹⁸⁴ 2020 GAO REPORT, *supra* note 120, at 2, 11.

¹⁸⁵ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. at 10,274.

¹⁸⁶ 2018 GAO REPORT, *supra* note 26, at 44.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 41.

engage in uniform, robust compliance programs that benefit all parties. Under such a regulatory regime, covered entities would be able to maintain more compliant programs and have confidence that their procedures are adequate. These procedures should also enable covered entities to uncover patterns of overcharging by manufacturers that they can use to initiate an ADR proceeding. Manufacturers would benefit from more compliant covered entities (reducing diversion and duplicate discounts) and from reduced auditing burdens.

HRSA, in turn, would be able to monitor covered entities and manufacturers much more closely than it could using its own resources. By receiving uniform audit results from all covered entities, the agency will be able to detect patterns, initiate compliance actions, and uncover other vital information about how the expanding 340B program is working. HRSA could also share that data with GAO, the HHS Office of Inspector General, and other oversight bodies that could analyze the information to assist the agency in overseeing the program.

VI. CONCLUSION

The final ADR rule issued in 2020 compounds the 340B program's existing deficiencies. Even if HRSA successfully fixes the rule's procedural deficiencies, the rule circumvents HRSA's acknowledged lack of rulemaking authority by extending to three ADR panel members the ability to issue precedential decisions. These ADR adjudications will, over time, create a "common law" definition of patient, define guidelines for contract pharmacies, and clarify acceptable compliance procedures for covered entities. While such clarity is desperately needed, it is unlikely that courts will permit HHS to accomplish this through a handful of carefully selected ADR panelists when they have already ruled that Congress denied the agency this authority.¹⁸⁹ This ADR rule further cements HRSA's abdication of oversight of the 340B program and the shifting of that burden to manufacturers who must take on costly and time-consuming audits to reveal what HRSA already knows—contract pharmacy arrangements are exacerbating diversion and duplicate discounting of 340B drugs. The ADR rule is a distraction from much-needed reform of the 340B system. The ADR process will be less necessary and its shortcomings less noticeable if the entire program works better for patients.

¹⁸⁹ Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs., 43 F. Supp. 3d 28, 30 (D.D.C. 2014).

