HEALTH AND HUMAN SERVICES' CATCH-22: AN ONGOING FEUD OVER ADR RULES RESOLVING CLAIMS BETWEEN 340B DRUG PRICING PROGRAM MANUFACTURERS AND COVERED ENTITIES

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I. INTRODUCTION

The United States healthcare system is the most expensive system in the world but for decades has failed to provide low-income Americans with adequate care.[1] As of 2020, 37.2 million Americans live in poverty[2], and 28 million (8.6 percent) did not have health insurance at any point during the year.[3] Forecasts predict that spending for retail prescription drugs is on track to become the fastest-growing healthcare expense in the United States, all while one in four people taking prescription drugs already report having difficulty affording their medication.[4]

The high cost of prescription drugs is not a new phenomenon. The United States has been battling with how to provide medication to low-income communities at a lower price for decades. In 1992, Congress created the 340B Drug Pricing Program ("340B Program").[5] The program protects safety-net hospitals[6] from escalating drug prices by allowing them to purchase outpatient

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[1] PBS, https://www.pbs.org/healthcarecrisis/history.htm [https://perma.cc/9AUD-JN5M] (last visited Mar. 27, 2022); Margo Snipe, *American Health Care is 'Broken' and 'Expensive,' Floridians Say*, TAMPA BAY TIMES (Dec. 23, 2021), https://www.tampabay.com/news/health/2021/12/23/american-health-care-is-broken-and-expensive-floridians-say/#:~:text=The%20United%20States%20spends%20nearly,according%20to%20the%20Commonwealth%20Fund [https://perma.cc/2EGN-BJPU].

[2] Emily A. Shrider et al., *Income and Poverty in the United States: 2020*, U.S. CENSUS BUREAU (Sept. 14, 2021), https://www.census.gov/library/publications/2021/demo/p60-273.html#:~:text=In%202020%2C%20there%20were%2037.2,non%2DHispanic%20Whites%20and%20Hispanics [https://perma.cc/LVA8-HZT3].

[3] Katherine Keisler-Starkey & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2020*, U.S. CENSUS BUREAU (Sept. 14, 2021), https://www.census.gov/library/publications/2021/demo/p60-274.html [https://perma.cc/2NHP-6QB6].

[4] Darrell G. Kirch, *Spiraling Drug Costs and Threats to the 340B Program Hurt Patients*, ASS'N OF AMERICAN MED. COLLEGES (Oct. 12, 2018), https://www.aamc.org/news-insights/spiraling-drug-costs-and-threats-340b-program-hurt-patients [https://perma.cc/Z2N2-6TZF] (explaining that prescription drugs will grow 6.3% each year through 2026—which is a hike that will far exceed the rate of inflation and the growth of family income).

[5] *340B Drug Pricing Program Overview*, 340B HEALTH, https://www.340bhealth.org/members/340b-program/overview/ [https://perma.cc/99DG-2CDT] (last visited Mar. 27, 2022).

[6] Paula Moura, *What Is a Safety-Net Hospital and Why Is It So Hard to Define?*, PBS (May 18, 2021), https://www.pbs.org/wgbh/frontline/article/what-is-a-safety-net-hospital-covid-19/ [https://perma.cc/W9U7-57PN] (explaining that there is not just one definition of what is considered a safety net hospital—they can be rural, urban, public, or nonprofit. "Almost all have a state mission or mandate of serving a low-income population, regardless of insurance coverage, ability to pay, or immigration status.").

drugs at a discount from drug manufacturers. In turn, low-income patients receive a discount on their prescription drugs, and safety-net hospitals use 340B savings to increase healthcare access and support vital services that otherwise would not have been financially possible.[7]

Currently, the 340B Program is at a crossroads. Since its inception, the 340B Program has grown by leaps and bounds, becoming a major source of revenue support for a multitude of programs provided by safety-net hospitals.[8] However, safety-net hospitals face an outdated structure that cannot keep up with how current health care is provided. The 340B Program's lack of oversight by the U.S. Department of Health and Human Resources ("HHS") and safety-net hospitals' inability to enforce pricing contracts has allowed participating pharmaceutical companies to overcharge participating 340B hospitals and other covered entities.[9] As of December 2021, forty-one drug companies have acknowledged that they overcharged 340B hospitals, health centers, and clinics.[10]

Statutorily, HHS is the only entity allowed to enforce pricing agreements against pharmaceutical manufacturers.[11] Thus, to keep claims out of court, at its inception, HHS was instructed to create an internal dispute resolution process to review claims of misconduct from both covered entities and pharmaceutical manufacturers.[12] In 2010, Congress instructed HHS to restructure the initial process to create an alternative dispute resolution process through APA's notice-and-comment procedure.[13] HHS announced the 340B Program's ADR Final Rule in January 2020.[14]

This Article argues that the ADR Final Rule is moot, inhibiting the overlying purpose of the 340B Program of providing low-income Americans with discounted prescription drugs. HHS adopted the ADR Final Rule in

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[7] Kirch, *supra* note 4 (providing an example of vital services). Hospitals use their savings to provide free vaccinations, neighborhood clinics in underserved areas, smoking cessation programs, substance abuse clinics, medical care for children in foster care, mobile units to communities, etc.

[8] *Biden Administration Throws Down Its First Gauntlet on 340B,* MINTZ (May 18, 2021), https://www.mintz.com/insights-center/viewpoints/2146/2021-05-18-biden-administration-throws-down-its-first-gauntlet-340b [https://perma.cc/RY8L-EUST].

[9] *340B Transparency Efforts Uncovering More Drug Company Overcharges*, 340B INFORMED (Dec. 8, 2021), https://340binformed.org/2021/12/340b-transparency-efforts-uncovering-more-drug-company-overcharges/ [https://perma.cc/5D56-X3ZV].

[10] *Id.*

[11] Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110, 120 (2011).

[12] Ken Perez, *The History and Noble Purpose of the 340B Drug Pricing Program*, OMNICELL (Oct. 8, 2020), https://www.omnicell.com/blog/the-history-and-noble-purpose-of-the-340b-drug-pricing-program [https://perma.cc/FVE3-MCS8].

[13] *Id.*

[14] *Id.*

violation of the APA's notice-and-comment requirements, allowing multiple pharmaceutical manufacturers to enjoin HHS from using the rule against them. Because one pharmaceutical manufacturer has been successful in court, other manufacturers now have a route (and winning argument) to quickly enjoin HHS from ever employing its ADR Final Rule against them. Thus, drug manufacturers will not be reprimanded for overcharging covered entities, and covered entities will not be reimbursed for wrongful drug pricing charges. Subsequently, hospitals will lose the revenue they depend upon to provide low-income and vulnerable patients with access to health care and discounted prescription drugs. In the end, low-income Americans will once again be at odds with the most expensive healthcare system in the world.

Section II shares introductory materials and presents the purpose of the 340B Program; it further introduces the contemporary climate of the 340B Program and how conflicting interests between pharmaceutical manufacturers and covered entities may be inhibiting the 340B Program's intended purpose. Section III introduces the current ADR Final Rule promulgated by HHS and how it is functioning (or not functioning) to resolve claims by either pharmaceutical manufacturers or covered entities; it also discusses legal challenges to the ADR Final Rule that have inhibited the rule's use. Section IV discusses a suggestion on what HHS must do to ensure that the 340B Program has a functioning ADR process as required by the Patient Protection and Affordable Care Act of 2010 ("ACA"). Section V discusses other legal challenges to the 340B Program and how those legal challenges may inhibit HHS from ensuring that the 340B Program has a functioning ADR Process. Section VI concludes this Article.

II. 340B DRUG PRICING PROGRAM

This Section provides critical background information about the promulgation and purpose behind the 340B Drug Pricing Program. This section then details the legal challenges between drug manufacturers and qualifying healthcare facilities brought forth by competing incentives between the two. Lastly, this section introduces how the Patient Protection and Affordable Care Act of 2010 ("ACA") directed the U.S. Department of Health and Human Services ("HRSA") to adopt an informal dispute resolution process.

A. *340B's Promulgation and Purpose*

The 340B Program, administered by the HHS through its agency, HRSA, was enacted in 1992 to make drugs more affordable and widely

available to low-income Americans. [15] The 340B Program requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement ("PPA"), with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B.[16] Under the PPA, the pharmaceutical manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers called "covered entities."[17] Covered entities are healthcare organizations that serve the country's most vulnerable patients, mostly uninsured, rural, and low-income patients.[18] Common entities include, but are not limited to, community healthcare centers, children's hospitals, critical access hospitals, public and nonprofit disproportionate share hospitals that serve low-income and indigent populations, and rural hospitals serving patients in remote locations.[19]

The 340B Program allows covered healthcare organizations to stretch scarce federal resources as far as possible to reducethe price of outpatient pharmaceuticals for patients, reach more eligible patients, and provide more comprehensive services to the communities they serve.[20] Overall, the 340B Program allows covered healthcare organizations to purchase outpatient drugs at a 20–25 percent discount and to use savings to support critical services and access to care for their patients.[21] Scholars debate whether covered healthcare organizations use their savings to enhance the care of their low-income patients[22]; however, others suggest that any cuts to the 340B Program could inadvertently restrict low-income patients' access to drugs and treatment,

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[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Meeting Varied Community Needs with 340B Savings: Case Examples From the Field*, 340B HEALTH (Oct. 2021), https://www.340bhealth.org/files/Meeting_Varied_Community_Needs_with_340B_Savings.pdf [https://perma.cc/8PS8-H6TM].

[19] *Id.*

[20] *340B Drug Pricing Program*, HEALTH RES. & SERV. ADMIN., https://www.hrsa.gov/opa/index.html [https://perma.cc/5TAG-BBV6] (last visited Mar. 27, 2022).

[21] Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC SCHAEFFER LEONARD D. SHAEFFER CTR. FOR HEALTH POL'Y & ECON. (Oct. 14, 2021), https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/ [https://perma.cc/Z4LS-26ZW].

[22] *Id.*

which could be particularly devasting, especially during the COVID-19 public health crisis.[23]

B. *340B Struggling to Serve its Intended Purpose*

Although the 340B Program plays an integral role in how millions of Americans obtain prescription drugs, scholars question whether the Program operates in accordance with its statutory foundation. Competing incentives between drug manufacturers and qualifying healthcare facilities, lack of Congressional oversight, and vague language in the statute and regulations are often cited as some of the program's main faults.[24] Since 340B's promulgation, HRSA has relied heavily on self-policing, allowing drug manufactures to overcharge covered entities for medication purchased under the program.[25] Although HRSA has the authority to conduct audits on the Program, in 2011, a report found that HRSA had not conducted any audits since 340B's inception.[26] As a result of the lack of oversight, legal challenges between pharmaceutical manufactures and covered entities started popping up in courts around the nation, with one making it to the Supreme Court in 2011.

C. *Astra USA, Inc. v. Santa Clara Cnty., and the 340B ADR Requirement Set Forth in the Patient Protection and Affordable Care Act of 2010*

With little to no help from HHS in combating pharmaceutical manufacturers overcharging covered entities contrary to concerted PPAs between HHS and the manufacturers, covered entities brought the issue to court.[27] One issue stood in the way of covered entities' suit. When promulgating the 340B Program, Congress did not authorize a private right of action for entities claiming to be overcharged.[28] Instead, Congress directed HRSA to create an informal dispute resolution process.[29] However, the

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[23] Sravya Chary, *Cuts to the 340B Drug Reimbursement May be Harmful During COVID-19*, BILL OF HEALTH (Nov. 19, 2020), https://blog.petrieflom.law.harvard.edu/2020/11/19/340b-reimbursement-cuts-covid/ [https://perma.cc/J2NE-3NNC].

[24] 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, 25 (2019).

[25] *Id.* at 27.

[26] *Id.*

[27] *See generally* Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110 (2011).

[28] Fisher, *supra* note 24, at 55.

[29] *Id.* at 54.

informal dispute resolution promulgated by HRSA in December 1996 failed to provide the necessary oversight, and covered entities had no choice but to go to court.

In *Astra USA, Inc. v. Santa Clara Cnty.*, Santa Clara County, California filed suit against Astra USA and eight other pharmaceutical manufacturers alleging that county-operated medical facilities were being overcharged for certain covered drugs in violation of concerted PPAs between HHS and manufacturers.[30] Santa Clara conceded that Congress had not authorized private rights of actions for covered entities, but argued that covered entities and the counties that fund them are intended beneficiaries of the concerted PPAs.[31] In an opinion by Justice Ginsburg, the court held that covered entities may not enforce PPAs between pharmaceutical manufacturers and HHS.[32] The rationale behind the ruling? Section 340B of the Veterans Health Care Act of 1992 did not give covered entities the right to sue pharmaceutical manufacturers. The court concluded that the PPAs, "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them. The agreements have no negotiable terms."

The court concluded that PPAs incorporate statutory obligations and record the pharmaceutical manufacturers agreement to abide by them and contain no negotiable terms.[33] Thus, PPAs serve as a means to opt into the statutory scheme, and Congress intended for centralized enforcement from the government in which covered entities were required to rely on an informal dispute resolution process promulgated by HHS.[34]

While the *Astra* case was in process, amendments to the ACA required HRSA to adopt alternative dispute resolution procedures to replace HRSA's informal dispute resolution guidelines promulgated in December 1996.[35] In the *Astra* opinion, Justice Ginsburg references ACA's amendments, stating, "Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits on manufacturers."[36] In the directive outlined in the ACA, HRSA was directed to "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs" and "claims by pharmaceutical manufacturers" following an audit.[37] Almost 10 years following the *Astra* decision, on

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[30] *Id.*
[31] *Id.* at 55.
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.* at 54.
[36] Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110, 121 (2011).
[37] 42 U.S.C. § 256b.

December 10, 2020, HRSA issued the 340B Drug Pricing Program Alternative Dispute Resolution Final Rule ("ADR Final Rule").[38]

III. THE ADR FINAL RULE

This Section first provides critical background information on the ADR Final Rule promulgation and purpose. Second, this Section discusses how HHS handled pressure from 340B covered entities demanding an adequate remedy to be developed to allow covered entities to remedy pharmaceutical manufacturer overcharges. Third, this Section discusses the legal challenges brought forth by pharmaceutical associations and manufacturers challenging the validity of the ADR Final Rule. Lastly, this Section discusses the state of the ADR Final Rule today.

A. *ADR Final Rule Promulgation & Purpose*

The ADR Final Rule sets forth the requirements for the 340B Program's ADR Process. The purpose of the ADR process is to resolve claims between covered entities and drug manufacturers. Claims brought forth by covered entities usually involve arguments that the entities have been overcharged for covered outpatient drugs by manufacturers. Conversely, claims by drug manufacturers usually entail arguments that a covered entity has violated the 340B prohibition on diversion or duplicate discounts.[39] The ADR Final Rule establishes an ADR Board consisting of members with complex litigation, drug distribution, drug pricing, or 340B Program expertise, appointed by the HHS Secretary.[40] Three members are selected from the ADR Board to from an ADR panel. The panel is selected and convened by the HRSA Administrator and is assisted by one, ex-officio, non-voting HRSA, Office of Pharmacy Affairs staff member.[41] The panel reviews petitions on a case-by-case basis and has the authority to make final agency decisions.[42]

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[38] *HRSA Releases Final Rule Establishing Resolution Process for the 340B Program*, ROPES & GRAY (Dec. 22, 2020), https://www.ropesgray.com/en/newsroom/alerts/2020/12/HRSA-Releases-Final-Rule-Establishing-Dispute-Resolution-Process-for-the-340B-Program [https://perma.cc/322D-JGGE].

[39] *340B Administrative Dispute Resolution (ADR)*, HEALTH RES. & SERV. ADMIN., https://www.hrsa.gov/opa/340b-administrative-dispute-resolution [https://perma.cc/F9P5-72LZ] (last visited Mar. 27, 2022).

[40] *Id.*

[41] *Id.*

[42] *Id.*

HRSA classifies the ADR Final Rule as a "last resort," encouraging covered entities and manufacturers to attempt to resolve issues in good faith before beginning the formal ADR process through HRSA.[43] In compliance with the rule, petitioners must submit documentation of any prior good faith efforts to resolve their dispute.[44] Further, the ADR Final Rule only covers petitioners that seek monetary damages over $25,000.[45]

B. *ADR Final Rule Promulgated in a Procedurally Invalid Manner*

Congress ordered HHS to promulgate regulations to establish the 340B Program ADR process within 180 days of the ACA's enactment, meaning that an ADR process was to be promulgated by September 10, 2010.[46] It was not until August 2016, six years following the deadline, that HHS issued a proposed ADR process and issued a Notice of Proposed Rulemaking ("NPRM") and invited comment.[47]

The APA requires that, to become effective, a legislative rule must go through notice-and-comment rulemaking.[48] First, the general NPRM is published in the Federal Register.[49] Second, the agency promulgating the rule must give interested parties an opportunity to comment.[50] During notice-and-comment rulemaking, the public and interested parties are given an opportunity to comment on a proposed version of the rule; the agency is then allowed to respond to the comments.[51] The APA sets forth the notice-and-comment requirements so that the public and interested parties can influence the content of legislative rules.[52] After consideration of the comments presented, the agency then must incorporate the rules adopted in a concise general statement of their basis and purpose.[53] Withdrawing a proposed rule that an agency previously issued but has not yet finalized effectively erases the earlier proposal, which then requires the agency to start over if it wants to

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[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] Fisher, *supra* note 24, at 53.

[47] *Id.* at 54.

[48] 5 U.S.C. § 553.

[49] *Id.*

[50] *Id.*

[51] *Id.*

[52] Brian Wolfman & Bradley Girard, *Argument Preview: The Administrative Procedure Act, Notice-and-Comment Rule Making, and "Interpretive" Rules*, SCOTUS BLOG (Nov. 26, 2014), https://www.scotusblog.com/2014/11/argument-previewthe-administrative-procedure-act-notice-and-comment-rule-making-and-interpretive-rules/ [https://perma.cc/Y33N-WPVP].

[53] § 553.

proceed with a rule.[54] A withdrawal communicates to the public that the rule is off the table.[55]

Following the August 2016 NPRM and invitation to comment, several pharmaceutical manufacturers filed timely comments raising concerns regarding the proposed ADR rule.[56] An overarching complaint that several pharmaceutical manufacturers seemed to have included concerns regarding potential biases of the ADR panelist due to their appointment by the HHS Secretary.[57] Following the conclusion of the notice and comment period, HHS removed the NPRM from the Unified Agenda of Regulatory and Deregulatory Actions ("Unified Agenda"), a semiannual compilation of information about regulations under development by federal agencies, published every spring and fall.[58] HHS never published a notice of withdrawal in the federal registry.[59]

Approximately four years later in March 2020, a 340B concentrated news publication reported that an official speaking on behalf of HRSA communicated with them that HRSA had no plans to create a binding ADR process for 340B "until such time that HRSA received regulatory authority for the issues that would be addressed" because "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" thus "HRSA does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance."[60]

HHS soon began to feel pressure from 340B covered entities to create an ADR Process. 340B covered entities started filing multiple suits against the Secretary of HHS demanding an adequate remedy to be developed to allow

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[54] Bridget C.E. Dooling, *Going Through Regulatory Withdrawal,* YALE J. ON REG. (Oct. 13, 2020), https://www.yalejreg.com/nc/going-through-regulatory-withdrawal/#:~:text=Withdrawing%20a%20proposed%20rule%20that,rule%20is%20off%20the%20table [https://perma.cc/JML5-LLTZ].

[55] *Id.*

[56] Eli Lilly & Co. v. Cochran, 526 F. Supp. 3d 393, 400 (S.D. Ind. 2021).

[57] *Id.*

[58] *Id.* at 401; *Unified Agenda of Federal Regulatory and Deregulatory Actions*, GEN. SERV. ADMIN., https://www.gsa.gov/policy-regulations/policy/federal-regulation-policy/unified-agenda-of-federal-regulatory-and-deregulatory-actions [https://perma.cc/S8KA-M28Z] (last visited Mar. 27, 2022).

[59] *Unified Agenda of Federal Regulatory and Deregulatory Actions*, *supra* note 58.

[60] Tom Migra, *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/ [https://perma.cc/7CDG-QQXW].

covered entities to remedy pharmaceutical manufacturer overcharges.[61] Nine months after the statement from HRSA in which a representative said the agency was not moving forward with an ADR process and three years after the proposed rule was removed from the Unified Agenda, HHS issued the ADR Final Rule without an additional notice or comment period.[62] The ADR Final Rule was nearly identical to the proposed rule that was published by HHS in 2016.[63] The lawsuits brought forth by the 340B covered entities were stayed following the promulgation by HRSA of the ADR Final Rule; however, HHS would face a new challenger in court: the pharmaceutical associations and manufacturers.[64] The ADR Final Rule went into effect on January 13, 2021, and was challenged in court less than 10 days later.[65]

C. *Pharmaceutical Manufacturers Fight the Implementation of the ADR Final Rule*

Multiple pharmaceutical associations, manufacturers, and organizations that operate as both sued HHS in federal court over the implementation of the ADR Final Rule. Drug manufacturing lobbying group, Pharmaceutical Research and Manufacturers of America ("PhRMA"), sued HHS, claiming that the Trump administration had rushed to finalize the rule, ignoring many of its flaws.[66] In its complaint, PhRMA argued that the ADR Final Rule was arbitrary and capricious in violation of the APA.[67] Claiming

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[61] Samantha Robbins Jamali & Anil Shankar, *Court Sides with Drug Manufacturers in Ongoing 340B Litigation*, JD SUPRA (June 22, 2021), https://www.jdsupra.com/legalnews/court-sides-with-drug-manufacturers-in-9782847/ [https://perma.cc/XUN3-ANHK].

[62] 304B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10).

[63] Alana Broe, *Federal Judge Blocks Implementation of 340B ADR Final Rule*, JD SUPRA (Mar. 24, 2021), https://www.jdsupra.com/legalnews/federal-judge-blocks-implementation-of-4460340/ [https://perma.cc/82X4-3SXN].

[64] *Id.*

[65] Samantha McGrail, *PhRMA Challenges 340B Drug Pricing Program ADR Rule*, PHARMANEWS INTEL. (Feb. 8, 2021), https://pharmanewsintel.com/news/phrma-challenges-340b-drug-pricing-program-adr-rule [https://perma.cc/U2CD-AW2J].

[66] Robert King, *PhRMA sues HHS to Overturn Dispute Resolution Rule for 340B Program*, FIERCE HEALTHCARE (Jan. 25, 2021), https://www.fiercehealthcare.com/hospitals/phrma-sues-hhs-to-overturn-dispute-resolution-rule-for-340b-program [https://perma.cc/EDL3-KRBD].

[67] *Id.* PhRMA also argued that the pharmaceutical manufacturer audit guidelines were arbitrary to law, and that the Final Rule was in violation of the Appointments Clause of the U.S. Constitution. For purposes of this discussion, I will only be focusing on PhRMA's claim that the ADR Final Rule was implemented contrary to APA regulation.

that the 340B Program is, "riddled with problems that prevent it from truly working," the lobbying group emphasized that the ADR Final Rule further inhibited the 340B Program as a whole and was not the product of reasoned decisionmaking.[68]

Seeking declaratory and injunctive relief to set aside, vacate, and remand the ADR Final Rule, PhRMA argued that HHS completely failed to engage in reasoned decisionmaking by ignoring the multitude of comments and concerns from pharmaceutical manufacturers by enacting the ADR Final Rule that was almost identical to the one initially proposed in 2016, before notice-and-comment.[69] Because HHS rushed out the previously withdrawn proposal and finalized it without taking present data and opinions into consideration, PhRMA argued that HHS violated its duty under the APA by failing to consider stakeholder comments and changed circumstances.[70]

Similarly to the PhRMA, Eli Lilly and Company quickly moved to bring suit against HHS regarding the implementation of the ADR Final Rule. On the same day that HRSA launched its website announcing that stakeholders could begin submitting petitions to be reviewed under the ADR Final Rule, Eli Lilly filed suit.[71] Rather than bringing multiple claims, Eli Lilly focused on HHS's move to suddenly withdraw the proposed rule from the Unified Agenda in 2017.[72] Eli Lilly argued that HHS, under the APA, was required to do an additional notice-and-comment period before releasing a final regulation because HHS had effectively withdrawn the proposed rule.[73]

HHS argued that it did not violate the APA notice-and-comment requirement because HHS had never formally withdrawn the rule.[74] In the preamble to the ADR Final Rule, HHS included a statement that the notice-and-comment was never withdrawn, but "merely paused as part of a freeze of regulatory actions implemented by the Trump Administration on January 20, 2017."[75] However, the statement in the preamble did not help HHS in court; the judge took it as showing that HHS had preemptively anticipated pushback from interested parties at the outset of the rule's implementation.[76]

On March 16, 2021, the United States District Court for the Southern District of Indiana issued a preliminary injunction in favor of Eli Lilly and

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[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *See generally* Eli Lilly & Co. v. Cochran, 526 F. Supp. 3d 393 (S.D. Ind. 2021).
[72] *Id.* at 401.
[73] *Id.* at 405.
[74] *Id.* at 406.
[75] *Id.*
[76] *Id.*

Company.[77] The judge did not agree with HHS's defense that the rule was never withdrawn. Citing the purpose of the APA as "fair notice" and analyzing the relevant inquiry of whether, through their actions and statements, HHS effectively communicated a withdrawal of the proposed rule to the public, the court concluded that HHS had effectively withdrawn its 2016 proposed rule.[78] The court cited to the fact that the proposed ADR Rule entry on the Unified Agenda displaying that the rule had been "withdrawn" in August 2017 would have led a reasonable observer to believe that the rule had in fact been withdrawn.[79] Additionally, HHS was silent for years and had not mentioned anything regarding any pending ADR rulemaking following the withdrawal from the Unified Agenda.[80] The statement from an HRSA representative indicating that the agency had no plans to engage in rulemaking regarding the ADR process further helped Eli Lilly's Case.[81]

Because Eli Lilly demonstrated a likelihood of establishing that HHS did in fact withdraw the proposed rule, the agency was then required to engage in a second notice-and-comment procedure before promulgating the ADR Final Rule. All and all, the court found that the agency's mixed messaging about the ongoing rulemaking regarding the ADR proposed rule was, "ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA."[82]

D. *The ADR Rule: Unworkable in its Current State*

With the success of Eli Lilly and Company in the District Court for the Southern District in Indiana and the harsh opinion ruling in favor of HHS acting contrary to its obligations under the APA, it is hard to imagine a world in which pharmaceutical associations and manufacturers will not bring another challenge to the ADR Final Rule. Currently, HHS is only enjoined from enforcing the ADR Final Rule against Eli Lilly and Company and Lilly USA, LLC., as they were the plaintiffs in that specific suit.[83] However, other pharmaceutical associations and manufacturers now have a prime example on how to enjoin HHS from forcing them to comply with the ADR Final Rule.

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[77] *Id.* at 410.
[78] *Id.* at 407.
[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] *Id.*
[83] *340B Administrative Dispute Resolution (ADR)*, *supra* note 39.

Although HHS lost against Eli Lilly, the agency has indicated that it fully intends to forge ahead with its current ADR Final Rule and process.[84] On June 21, 2021, the Secretary of HHS appointed the ADR Board members.[85] However, any time the HHS ADR Board attempts to use the ADR Final Rule in proceedings against pharmaceutical associations or manufacturers, they can go to court and most likely win on their claim to enjoin HHS from using the ADR Final Rule against them; this has already played out following the Eli Lilly decision.[86] In October 2021, Sanofi, a pharmaceutical manufacturer, filed a request to the D.C. District Court to temporarily halt any 340B ADR Proceedings filed against it.[87]

If pharmaceutical associations or manufacturers bring suit against HHS every time they might be subject to HHS ADR proceedings regarding their participation in the 340B Program, no dispute will ever be resolved. The Eli Lilly decision has opened the door for pharmaceutical associations or manufacturers to avoid repercussions for overcharging covered entities by enabling them to bring a winning argument against HHS due to the flaw in their notice-and-comment procedure regarding the ADR Final Rule. In turn, covered entities will have to start spreading their already scarce federal resources more thinly, and low-income Americans who need relief regarding their drug prices will suffer. This is especially frightening during the ongoing COVID-19 public health crisis.

Further, HHS might receive pushback in court from the covered entities who are not being granted proper relief because of the flawed ADR Final Rule. If HHS cannot participate in its ADR proceedings against pharmaceutical manufacturers that covered entities submit petitions against, those covered entities are not receiving relief. Thus, HHS is in a catch-22 until it properly addresses its APA faults.

IV. HOW HHS CAN SAVE THE 340B PROGRAM'S REQUIRED ADR PROCESS

With pharmaceutical manufacturers and covered entities both having reasons to bring HHS to court in regard to its flawed ADR Final Rule, HHS must roll back the rule and complete another notice-and-comment period.

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[84] *Secretary Of HHS Names ADR Board Members*, RYAN WHITE CLINICS FOR 340B ACCESS, https://rwc340b.org/secretary-of-hhs-names-adr-board-members/ [https://perma.cc/TN33-KQRA] (last visited Mar. 27, 2022).

[85] *Id.*

[86] *Sanofi Files Emergency Motion To Halt ADR Proceedings*, RYAN WHITE CLINICS FOR 340B ACCESS, https://rwc340b.org/sanofi-files-emergency-motion-to-halt-adr-proceedings/ [https://perma.cc/HMN2-A8ZP] (last visited Mar. 27, 2022).

[87] *Id.*

Anytime HHS tries to bring an ADR proceeding against a pharmaceutical manufacturer, the manufacturer is likely going to go to court. Seeing as though other courts have expressed that HHS has acted contrary to its obligations under the APA in enacting the ADR Final Rule without an additional notice-and-comment period, these manufacturers have a high likelihood of success. Further, this gives covered entities little to no way to recover from overcharges by pharmaceutical manufacturers.

While rolling back the rule and completing another notice-and-comment period may sound daunting, in the long run, it might save the required ADR process. Although it could take a while for any revised ADR rule to be completed if HHS were to participate in another notice-and-comment period, the way that the ADR Final Rule is functioning now is unworkable. HHS, if it does not comply with its duties under the APA, will have a never-ending cycle in court between both the pharmaceutical manufacturers and covered entities. HHS is truly in a catch-22 until the agency backtracks and comes up with a rule cleanly.

In the end, the faulty ADR Final Rule is going to hurt low-income Americans who rely on the 340B covered entities' relief to receive their prescription drugs at a discount. The catch-22 that the HHS has gotten itself into will hurt the 340B Program immensely if pharmaceutical manufacturers are not following their PPAs. Because covered entities have no private right of action to enforce a PPA[88], HHS must come up with a functioning way to resolve these disputes. Without a functioning dispute resolution process, pharmaceutical manufacturers can overcharge, and covered entities will have to spread their funds too thin. In turn, low-income Americans that are the intended beneficiary of the 340B Program are no longer served as intended.

V. THE FUTURE OF THE 340B DRUG PRICING PROGRAM

A. *American Hospital Association (AHA) v. Becerra*

Problems with the 340B Program do not end at the implementation of an ADR Rule. In fact, they go much further. In November 2021, the Supreme Court heard oral arguments in *American Hospital Association (AHA) v. Becerra*, centering on HHS's 2018 decision to cut outpatient Medicare drug reimbursements to 340B facilities by nearly 30%.[89] HHS argued that its decision to make the cuts was necessary to reimburse hospitals for actual

[88] Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110, 114 (2011).

[89] Robert King, *Supreme Court Justices Grill HHS in Lawsuit Surrounding Nearly 30% Cut to 340B Payments*, FIERCE HEALTHCARE (Dec. 1, 2021), https://www.fiercehealthcare.com/hospitals/supreme-court-justices-grill-hhs-lawsuit-surrounding-nearly-30-cut-to-340b-payments [https://perma.cc/A7D7-TQQM].

acquisition costs of the drugs.[90] AHA and other hospital groups sued to halt the cuts, arguing that HHS did not have the statutory authority to make such cuts.[91] The backing for AHA's argument is found in the statutory language. AHA argued that the law says that HHS should do a cost study before it sets aside the rate changes for a specific group of hospitals.[92] Before it decided to cut drug reimbursements by 30%, it did not conduct a cost study.[93] HHS argued that the cost study/survey is not a requirement to adjust rates; the agency's only study requirement is to take a survey periodically.[94]

It is unclear what the court will decide, with judges seemingly on both sides of the aisle during oral argument. Justice Breyer stated that the statute does say that the HHS Secretary can adjust rates as necessary.[95] However, other justices questioned why HHS wouldn't have done a cost study before making the cut anyway.[96] Justice Kagan said that the basic statute appears to say, "you can charge acquisition cost when you've done a survey."[97] A decision is likely to be released sometime next year.[98]

B. *Current Legal Challenges Regarding Contract Pharmacies*

Additional problems and legal challenges exist. Six drug makers and the Biden administration are currently in a legal fight over whether the drug makers must offer discounted products to contract drug pharmacies.[99] To expand the reach of the 340B Program, HRSA allows covered entities to

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[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.* On June 15, 2022, after the completion of this note, the Supreme Court ruled in favor of the AHA. In an opinion written by Justice Kavanaugh, the Court ruled that HHS may not vary the reimbursement rates only for certain hospitals and not others without a survey; permitting it to do so would be contrary to the text and structure of the statute. AHA v. Becerra, 142 S. Ct. 1896, 1899 (2022).Thus, HHS's decision to change reimbursement rates only for 340B hospitals without conducting a survey was unlawful. *Id.*
[99] Robert King, *Drugmakers Get Mixed Bag in Lawsuit Rulings Over 340B Contract Pharmacy Moves*, FIERCE HEALTHCARE (Nov. 8, 2021), https://www.fiercehealthcare.com/hospitals/drug-makers-get-mixed-bag-lawsuit-rulings-over-340b-contract-pharmacy-moves [https://perma.cc/BJ7S-FZ5D] [hereinafter King, *Drugmakers*].

contract with outside pharmacies to dispense drugs to eligible patients.[100] Contract pharmacies serve as an extension of the 340B provider and provide patients access to prescription drugs outside of the hospital or community clinic.[101] Accordingly, contract pharmacies help hospitals better serve their vulnerable communities by increasing access to more affordable healthcare services.[102]

In May 2021, the Biden administration alerted six drug makers—AstraZeneca, Eli Lilly, Novartis, Novo Nordisk, Sanofi, and United Therapeutics—that they were violating federal law by restricting safety net providers' access to products discounted under the 340B program.[103] The letters demanded the six drug makers to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements."[104] The distribution of the letters came after the six drug makers sought to restrict access to 340B discounted products to the third-party contract pharmacies that dispense drugs on behalf of the covered entities; drug companies had previously announced that they would no longer provide discounted products to contract pharmacies, or aimed to limit sales unless the covered entity provided data on claims to assuage concerns over duplicative discounts.[105] Drug diversion occurs when drugs purchased with 340B discounts are given to an ineligible patient.[106] The only qualification patients need to receive drugs purchased with the 340B discount is a record of receiving care from a covered entity.[107] So, an ineligible patient may receive the drug discount when treated by a doctor not employed by the covered entity so long as they have a record of receiving care from a covered

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[100] *Fact Sheet: 340B Drug Pricing Program Contract Pharmacy Arrangements*, AMERICAN HOSPITAL ASS'N, https://www.aha.org/fact-sheets/2020-10-06-fact-sheet-340b-drug-pricing-program-contract-pharmacy-arrangements [https://perma.cc/PQX5-KZ26] (last visited Mar. 27, 2020).

[101] *Id.*

[102] *Id.*

[103] *HRSA Demands 6 Drugmakers Stop Cutting Off Sales of 340B Drugs to Contract Pharmacies,* AMERICAN HOSPITAL ASS'N, https://www.fiercehealthcare.com/hospitals/hrsa-demands-6-drug-makers-stop-cutting-off-sales-340b-drugs-to-contract-pharmacies [https://perma.cc/Q899-FHB7] (last visited Mar. 27, 2020) [hereinafter *HRSA Demands*].

[104] *Id.*

[105] *Id.*

[106] *Federal 340B Drug Pricing Policies Need Reform to Realize Potential*, USC SCHAEFFER LEONARD D. SHAEFFER CTR. FOR HEALTH POL'Y & ECON. (Oct. 14, 2021), https://healthpolicy.usc.edu/article/federal-340b-drug-pricing-policies-need-reform-to-realize-potential/ [https://perma.cc/CVB7-8CXY].

[107] *Id.*

entity.[108] Drug manufacturers argue that contract pharmacies face a higher risk of drug diversion because of the wide range of eligible and ineligible patients that they serve.[109]

To some, the letters seemed to be the end of the contract pharmacy feud that had begun in July 2020. However, the feud persists to this day. Unsurprisingly, some of the drug makers took the issue to federal court.[110] The drug makers argued that they have the statutory right to restrict access to contract pharmacies to help avoid duplicative discounts for Medicaid and 340B.

Drug makers got mixed results in federal court.[111] One federal judge found drug companies cannot unilaterally restrict sales of products discounted under the 340B program to contract pharmacies.[112] Another separate ruling at a federal district court found that manufacturers do not have to provide discounts.[113] Even though the results in federal court were mixed, in the end, each ruling had one thing in common: a plea to HHS and Congress to enact a new statutory provision or new legislative rule to make a clear fix to the issue.[114] Various federal judges called for Congress to intervene to settle the issue with new legislation. In September 2020, a bipartisan group of senate and house lawmakers pressed HHS to quash drug companies' move restricting access to 340B drugs sold via contract pharmacies.[115] The group, including 243 House lawmakers and 28 senators sent a letter to HHS urging swift action from the agency to restrict the move by drug companies to ensure proper compliance with the 340B Program.[116] However, to date, no legislation has been introduced to make the fix regarding the contract pharmacy problem. With mixed rulings at the federal district court, the issue will likely persist and further challenges are likely to come.

With so many issues revolving around the 340B Program, it is hard to imagine that HHS and HRSA have the capability to put finalizing a workable ADR Rule at the forefront of their agenda. At the rate at which the 340B Program ends up in court, some are starting to think that the Program is an

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[108] *Id.*

[109] *Id.*

[110] *See generally* AHA v. Becerra, 142 S. Ct. 1896 (2022).

[111] King, *Drugmakers*, *supra* note 99.

[112] *Id.*

[113] *Id.*

[114] *Id.*

[115] Robert King, *Bipartisan Group of Senate, House Lawmakers Press HHS to Quash Drug Companies' 340B Moves*, FIERCE HEALTHCARE (Sept. 24, 2020), https://www.fiercehealthcare.com/hospitals/bipartisan-group-senate-house-lawmakers-press-hhs-to-quash-drug-companies-340b-moves [https://perma.cc/Y9V6-49WL].

[116] *Id.*

"increasingly dysfunctional" initiative.[117] Scholars argue that the biggest roadblock to enhancing the 340B Program is HRSA's limited enforcement authority.[118] Additionally, another frequently cited hurdle is the fact that Congress has not passed into law any of the more than 50 proposed improvements offered by Congress over the past decade.[119] Like the federal courts that issued [rulings? decisions?] on the contract pharmacy feud between HHS and drug makers, scholars agree that the 340B Program needs vast modification to "fulfill its ideals and ensure future sustainability."[120] It is clear that the 340B Program as written and functioning right now is outdated and in need of a major edit. Further, if HHS and HRSA had implemented the ADR Final Rule in a legal, workable, and quicker fashion, some of these legal challenges and legislative edits possibly could have been moot.

VI. CONCLUSION

The current state of the 340B Program's ADR Final Rule is unworkable, and the 340B Program is at a detriment because of it. As prescription drugs stay on track to become the fastest-growing healthcare expense in the United States, the 340B Program's various flaws are on track to derail the Program as a whole. In turn, the mission of the 340B Program, to provide low-income communities with affordable prescription drugs, is no longer being served.

With HRSA having little to no oversight with no legally working ADR Final Rule, the Program continues to unravel. While the 340B Program needs more than one update, implementing a workable ADR Final Rule could possibly solve some of the issues between covered entities and drug manufacturers. HHS must prioritize rolling back its ADR Final Rule and completing another notice-and-comment period. If not, anytime HHS tries to bring an ADR proceeding against a drug manufacturer, the manufacturer will likely go to court seeking an injunction against the proceeding. Thus, HHS and HRSA continue to have little to no oversight over the 340B Program. To ensure that the 340B Program can continue to serve low-income Americans in affording their prescription drugs, HHS, HRSA, and Congress are going to

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[117] Paige Minenyer, *Pioneer Institute Report Calls 340B an 'Increasingly Dysfunctional' Program*, FIERCE HEALTHCARE (Mar. 22, 2022), https://www.fiercehealthcare.com/hospitals/pioneer-institute-report-calls-340b-increasingly-dysfunctional-program [https://perma.cc/NX7R-TBCU].

[118] *Federal 340B Drug Pricing Policies Need Reform to Realize Potential*, *supra* note 106.

[119] *Id.*

[120] *Id.*

need to put in the work to fix the Program's flaws. If not, the 340B Program will continue to become inoperable.