July 28, 2023

VIA ELECTRONIC MAIL
Bipartisan340BRFI@email.senate.gov

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin:

On behalf Ryan White Clinics for 340B Access ("RWC-340B"), we write in response to your request for information ("RFI") published on June 16, 2023, regarding the federal 340B Drug Pricing Program (the "340B program"). We appreciate the opportunity to provide input on your request for bipartisan solutions to "provide stability and appropriate transparency to ensure the 340B program can continue to achieve its original intent of supporting entities serving eligible patients."

RWC-340B is a national association of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program. Ryan White clinics rely on 340B savings to provide critical services that would otherwise be uncompensated, ranging from free or discounted medications to critical wrap-around support services for people living with HIV including primary care, case management, dental and behavioral health, and other support services.

340B Program's Essential Role for Ryan White Clinics & Public Health
The 340B program serves as the backbone of the U.S. public health infrastructure, without taxpayer expense, by allowing manufacturers to voluntarily access the massive Medicaid and Medicare Part B payer markets in exchange for their participation in the 340B program. The stated legislative intent of the 340B program is to "enable(s) covered entities to stretch scarce

federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." [1]

The savings and revenue generated by the 340B program enable Ryan White clinics ("RWCs") to care for their patients holistically, which is why the program is a key driver in the Ending the HIV Epidemic ("EHE") initiative advanced by the Department of Health and Human Services ("HHS") under multiple administrations.[2] Data shows that RWCs are extremely successful in helping patients achieve sufficient viral suppression so that they cannot transmit HIV. The key to controlling and ultimately ending the AIDS epidemic is testing people who don't know they have the virus, getting them into treatment if they test positive, and retaining them in treatment – none of which is currently covered or adequately reimbursed by insurance. Grant funding alone is woefully insufficient to meet these critical patient needs.

Key Principles Should Guide Policy Discussions on 340B

The 340B program is a carefully constructed policy solution to reign in drug prices for specific safety new providers, as determined by Congress. With drug prices rising exponentially, we hope you will agree that now is not the time to undermine the 340B program.

RWC-340B believes that there are several immutable principles that should guide any policy discussion about the 340B program. Those principles are outlined in RWC-340B's Statement of Principles summarized below:

- The legislative intent of the 340B program should not be reinterpreted, re-envisioned, or stated any differently than it already is.
    - The 340B program should not be restructured as only a patient drug assistance program or focus only on low-income and uninsured patients because doing so would mean that RWCs no longer have the resources to provide more comprehensive care to all people living with HIV/AIDS.
    - Taxpayers should not bear any burden for an untested new construct for the 340B program to relieve drug companies of their responsibility to provide discounted medications to safety net providers.
- Narrowly defined limits on access to 340B drugs, by disease state or condition, are unacceptable.
- Policymakers and/or the courts must stop manufacturers from dictating the rules for the 340B contract pharmacy program.
- Onerous reporting requirements are unnecessary and will force RWCs to take time away from patient care and community service.
- PBMs must be prohibited from siphoning off 340B savings.
- A national clearinghouse should be established to reduce the risk of duplicate discounts on Medicaid drugs.
- Congress should not nullify state laws that are protective of the 340B program.

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[1] H.R. Rep. No. 102-384(II), at 12 (1992).

[2] *See, e.g., FACT SHEET: The Biden-Harris Administration's Efforts to End HIV/AIDS At Home and Abroad*,White House (Dec. 1, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/12/01/fact-sheet-the-biden-harris-administrations-efforts-to-end-hiv-aids-at-home-and-abroad/#:~:text=Requesting%20unprecedented%20investments%20to%20end,equitable%20access%20to%20support%20services; RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction* (Sept. 2020), https://rwc340b.org/rwc-340b-key-research/.

Ryan White Clinics for 340B Access

Question Category 1

What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

HRSA Has Adequate Authority to Oversee the Program

Section 340B of the Public Health Service Act gives HRSA regulatory authority: (1) to establish an administrative dispute resolution process ("ADR"), (2) to issue precisely defined standards of methodology for calculating ceiling prices, and (3) to impose civil monetary penalties.[3]

RWC-340B cautions that providing increased regulatory authority to HRSA beyond these areas could undermine the role of the 340B program in supporting public health care in the U.S. It could place unreasonable administrative burdens on covered entities, and hinder patient access to care in underprivileged communities. HRSA has sufficient regulatory authority – specifically established under the 2010 Affordable Care Act – to oversee the 340B program and to ensure that it fulfills its purpose.

HRSA Actions Evidence Overstepping Existing Authority

Rather than exercise its existing authority to establish helpful precedent through the ADR process, HRSA has overstepped its authority by trying to issue legally binding rules. A good example relates to the 340B prohibition against diversion, an area where HRSA tried twice to define the statutory term "patient" without having the requisite authority. First, it attempted to remove a South Carolina health center from 340B for diversion but was ultimately struck down by the Fourth Circuit. The Court held that HRSA's authority to implement patient eligibility standards was not clearly supported by the 340B statute.[4] Second, HRSA attempted to adopt a 340B program "Mega Guidance"[5] that would have, among other things, significantly narrowed the definition of "patient" by establishing an unauthorized six-part test.[6]

PROPOSED POLICY SOLUTIONS

Urge HRSA to Finalize and Implement the ADR Program

By adjudicating ADR disputes between covered entities and manufacturers, HRSA already has the authority to issue legally binding decisions that would help guide permissible uses within the 340B program. The ADR process can be used to clarify the definition of "patient", covered entity responsibilities to avoid duplicate discounts and even the appropriate use of contract pharmacies. HRSA should expedite finalization and implementation of its pending ADR rule and use it to clarify program requirements.

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[3] *See Pharm. Rsch. v. Dept. of Health & Hum. Serv.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014).
[4] *Genesis Healthcare, Inc. v. Becerra*, No. 20-1701, 2022 WL 2375178 (4th Cir. July 1, 2022). This case was remanded to the district court and is pending.
[5] 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg, 52,300 (Aug. 28, 2015).
[6] The Mega Guidance was not formally advanced, but instead lapsed, presumably because of objections from the covered entities or perhaps because of expected threats of industry lawsuits.

Clarify HRSA's Regulatory Authority to Audit Manufacturers

Increased funding is necessary for HRSA to continue its practice of auditing manufacturers. Since 2015, HRSA has performed only 36 audits on manufacturers. In the last two years, seven out of ten manufacturer audits have resulted in HRSA requiring manufacturers to repay covered entities for overcharges. This high percentage of adverse findings is indicative of a pervasive problem in which covered entities are overcharged, thereby resulting in a decreased ability for these safety-net providers to administer adequate healthcare to individuals living in poverty.

Question Category 2

What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

How and Why Contract Pharmacies Work

Most illnesses and injuries are treated with drugs and most drugs are self-administered. That means, to obtain optimal treatment outcomes and quality care, health care providers –whether a doctor, clinic, or hospital – must ensure that each of their patients has convenient and consistent access to a pharmacy to fill prescriptions.[7] Covered entities often lack their own outpatient pharmacies or, if they have one, the pharmacies may be difficult to access. Contract pharmacy arrangements are the only way, short of mail order or courier services, to make 340B self-administered drugs more accessible to patients. Drugs dispensed by contract pharmacies are purchased by the covered entity using a "bill to/ship to" process – the drugs are purchased by, and billed to, the covered entity but shipped to the contract pharmacy. Contract pharmacies are not permitted to purchase 340B drugs.[8] After receiving the covered entity's 340B drugs, the contract pharmacy dispenses the drugs to the covered entity's patients, collects reimbursement for the drugs from both the patient and the patient's third-party payer (if any), and remits the collected reimbursement to the covered entity. The covered entity, in turn, pays the pharmacy a fee for its dispensing and billing services.

Contract Pharmacy Use: Vital for RWC Patients' Access to Medications

The availability of contract pharmacies is especially important for persons living with HIV/AIDS. Many RWCs prescribe or manage specialty HIV medication regimens that require complex storage and handling and can only be dispensed by a specialty contract pharmacy[9] or through a mail order program, both of which are subject to limited distribution by

[7] Sofia Fernandez, et al., *Barriers to Medication Adherence and Retention in Care among Women Living with HIV in the Face of Homelessness and Unstable Housing*, 19 Int. J. Environ Res. Pub. Health. 11484 (Sept. 13, 2022); Caroline Walsh, et al., *The Association Between Medication Non-Adherence and Adverse Health Outcomes In Ageing Populations: A Systematic Review and Meta-Analysis.* 85 British J. Clinical Pharmacology 2464-2478 (Nov. 2019).

[8] This is a fundamental program tenet often misrepresented by opponents, including drug manufacturers.

[9] A "[s]pecialty pharmacy focuses on high cost, high touch medication therapy for patients with complex disease states." *Specialty Pharmacies*, Am. Pharmacists Ass'n, https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty (last visited July 27, 2023). *See, e.g.*, Erica Conroy, *Help Patients Obtain HIV Medications*, Pharmacy Times (Sept. 17, 2020), https://www.pharmacytimes.com/view/help-patients-obtain-hiv-medications.

manufacturers.[10] In some instances, manufacturers or payers require the use of specialty pharmacies for patients to access specialty drugs; these pharmacies can be hundreds of miles away from the RWC's main location and the patient's home, leaving the HIV patient with little choice but to use the distant specialty pharmacy to fill the patient's prescriptions. RWCs have concluded that the use of contract pharmacies is a better option because they are more convenient and accessible to where patients live.

Many RWCs, like other safety net providers, are unable to fill prescriptions for their patients because they cannot afford to "expend precious resources to develop their own in-house pharmacies."[11] They lack the infrastructure to dispense or administer drugs themselves but, through the 340B program, are able to purchase life-saving HIV drugs that are stored and dispensed to their patients by contract pharmacies.[12] Contract pharmacies provide important social work and linkage services to ensure that people living with HIV can access care, a critical component of HIV care that a mail order or courier service program cannot provide. Contract pharmacies enable RWCs to curb the spread of HIV because their use increases access to care and 340B savings. Studies demonstrate that "inconsistent access" to medication results in "suboptimal HIV outcomes," even when the patients have been linked to treatment by safety net providers. As such, achieving the goals outlined in "Ending the HIV Epidemic: A Plan for America"[13] become more challenging – especially in geographic HIV hotspots and among groups with a disproportionate burden of poor HIV outcomes" [14] – when contract pharmacies are subject to manufacturer restrictions.

Unilateral Manufacturer Actions to Limit Contract Pharmacy Use

For approximately 26 years, every drug manufacturer participating in the 340B program honored contract pharmacy arrangements and treated contract pharmacies the same as in-house pharmacies. That practice changed abruptly beginning in July 2020, when manufacturers began either to eliminate fully or significantly restrict distribution of 340B drugs ordered through bill to/ship to arrangements.[15] As of todays' date, 24 manufacturers are unilaterally imposing restrictions on contract pharmacy arrangements.[16] These actions are dramatically reducing resources available to safety net providers, harming their ability to meet the needs of vulnerable

[10] "Under a limited distribution network, a manufacturer contracts with one or a few specialty pharmacies to dispense high-maintenance medications." Indu Pillai, *Limited Distribution Drugs 101*, Clarivate (Sept. 27, 2019), https://clarivate.com/blog/limited-distribution-drugs-101/. Often, these distribution limitations are profit driven.
[11] 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) ("1996 Guidance").
[12] *See, e.g.*, 42 U.S.C. § 300ff-22(b)(3)(M); § 247c(c) (some sexually transmitted disease clinics provide testing and case management services only).
[13] HHS Off. of Infectious Disease & HIV/AIDS Pol'y, *HHS Ending the HIV Epidemic: About Ending the HIV Epidemic in the US: Overview* (2021), https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview.
[14] Sofia Fernandez, et al., *Barriers to Medication Adherence and Retention in Care among Women Living with HIV in the Face of Homelessness and Unstable Housing*, 19 Int. J. Environ Res. Pub. Health. 11484 (Sept. 13, 2022).
[15] *See, e.g.*, Sanofi, Sanofi Policy (Feb. 1, 2021), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/sanofi-letter-to-340b-covered-entities-february-2021.pdf.
[16] The following drug companies have restricted 340B drug distribution and are members of Plaintiff: AbbVie, Amgen Inc., Astellas Pharma Inc., AstraZeneca Pharmaceuticals LP, Bausch Health, Bayer, Biogen, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol Myer Squibb, Eli Lilly and Company, EMD Serono, Exelixis, Gilead Sciences, Inc., GlaxoSmithKline, Johnson & Johnson, Merck and Company, Novartis Pharmaceuticals Corporation, Novo Nordisk, Inc., Organon, Pfizer Inc., Sanofi-Aventis US LLC, Teva, United Therapeutics Corporation, and UCB

patients and jeopardizing patient access to affordable and accessible prescription drugs. Two states – Arkansas and Louisiana – recently enacted laws prohibiting drug manufacturers from restricting access to contract pharmacies but covered entities in the rest of the country enjoy no such protection.[17]

Clear Congressional Intent to Support Contract Pharmacy Arrangements

The legislative history of the 340B statute clearly demonstrates that Congress considered adding provisions to the 340B statute *to restrict* access to 340B drugs by requiring providers dispense them through on-site pharmacies. *Congress chose to refrain* from enacting that limitation after hearing testimony from covered entities like RWCs.[18] Moreover, every administration, Republican and Democrat, has consistently interpreted the 340B statute as allowing contract pharmacy arrangements, as evidenced by the HRSA's multiple contract pharmacy guidelines and nearly 30 years of program operations.[19]

HRSA Has Long Recognized Covered Entities' Right Under State Law to Use Contract Pharmacies

HRSA first addressed the contract pharmacy question in 1996 and observed that the use of contract pharmacies does not constitute "an unauthorized expansion of the [340B] program" because "[t]he statute is silent as to permissible drug distribution systems," and contains "*no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself*."[20] HRSA emphasized that contract pharmacy distribution arrangements did not "create a new right but rather [was] simply recognizing *an existing right that covered entities enjoy under State law*."[21]

PROPOSED POLICY SOLUTIONS

Codify Covered Entities' Right to Use Contract Pharmacies and States' Rights to Regulate Them

Congress must take a stand against manufacturers' unilateral and damaging restrictions on 340B contract pharmacy arrangements. It must recognize covered entities' right to enter into such arrangements and protect state laws that enable access to them. Section 340B(a)(1) of the Public Health Service Act should be amended to prohibit:

- manufacturers from limiting or obstructing in any way a covered entity's access to 340B drugs at contract pharmacies, including by refusing to pay wholesaler chargebacks or requiring information on 340B drug claims; and
- wholesalers from refusing to deliver 340B drugs or to provide access to a manufacturer's 340B pricing file.

Such legislation should also:

[17] Ark. Code Ann. § 23-92-604(c); La. Stat. Ann. § 40:2884.
[18] S. Rep. No. 102-259, at 2 (1992) (considering S. 1729, 102d Cong. (1992)).
[19] *Astra, U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[20] 1996 Guidance, 61 Fed. Reg. at 43,549 (emphasis added).
[21] *Id.* at 43,550 (emphasis added).

- contain a "savings clause" to protect state laws from preemption if they are not less restrictive on drug manufacturers and not more restrictive on covered entities than federal law;
- impose civil monetary penalties and other consequences on drug manufacturers and distributors that violate the above protections; and
- define a manufacturer violation as an "overcharge" for purposes of the ADR process.[22]

Question Category 3

What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

The 340B Program Works as Intended to Benefit Patients

Since 1992, the 340B program has served as a critical component of this nation's public health infrastructure. The program was intended to provide vital support to nonprofit federal grantees and other safety-net providers, including RWCs and community health centers, that serve our country's most vulnerable communities, at no cost to taxpayers. Program eligibility was carefully crafted by Congress to target specific types of clinics, centers, and hospitals that comprise this nation's health care safety net. Congress was wise in realizing that the best way to support underserved and medically vulnerable patients was to provide more resources to the safety net clinics and hospitals that are required to care for them. And covered entities need for support is unequivocal. Because the patient populations they serve are generally poor and without adequate insurance, they are routinely undercompensated for their services or not paid at all.

Safety Net Providers Need Flexibility in How They Use Program Savings

Congress was purposefully silent on how covered entities use 340B savings because Congress carefully limited eligibility to entities that are already subject to strict income utilization and transparency requirements. For example, almost all covered entities are non-profit organizations whose income must be used to further their nonprofit missions and are subject to audit by the Internal Revenue Service.[23] RWCs are bound by statute to care for vulnerable HIV patients who are low-income, regardless of their ability to pay.[24] RWCs are also bound by income use restrictions and other limitations on their use of federal funding, which includes 340B savings.[25] By the explicit terms of the Ryan White HIV/AIDS Program ("RWHAP"), RWCs are required to use their savings to benefit low income people living with HIV, through detailed "core medical services" and "support services."[26] They are meticulously audited by the HRSA HIV/AIDS

[22] House Report statement on intention not to limit purchasing.
[23] 26 U.S.C. 501(c)(3); IRS 990 for all nonprofits; IRS, *Charity and Nonprofit Audits: Scope of Audits and Compliance Checks* (Feb. 8, 2020), https://www.irs.gov/charities-non-profits/scope-of-audits-and-compliance-checks-of-exempt-organizations.
[24] *Supra* note 22.
[25] *Supra* note 22.
[26] *See, e.g.*, 42 U.S.C. § 300ff-14, § 300ff-22, § 300ff-51 (requiring that specific percentages of Ryan White funding be used on core medical services, support services, and administrative expenses and that such services be furnished to low-income individuals); 42 U.S.C. § 254b (requiring that health center funding be used on primary health services to medically underserved populations regardless of their ability to pay); 42 C.F.R. Part 75 (establishing strict program income use restrictions for federal grantees).

Bureau to ensure their compliance with this criterion.[27] The federal government, therefore, has very specific and longstanding knowledge that RWCs' use of 340B savings inures to the benefit of their vulnerable HIV patients.

Congress understood that 340B providers require flexibility in how they use their savings, in order to cover the cost of critical services that are uncompensated, to make up for reimbursement deficits, and to keep their doors open. Critics claim that 340B entities, including RWCs and community health centers, do not use their savings to help patients in need. Clinical literature suggests otherwise. Patient outcomes data demonstrate that RWCs are clearly using their 340B savings to meet the needs of HIV patients. Ryan White covered entities have a significantly higher rate of success in treating patients living with HIV than non-340B RWCs. In 2017, 87.1% of RWC clients receiving HIV care were virally suppressed, exceeding the national average of 62.7%. RWCs help their patients achieve these favorable outcomes by forging partnerships with third-party administrators, contract pharmacies and other 340B vendors that are skilled at helping covered entities provide quality care in a compliant way. For example, RWCs are caring for an increasing number of patients who struggle with other chronic conditions that must be managed by prescription medications.[28] They rely on their 340B partners to meet the complex challenges of treating co-morbidities. Congress therefore should refrain from regulating how 340B providers use their savings because, simply put, they are in a better position than Washington bureaucrats to make sure that the value of the 340B program in meeting patient needs is maximized.

Discriminatory Reimbursement Threatens the Safety Net and Public Health

Congressional silence on the use of 340B savings is being exploited by certain insurance plans and their pharmacy benefit managers ("PBMs") that engage in discriminatory reimbursement. Discriminatory reimbursement is a term used to describe a form of spread pricing, through which for-profit PBMs and other payers reimburse safety net providers and their pharmacies at a lower amount for 340B drugs than non-340B drugs. In doing so, these companies usurp the 340B benefit for their own profit.

HRSA has expressed concern that safety net providers will have no reason to participate in the 340B program if PBMs and other payers continue to take the benefit of 340B savings from them. HRSA has explained that "if covered entities were not able to access resources freed up by the drug discounts when they…bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities."[29] Twenty-eight states have responded to this direct attack on the 340B program by enacting laws that protect 340B covered entities from discriminatory payer practices.[30] At the federal level, Congress is seeking to advance the PROTECT 340B Act of

[27] HRSA, *Ryan White HIV/AIDS Program Recipient Audit Reports*, https://ryanwhite.hrsa.gov/grants/audits (last visited July 27, 2023).
[28] HRSA, *Ryan White HIV/AIDS Program Biennial Reports*, (Feb. 2022), https://ryanwhite.hrsa.gov/data/biennial-reports.
[29] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005).
[30] *See, e.g.*, Alabama (Ala. Code § 27-45A-10); Arizona (Ariz. Rev. Stat. Ann. § 36-2930.03); Arkansas (Ark. Code Ann. § 23-92-604); Colorado (Colo. Rev. Stat. Ann. § 10-16-1505); Georgia (Ga. Code Ann. § 33-64-9.1(b));

2023, H.R. 2534 that would not only prohibit discriminatory reimbursement, but would protect against other kinds of predatory contracting practices by PBMs. The PROTECT Act would stop PBMs from imposing onerous 340B claims identification requirements, removing 340B providers from the payer's network solely because they participate in 340B, or taking any other action that would interfere with a covered entity's ability to use 340B drugs for its eligible patients.

PROPOSED POLICY SOLUTIONS

Protect Covered Entity Discretion in How Program Savings Is Used

- To ensure that the value of the 340B program continues to benefit patients, the program should retain its inherent flexibility in how safety net providers serve those patients and communities as Congress wisely designed.

Enact the PROTECT Act

- Passage of the PROTECT Act would provide baseline protection in all fifty states against discriminatory reimbursement and other anti-340B predatory practices by PBMs.
- It would also allow states to establish stronger protections and not interfere with the twenty-eight states that have already enacted discriminatory reimbursement laws.

Question Category 4

What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

Duplicate discounts occur when a manufacturer provides a Medicaid rebate and 340B discount on the same drug. The law is clear that 340B drugs are not eligible for Medicaid rebates when they are billed to a Medicaid managed care organization ("MCO").[31] To implement this prohibition on duplicate discounts, CMS directed state Medicaid agencies to develop mechanisms to ensure Medicaid rebates are not collected on 340B drugs billed to Medicaid MCOs.[32] RWC-340B believes these mechanisms have yielded mixed results and that state or federal legislation would solve the problem. At the state level, RWC-340B supports the use of

Illinois (215 Ill. Comp. Stat. Ann. § 5/513b1; 305 Ill. Comp. Stat. Ann. § 5/5-36); Indiana (Ind. Code Ann. § 27-1-24.5-19.5); Louisiana (La. Stat. Ann. § 40:2883); Maryland (Md. Code Ann., Ins. § 15-1611.2); Michigan (Mich. Comp. Laws Ann. § 550.829; Mich. Comp. Laws Ann. § 550.926); Minnesota (Minn. Stat. Ann. § 62W.07); Montana (Mont. Code Ann. § 33-2-2410); Nebraska (Neb. Rev. Stat. Ann. § 44-4609); North Carolina (N.C. Gen. Stat. Ann. § 58-56A-50); North Dakota (N.D. Cent. Code Ann. § 19-02.1-16.5); Ohio (Ohio Rev. Code §§ 3902.70, 3902.71, 4729.49, 5164.753, 5167.01, 5167.123); Oregon (Or. Rev. Stat. Ann. § 735.534); South Dakota (S.D. Codified Laws § 58-29E-15); Tennessee (Tenn. Code Ann. § 56-7-3119); Utah (Utah Code Ann. § 31A-46-309); Vermont (Vt. Stat. Ann. tit. 18 § 9473); Virginia (Va. Code Ann. § 38.2-3467); West Virginia (W. Va. Code Ann. § 33-51-9); and Wyoming (Wyo. Stat. Ann. § 26-52-104).

[31] 42 U.S.C. § 1396r-8(j)(1).

[32] Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5289-90 (Feb. 1, 2016); 42 C.F.R. § 447.511(c); *see also* 42 C.F.R. § 438.3(s)(3) (providing that state contracts that obligate MCOs to provide coverage of covered outpatient drugs must include a requirement that the MCO establish procedures to exclude utilization data for drugs subject to 340B discounts).

retrospective claims identification pioneered by the Oregon Medicaid program.[33] Covered entities and contract pharmacies submit 340B claims data retroactively and periodically (e.g., monthly, quarterly) to a state vendor. The data file contains the information necessary for the state Medicaid agency to remove 340B claims from its rebate requests to the manufacturer. At the federal level, RWC-340B supports passage of the PROTECT 340B Act of 2023 (H.R. 2534), introduced by Rep. Abigail Spanberger (D-VA) and Dusty Johnson (R-SD), because it would require HHS to contract with a neutral third party to serve as a national clearinghouse to prevent duplicate discounts under Medicaid.

PROPOSED POLICY SOLUTION

Urge CMS and States to Adopt the Oregon Model

- The Oregon model has a proven record of preventing duplicate discounts by accurately identifying 340B MCO claims and removing them from state rebate requests.

Enact the PROTECT Act

- The PROTECT Act would establish a neutral clearinghouse that would protect against Medicaid duplicate discounts in all fifty states.

Question Category 5

What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

RWC-340B applauds HRSA's robust auditing of covered entities that commenced in 2012. HRSA has continued to audit approximately 200 covered entities per year since 2015, which we believe is appropriate and sufficient.[34] The results of covered entity audits demonstrate that covered entity compliance with the 340B program has improved. In fact, most audits of covered entities find inadvertent and simple errors that are readily corrected. To improve integrity within the 340B program, we recommend that HRSA focus its attention on manufacturer integrity and transparency. HRSA should implement and enforce the manufacturer integrity provisions in the 340B statute, which require verification of the accuracy of 340B prices in the OPAIS database and the levying of civil monetary penalties for manufacturer overcharges.

We believe the most impactful change HRSA can make to improve program accountability and give 340B stakeholders more confidence in program oversight would be to increase the frequency of audits of manufacturers to verify their 340B price calculations comply with the 340B statute's discount formula. To date, HRSA has audited very few manufacturers—auditing only about five manufacturers every year—and has utilized a process that, compared to the covered entity audit protocol, is still in its infancy.

PROPOSED POLICY SOLUTION

[33] This Medicaid managed care claims identification model is one of the few "best practices" recognized by CMS. CMS, *Best Practices for Avoiding 340B Duplicate Discounts in Medicaid* at 6 (Jan. 8, 2020).
[34] HRSA, *Program Integrity: Audit Results,* https://www.hrsa.gov/opa/program-integrity (last reviewed July 2023).

Increase and Expand Manufacturer Audits

- Manufacturer audits should be performed at the same frequency as covered entity audits to improve program integrity.

Question Category 6

What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

The 340B Program Should Not be Re-Envisioned as a Mandatory Direct-to-Patient Discount on Drugs

Covered entities have long used 340B program savings and revenue, as Congress intended, to expand and improve health care within their service areas to populations desperately in need of care. While money saved or generated through 340B program participation is used to cover the cost of medications for uninsured or underinsured patients, it can be used in other ways to support patient care, for example, to furnish necessary medical and social services that would otherwise be uncompensated.

The 340B program does not and was not intended to entitle patients to receive low-cost medications.[35] Rather, discounted pharmaceuticals are but one of many types of critical services provided by covered entities to vulnerable communities as Congress intended.[36] Some critics would like to redefine the purpose of the 340B program to one that simply provides free or low-cost drugs to patients, similar to the patient assistance programs ("PAPs") that many manufacturers offer to needy patients. Under this model, the covered entity would merely serve as a conduit for extending drug discounts to individuals.

Affordable Medications Is Just One Aspect of Public Health

Studies show that merely eliminating cost-sharing requirements, without a broader system of support, has a negligible impact on patient outcomes and overall health care costs and may even reduce compliance with medication regimens.[37] According to peer-reviewed literature, drug costs *are only one relevant factor* among many for addressing patient health outcomes, quality of care, and care costs. To lower health care costs and improve patient outcomes, interventions

[35] Drug manufacturers have understood this key characteristic of 340B since the program's inception. Manufacturers continue to agree to participate in the program in exchange for their drugs being reimbursed by Medicare Part B and Medicaid. Manufacturers therefore sell *extensively* more product under Medicare and Medicaid beneficiaries in exchange for providing a 340B discount to safety-net providers. The 340B program is therefore a taxpayer relief program.

[36] The 340B program provides steep discounts on drugs purchased by covered entities to enable them "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. II (Sept. 22, 1992).

[37] Niteesh K Choudhry et al., *Full Coverage for Preventive Medications after Myocardial Infraction*, 365 New Engl. J. Med. 2088 (2011).

must address patient knowledge, attitudes, complexity of prescription regimens, and other difficulties in accessing medications, which are all services provided by covered entities.[38]

In many communities – particularly low-income rural and urban areas – safety net providers and the contract pharmacies they rely on for dispensing medications – offer the only pathway to affordable health care for underserved populations. Most covered entities do, in fact, provide medications to needy patients at little or no cost, often below the covered entity's 340B acquisition cost. But using the program for the sole purpose of lowering patient drug costs would do a grave injustice to patients. The high cost of drugs is just one of a myriad of obstacles that vulnerable patients face in accessing clinically appropriate health care in the U.S. The strength of the 340B program is that it allows a covered entity to use drug savings to address and mitigate the barriers to care that are unique to patients within that entity's service area.

PROPOSED POLICY SOLUTIONS

Refrain from Imposing Patient Entitlement or Transparency Requirements

- Continue to allow safety net providers to determine the most effective use of their 340B program savings so that safety net providers can address their local community's unique needs rather than turning 340B into a federally determined, one-size-fits-all patient assistance program.
- If the 340B program were administered as a patient assistance or entitlement program, the ability of 340B covered entities to meet the public health needs of their communities would be dramatically undercut.

For further information, contact Peggy.Tighe@PowersLaw.com, Legislative Counsel to RWC-340B.

Sincerely,

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President
Ryan White Clinics for 340B Access

[38] For example, most insurance plans do not cover medication therapy management, yet the literature clearly shows that these kinds of programs improve patient outcomes and lower health care costs. In the longest running study of these programs, researchers found that they improved patient outcomes, decreased annual direct medical costs, and saved an estimated $4 for every $1 invested. Carole W. Cranor et al., *The Asheville Project: Long-Term Clinical and Economic Outcomes of Community Pharmacy Diabetes Care Program*, 43 J. Am. Pharm. Ass'n 173 (2003).