Ryan White Clinics for 340B Access

December 15, 2023

Chairman Ron Wyden
Committee on Finance
239 Dirksen
Washington, DC 20510-6200

Ranking Member Mike Crapo
Committee on Finance
221 Dirksen
Washington, DC 20510-6200

Re: Opposition to 340B Covered Entity Reporting Requirement Language

Dear Chairman Wyden, Ranking Member Crapo, and Members of the Committee:

On behalf of Ryan White Clinics for 340B Access ("RWC-340B"), **we write today to express our concern regarding a reporting requirement under consideration by the Senate Finance Committee that would discriminate against and undermine the purpose of the 340B drug pricing program ("340B Program")**. RWC-340B is a national organization of HIV/AIDS medical providers receiving funding under the Ryan White CARE Act, which provides financial support for services given to low-income and/or uninsured people with HIV/AIDS. Ryan White providers are eligible to participate as covered entities in the 340B Program. Ryan White clinics—like many other safety-net providers—rely on 340B savings to provide critical community services that would otherwise be uncompensated.

The proposed reporting requirement would require covered entities to report to the Secretary, on an annual basis, the amount that they receive for drugs above their acquisition cost from Medicaid managed care organizations ("MCOs").[1] RWC-340B is deeply concerned that any language requiring covered entities to report the amounts they spend and receive on 340B covered outpatient drugs would have dire unintended consequences on the 340B Program and the safety net as a whole. While we are very supportive of transparency in the 340B Program, we are concerned that this language has an ulterior motive of shifting 340B Program savings to Medicaid MCOs, thereby undermining the purpose of the 340B Program and subjecting 340B covered entities to discriminatory reimbursement.

<u>The Proposed Transparency Provision Would Undermine the Purpose of the 340B Program</u>
The proposed reporting requirement is inherently discriminatory against covered entities, as there is no similar reporting requirement applicable to non-340B providers or drugs. If transparency

[1] Lower Costs, More Transparency Act, H.R. 5378 § 202(a)(1) (2023).

were the real purpose of the requirement, it would apply to all drugs reimbursed by Medicaid MCOs, not just 340B drugs. The fact that it targets 340B drugs reveals a different purpose, namely, to invite state Medicaid programs and their MCO contractors to cut reimbursement for 340B drugs. That consequence would undermine the purpose of the 340B Program by shifting program savings from covered entities to Medicaid MCOs.

The 340B Program was enacted by Congress "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] The 340B Program allows covered entities to provide this community benefit by giving them discounts on prescription drugs from manufacturers.[3] Covered entities use the difference between the discounted acquisition cost of their drugs and the standard non-340B reimbursement they receive from payers to support their safety net mission, as Congress intended.[4] For Ryan White clinics, this ranges from free or discounted medications to critical wrap-around support services for people living with HIV.

It is important to note that in states where 340B Program discounts were eliminated in the name of cost savings, states spent hundreds of millions of dollars to attempt to compensate for the community care covered entities could no longer provide to their communities.[5] Those new state-funded initiatives merely replaced support that was reliable and not taxpayer-funded with

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[2] H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2d Sess. 1992); *see also Genesis Health Care, Inc. v. Becerra*, Case 4:19-cv-01531-RBH (Nov. 3, 2023) ("The legislative history indicates that Congress was not willing 'to continue to allow [covered entities] and their patients to remain unprotected against manufacturer price increases' . . . . Put simply, the purpose of the 340B program was to provide a means to make 340B entities profitable in order for those 340B entities to "stretch scarce Federal resources as far as possible."); HHS' Motion to Dismiss or, in the Alternative, for Summary Judgment, at 12, *Eli Lilly, et al., v. Becerra*, Case 1:21-cv-00081-SEB-MJD (Apr. 5, 2021) (The 340B Program allows covered entities to "generate much-needed revenue through sale of those medications (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has served a crucial role in facilitating healthcare for vulnerable patients ever since.").

[3] 42 U.S.C. § 256b.

[4] *See Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896 (2022) ("HHS insists that Congress could not have intended for the agency to "overpay" 340B hospitals for prescription drugs. But when enacting [the Medicare Prescription Drug, Improvement, and Modernization Act] in 2003, Congress was well aware that 340B hospitals paid less for covered prescription drugs. After all, that had been the law for the duration of the 340B program, which began in 1992 . . . 340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support.").

[5] In New York, Ryan White clinics and other safety net clinics estimated they would lose $316 million annually due to the carve-out. This figure excludes hospitals participating in 340B, which have also experienced significant losses. *2023 Joint Legislative Public Budget Hearing on Health*, (NY 2023) (Testimony of Jacquelyn Kilmer, CEO Harlem United and Perry Junjulas, Executive Director Albany Damien Center on behalf of the Save NY's Safety Net Coalition). New York had to make up for these revenue losses with tax-payer dollars through rate increases for hospitals and supplemental payments for FQHCs and Ryan White Clinics. *See* NYRx Transition: Federally Qualified Health Center (FQHC) Alternative Payment Model (APM) 4, New York State Department of Health, Office of Health Insurance Programs (2023). The same happened when California implemented a carve out ban in 2009. Since then, California has continued to pay safety net providers supplemental funds annually to make up for 340B program losses. These supplemental payments are estimated to total $52.5M in 2023. *See* Notice of General Public Interest and Request for Public Input on State Plan Amendment 23-0031 Which Proposes a Supplemental Payment for Non-Hospital 340B Clinics, CA Dep't of Health Care Servs. (2023).

unreliable funding and a new taxpayer burden. In short, the proposed transparency measure would not accomplish any identified Congressional goal, while at the same time eliminating the benefit of long-standing established federal policy.

The Reporting Language Is Antithetical to the Purpose of Managed Care

The proposed reporting requirement would also contravene long-standing federal law that protects the private payment arrangements inherent to the Medicaid managed care model. Under the Medicaid managed care rule issued by the Centers for Medicare and Medicaid Services ("CMS"), states are prohibited from directing the expenditures that the MCOs incur in contracting with and paying their participating providers.[6] In the Federal Register notice implementing this requirement, CMS stated that "the MCO . . . as a risk-bearing organization[], maintain[s] the ability to fully utilize the payment under that contract for the delivery of services."[7] A distinct feature of MCOs is their ability to achieve cost savings and improve quality of care through private negotiation with their participating providers – a feature that would be eroded if the providers are subject to federal reporting requirements. If such requirements are adopted, state Medicaid programs would be encouraged to underpay MCOs based on an expectation that the MCOs will lower drug reimbursement for covered entities to their acquisition cost. In effect, states would be micromanaging the discretion they have given to MCOs to negotiate privately the payment terms of their participation agreements. Such a practice would be antithetical to the private market philosophy of managed care.

The Reporting Language Is Inherently Discriminatory

The Health Resources and Services Administration views discriminatory reimbursement as a threat to the 340B Program itself—without the savings the 340B Program offers, covered entities would have no reason to participate in the 340B Program and to invest 340B savings on caring for underserved populations.[8] Further, the reporting requirement would conflict with the majority of states' laws prohibiting discrimination against covered entities. Over half of states have enacted legislation prohibiting such discriminatory practices.[9] The discriminatory nature of the proposed reporting requirement is also inconsistent with broad bi-partisan Congressional support for a bill that would prohibit health plans and pharmacy benefit managers from subjecting 340B covered entities to discriminatory reimbursement terms.[10]

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[6] 42 C.F.R. § 438.6(c)(1).
[7] Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27498, 27582 (May 6, 2016).
[8] *See* HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (July 2005).
[9] *See* CHART: STATE LAWS PROHIBITING DISCRIMINATORY REIMBURSEMENT, RWC-340B (2023), https://rwc340b.org/wp-content/uploads/2023/07/Condensed-Chart-340B-Discriminatory-Reimbursement-Laws-D0848211-15.pdf.
[10] PROTECT 340B Act of 2021, H.R. 4390 (2021).

For the above reasons, RWC-340B opposes the 340B-specific Medicaid MCO drug reimbursement reporting requirement currently under consideration by your committee. It would also oppose any comparable language requiring public disclosure of 340B savings if non-340B reimbursement is not also subject to disclosure. Alternatively, if the Committee chooses to adopt the requirement, we ask the Committee to include language prohibiting state Medicaid programs from using 340B savings information to lower reimbursement rates for 340B drugs. Without such protections, covered entities would inevitably be subject to discriminatory payment cuts, to the detriment of the vulnerable populations they serve.

We appreciate the Finance Committee's historic commitment to protecting the 340B Program and the value it brings to Ryan White clinics and their patients. For further information, please contact Peggy.Tighe@PowersLaw.com, Legislative Counsel to RWC-340B.

Sincerely,

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President
Ryan White Clinics for 340B Access