Ryan White Clinics 340B for 340B Access

April 22, 2022

Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

RE: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Commissioners Khan, Phillips, Slaughter, and Wilson,

On behalf of Ryan White Clinics for 340B Access (RWC-340B), this letter responds to the request by the Federal Trade Commission (FTC) for comments on the business practices of pharmacy benefit managers (PBMs) and their impact on independent pharmacies and consumers. RWC-340B greatly appreciates the opportunity to share our grave concerns about certain PBM practices that we believe significantly harm the healthcare safety net and the vulnerable communities they serve in direct contradiction to federal law.

RWC-340B is a national association of HIV/AIDS health care clinics and service providers receiving support under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Our clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and are serving on the frontlines of the HIV/AIDS epidemic as well as the COVID-19 pandemic, supporting high risk clients and communities. RWC-340B members support patients by providing primary care, case management, testing and behavioral health, and other support services.

Our members participate in the federal 340B Drug Discount Program (340B Program). The 340B Program was established in 1992 under section 340B of the Public Health Service Act and requires drug manufacturers to offer substantial discounts on outpatient drugs to certain safety net providers, including Ryan White clinics.[1] The discounts that RWC-340B members receive allows them to provide more comprehensive care to greater numbers of HIV/AIDS patients. This use of 340B Program savings is exactly the purpose that Congress intended when it adopted the 340B statute. Specifically, legislative history of the 340B statute states that the program's purpose is to help eligible safety net providers to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

Many RWC-340B members operate their own pharmacies as part of the clinical services that they provide to their patients. Some RWC-340B members also contract with third party pharmacies to provide access to 340B

[1] Veterans Health Care Act of 1992, Pub. L. No. 102-585, §§ 601-03, 106 Stat. 4943 (1992) (codified at 42 U.S.C. § 256b). The 340B program is administered by the Health Resources and Services Administration (HRSA) through its Office of Pharmacy Affairs (OPA), both agencies within the United States Department of Health and Human Services.
[2] H.R. Rep. No. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).

pricing under a contractual agreement known in the 340B Program as a "contract pharmacy." Under a contract pharmacy agreement, the third-party pharmacy dispenses drugs on behalf of the RWC-340B member to the member's patients. The term "340B pharmacies" is used in this letter to refer collectively to pharmacies that are owned and operated by a 340B covered entity and contract pharmacies.

Pharmacy benefit managers process nearly three-quarters of the over 37 billion prescriptions filled at retail pharmacies each year.[3] As such, the PBMs have outsized leverage in any contractual arrangements with pharmacies while safety net providers have significantly unequal bargaining power. While there are many PBM practices that impact pharmacies and patients, this letter focuses on PBM practices that are significantly harming patients and pharmacies nationwide.

Soon after the 340B Program's inception, PBMs began adopting practices that attempt to usurp 340B discounts from covered entities or put 340B pharmacies at a competitive disadvantage with respect to pharmacies affiliated with the PBM. The following is a list of the problematic PBM practices that impact 340B pharmacies and the patients that 340B safety net providers serve:

- PBMs offer reduced reimbursement for 340B drugs and to 340B pharmacies and thereby essentially transfer the benefit of the program from safety net providers to themselves.
- PBMs favor their own retail contract pharmacies in their network over 340B pharmacies.
- PBMs use various means to prevent 340B pharmacies from fully participating in a PBM pharmacy network. Pharmacy focused barriers range from excessive credentialing or recredentialing procedures to outright exclusion of 340B covered entities from a given network. Patient focused practices force or incentivize patients to exclusively use a PBM's mail order pharmacies over all other competitors.
- PBMs adopt "spread pricing" profiting schemes under which PBMs retain portions of what they are paid by insurance plan sponsors instead of transferring the full payments to pharmacies.
- PBMs force pharmacies to adhere to burdensome prescription claims identification methods for submitting 340B eligible claims.[4]

All these discriminatory practices are antithetical to the purpose of the 340B Program, which is intended to help 340B covered entities and the patients they serve, not to financially benefit for-profit PBMs. HRSA's original contract pharmacy guidance[5] and its expanded guidance[6] both reiterate that contract pharmacy arrangements are designed to realize Congressional intent. HRSA has expressed concern with several of the discriminatory reimbursement practices mentioned above, warning that they undermine the purpose and intent of the 340B Program. HRSA 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."[7]

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[3] *State Policy Options and Pharmacy Benefit Managers (PBMs)*, NCSL (Mar. 23, 2022), https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/.

[4] *See, e.g.*, Express Scripts, *New 340B Claims Identification and Submission* (Feb. 24, 2021), https://www.cv340b.org/express-scripts-issues-340b-claims-identification-requirements.

[5] 61 Fed. Reg. 43,549, 43,552, 43,555 (Aug. 23, 1996).

[6] 75 Fed. Reg. 10,272 (Mar. 5, 2010).

[7] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* 14 (July 2005), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf.

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Many states have adopted laws that prevent PBMs from the types of discriminatory activities listed above.[8] In just the last few years, 19 states passed laws prohibiting PBMs from discriminating against 340B safety net providers.[9] Another 20 state bills are pending in state legislatures.[10] State action is evidence of the severity of the problem and Congress has taken note, with Reps. McKinley (R-WV) and Spanberger (D-VA) introducing bipartisan legislation – the PROTECT Act (H.R. 4390). Introduced in July of 2021, the federal bill is co-sponsored by 85 members of the U.S. House of Representatives. A federal solution as envisioned in the PROTECT Act would uniformly end these discriminatory PBM practices.

For-profit PBMs usurp the benefit of the 340B Program for themselves by singling out non-profit and government-funded safety net providers and their pharmacies for reduced reimbursement and other unfair terms and conditions. These tactics limit the providers' ability to provide vital health care and other critical services to the vulnerable communities they serve and increases pressure on taxpayers to make up the difference. RWC-340B members use their 340B program savings to provide more comprehensive services to their patient populations and to expand the number of patients that they serve. For-profit PBMs do not have the same motives and should be prevented from continuing their discriminatory practices that harm 340B pharmacies and the 340B safety net community.

Sincerely,

Shannon Stephenson

Shannon Stephenson
President
RWC-340B

[8] *See, e.g.*, Or. Rev. Stat. §§ 735.530, 735.534 (2021) (prohibiting PBMs from, among other things, requiring that prescriptions be filled through mail order and reimbursing 340B pharmacies differently than other pharmacies); Ga. Code Ann. §§ 33-64-1 to 12 (prohibiting PBMs from engaging in spread pricing, applying retroactive fees, and treating 340B pharmacies differently than other pharmacies); Tenn. Code Ann. § 56-7-3119 (prohibiting PBMs from "[reimbursing] a 340B entity for pharmacy-dispensed drugs at a rate lower" than non-340B pharmacies and excluding 340B pharmacies from their networks "based on criteria that is not applied to non-340B entities").

[9] *State Policy Options and Pharmacy Benefit Managers (PBMs)*, NCSL (Mar. 23, 2022), https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/.

[10] *2022 State Legislative Action to Lower Pharmaceutical Costs*, NASHP (Apr. 15, 2022), https://www.nashp.org/rx-legislative-tracker/.