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:

Community Voices for 340B (CV340B) is a grassroots organization that seeks to raise awareness of the important role that the federal 340B drug pricing program (340B program) plays in protecting and improving health care access and the quality of care for communities nationwide. CV340B aims to educate, enable, and inspire support for the 340B program at the local level by helping individuals and community leaders tell their side of the story: why 340B is vital to them and why a sustained and vibrant 340B program is an essential tool for protecting and improving public health, especially for medically underserved populations. Recently, we published what we call our "Touchstones and Truths" document, detailing our strongly held beliefs about the 340B program.

CV340B hosts five Regional Advocacy Groups made up of representatives from every 340B stakeholder group. Community Voices is the only national organization where these groups can come together to discuss how to promote and educate the public about the benefits of the 340B program. Through CV340B's discussions with these stakeholders and our conversations with patients, community leaders and public health workers who support the 340B program, and with the understanding that our 501(c)(3) status as a non-profit prevents us from advocating for specific legislative proposals, we humbly submit to you the following response to your request for information.

340B Program Is Vital to Public Health But Is Under Attack

Established in 1992 through bipartisan legislation, the federal 340B drug discount program offers a lifeline to the neediest and most underserved patients in this nation. The program operates on the simple principle of requiring pharmaceutical companies to provide drugs at a discounted price to certain types of safety net hospitals and clinics that, in turn, use their 340B savings to underwrite the cost of serving patients in their communities. That reinvestment in patients and communities is what has made the 340B program so successful. 340B providers can do more with their limited dollars to benefit the communities that they serve.

Over the past 30 years, the 340B program has consistently helped safety net providers meet the unique public health needs of their communities, and Congress has built on that success to extend program eligibility to additional categories of safety net providers. However, despite affecting just a small percentage of drug sales in the United States, the program is the target of "reform" efforts by pharmaceutical companies that have taken program requirements into their own hands.

Today, more than twenty of the largest manufacturers are unlawfully and unilaterally restricting access to 340B pricing on drugs dispensed by contract pharmacies and that number continues to grow. If manufacturers can condition their participation in the program in this manner, imagine what other conditions they might apply in the future. These restrictions are undeniably threatening the ability of the nation's health care safety net to meet the public health needs of our country. Staff and services are being cut at an alarming rate leaving underserved communities in a precarious position. Meanwhile, pharmaceutical manufacturers seem unrelenting in their quest to shrink the program to increase their profits.

Efforts to Redefine the Program's Purpose Undermine Its Effectiveness

The 340B program is working as Congress intended, namely, to help safety net providers provide *more* comprehensive care to *more* patients. Unlawful limitations on how covered entities use the 340B program to deliver care to their communities are entirely unacceptable. Critics allege that the intent of the program should be changed, that there should be fewer 340B safety net providers and less use of the program, and that limitations are needed on safety net providers' use of contract pharmacies. However, these reform efforts, if implemented, would undermine covered entities' ability to provide comprehensive and accessible care to the individuals who need such support the most. Covered entities are in a better position than Washington lawmakers to identify and address the health care and social service needs of local communities.

The more than twenty pharmaceutical manufacturers that are currently limiting contract pharmacies' access to 340B drugs are not only depriving covered entities of the revenue and savings that contract pharmacies generate they are also effectively limiting the rights of patients to choose where they receive their medicine. These manufacturer restrictions are forcing patients to travel farther to fill their prescriptions and/or reducing the likelihood that patients will pick up their drugs in the first place. Such unilateral and illegal restrictions threaten public health by undermining the intended reach of the 340B program.

Beware of the True Motivation of Proposed Transparency Requirements

Critics allege that the 340B program needs more federal oversight and increased reporting requirements. However, "transparency" is often a cover for the real goal – to complicate participation in the program and redefine its purpose. In fact, CV340B determined through analysis of the publicly available HRSA audit reports that covered entity compliance with the 340B program has improved by 41% over the past five years. The percentage of covered entity audits in which HRSA has issued no sanctions have *increased* from 47% in 2018 to 75% in 2021. During that same period, the percentage of drug company audits in which HRSA issued no sanctions fell by 75%. While covered entities were fighting on the front lines of COVID-19, struggling with staffing and drug shortages, and navigating ever-changing unilateral and illegal drug company contract pharmacy restrictions, they have only gotten better at administrating their 340B programs responsibly.

Drug companies first justified their restrictions on contract pharmacy arrangements by claiming they increase program "transparency." They adopted policies requiring covered entities to submit 340B claims data as a condition of using contract pharmacies. Those policies have largely been replaced with outright bans against contract pharmacy arrangements except in the limited case of covered entities lacking their own in-house pharmacies. Manufacturers' real goal is to shrink their obligation to provide 340B discounts to covered entities. We see these same profit-driven behaviors elsewhere from drug companies. For example, three of the largest enemies of contract pharmacy arrangements – Johnson & Johnson, Merck, and Bristol Meyers Squibb – are also suing the Department of Health and Human Services to overturn the Inflation Reduction Act, signed into law on August 16, 2022. These companies will clearly go to any lengths to avoid giving discounts on their drugs to the Medicare program and the 340B safety net.

States Serve an Important Role in 340B That Should Be Protected

The 340B statute obligates manufacturers to offer their drugs at 340B prices but is silent on how 340B drugs are distributed to covered entities. Distribution of 340B drugs falls within the province of state regulation. Several pharmacy benefit managers (PBMs) have been siphoning off 340B discounts by reimbursing pharmacies at reduced and discriminatory rates. Many manufacturers have been discriminating against the 340B program by refusing to ship drugs to contract pharmacies when those drugs are subject to 340B discounts. Twenty-nine states have responded by enacting prohibitions on discriminatory reimbursement by PBMs. Two have passed laws protecting contract pharmacy arrangements. Now a drug company has gone to court alleging that the 340B program is only governed by federal law, an approach that defies the rights of state legislatures and exposes federal and state taxpayers to picking up the enormous cost of services now provided by 340B safety net providers.

Manufacturers Need Greater Oversight to Protect Program Integrity

Safety net providers know the value of the 340B program and work diligently to comply with program requirements. They conduct regular internal program audits to be prepared for a HRSA audit. Covered entities are being audited by HRSA at far higher rates compared to manufacturers. Each year HRSA audits 200 covered entities while only auditing five drug

companies. Results from HRSA audits are posted publicly on the HRSA website providing further proof of existing program transparency. Notably, it wasn't until 2016 that HRSA began auditing more than just a single manufacturer. In the hundreds of HRSA audits of covered entities conducted over the past 5 years, most findings were minor errors or omissions. Drug companies, by contrast, have been required to repay covered entities with increasing frequency for violating their discount obligations. It is clear from these publicly available observations that, to improve program integrity, HRSA needs to step up enforcement and oversight of manufacturers.

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The 340B program is working as intended by providing safety net providers with increased resources to meet the health care needs of their local communities. Data shows that covered entities are fulfilling their obligation to comply with 340B program requirements while using program savings for the benefit of their patients and community. That said, the program is at risk as a result of manufacturers' purported reform efforts, their unilateral restrictions on contract pharmacy arrangements, and PBMs' discriminatory contracting practices. Greater manufacturer and PBM oversight are therefore needed to protect the program.

Community Voices for 340B appreciates your effort to gather information and keep Congress properly informed about the 340B program. Please consider CV340B a resource if questions arise about the role of the 340B program in supporting communities across the nation.

For further information, contact Rhiannon Marshall Klein.

With gratitude,

George Puckett
President
Board of Directors
Community Voices for 340B