April 2, 2024

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:

Thank you for your efforts to protect and improve the 340B drug pricing program (340B program) and for the opportunity to share our views on the Senate 340B Working Group's second request for information (RFI). This letter responds to the RFI.

Community Voices for 340B (CV340B) is a grassroots organization that raises awareness of the important role that the 340B program plays in protecting and improving healthcare access and the quality of care for communities nationwide. CV340B provides an important forum for covered entities, patients, pharmacies, vendors and other 340B program supporters to work together to educate the American public about the value of the program in supporting public health in this country. For example, CV340B hosts monthly regional group meetings of more than 600 individuals who are dedicated to advocating for the 340B program. It launched several years ago the Together for 340B Campaign which provides funding for pro-340B digital education advertisements that have garnered over one million views to date. This year we look forward to hosting the Third Annual March to #Defend340B, which brings 340B program advocates from across the nation to Washington, DC to voice their support of the program to Congress.

CV340B responded to the Working Group's first RFI by preparing a document that we call "Touchstones and Truths." We urge the Working Group to revisit that document because it explains CV340B's deep conviction that the 340B program has evolved into a critical financing

mechanism for public health in the U.S. and, for that reason, must be protected. In this letter, CV340B wishes to reiterate the views expressed in its previous submission, with a special emphasis on the "Touchstones" and "Truths" that are most relevant to the new RFI. The second half of the letter focuses on key issues raised by the Working Group in the RFI: contract pharmacies, patient definition, transparency, program integrity, and user fees.

TOUCHSTONES AND TRUTHS

CV340B's Touchstones and Truth document responds in large part to a series of drug industry allegations about the 340B program that are either misleading or untrue. Several of the document's responses are pertinent to the RFI.

TOUCHSTONE: PROTECT THE PROGRAM'S ROLE IN ENHANCING PATIENT ACCESS TO CARE

The intent of the 340B program is well-established: to provide *more* comprehensive care to *more* patients. Uninsured and underinsured Americans are highly dependent on the healthcare services delivered by a network of safety net hospitals and clinics that are obligated by law and/or mission to provide care regardless of patients' ability to pay. Any changes to the 340B program that limit patients' access to care or that undermine covered entities' ability to deliver care to their communities, are entirely unacceptable. Manufacturers want to redefine the intent of the 340B program, to reduce the number of covered entities participating in the program and to limit covered entities' use of contract pharmacies.

TRUTH: Changing the intent of the program would…

- Deny covered entities the ability to provide comprehensive and accessible care to individuals who need it the most.
- Undermine safety net providers' ability and flexibility to best serve the individual needs of their communities.

TRUTH: Narrowing eligibility of safety net providers participating in the program would…

- Defy Congress' previous determinations of which groups are eligible for the program.
- Undermine the intended reach of the 340B program, threatening public health.

TRUTH: Limiting access to contract pharmacies would…

- Limit patients' access to care.
- Interfere with patients' right to choose where to receive their medications, forcing them to travel farther or not picking up their drugs at all.

TOUCHSTONE: BEWARE "TRANSPARENCY" PROPOSALS

CV340B supports transparency within the 340B program, but critics' transparency proposals would be unduly burdensome if adopted. Such proposals are unnecessary because covered entities are already subject to significant reporting requirements.

TRUTH: "Transparency" is often a cover for the real goal – to shrink the 340B program.

- Unless payers are prohibited from discriminating against 340B pharmacies, 340B claims identification requirements and similar disclosure provisions will exacerbate

the existing problem of 340B-specific reimbursement cuts and barriers to network participation.

- Preoccupation with publishing covered entities' "profits" and charity care levels are more about misleading the public than acquiring useful information.

TOUCHSTONE: PROTECT FEDERAL REGULATORY AUTHORITY & PRESERVE STATES RIGHTS

Manufacturers are subject to an unconditional obligation to offer 340B discounts on covered outpatient drugs to covered entities. Manufacturers "self-help" strategy of withholding 340B pricing on drugs delivered to contract pharmacies is a direct violation of this federal statutory obligation. On the other hand, even though the 340B program was established at the federal level, Congress never intended to interfere with state regulation of the supply chain used to deliver 340B drugs. Nor does it regulate coverage and reimbursement of 340B drugs by third party payers. State laws protecting contract pharmacy arrangements and prohibiting discriminatory reimbursement by payers should be preserved.

TRUTH: Drug company lawsuits are paralyzing use of the 340B program at both the federal and state levels.

- Some drug companies are abusing the judicial system as a way to interfere with covered entities' use of the 340B program. Their lawsuits make claims that misrepresent the carefully defined roles of the federal and state governments in regulating program activities.
- A recent drug company litigation strategy is to allege that 340B is only governed by federal law, an approach that defies the rights and importance of state legislatures and would result in federal and state taxpayers picking up the bill for services now provided by 340B safety net providers.

TOUCHSTONE: PROTECT PROGRAM INTEGRITY

Covered entities are fighting on two fronts to protect their use of the 340B program. They are combatting manufacturer "reform" efforts to shrink the size of the program and payer "pickpocketing" practices that threaten to reduce the program's value. To address these threats, more resources are needed to enforce program requirements. Otherwise, the ability of the program to support public health will erode and taxpayers will be left holding the bag.

TRUTH: 340B is being abused by drug companies and payers.

- Drug companies must be stopped from unilaterally and unlawfully withholding 340B pricing on drugs ordered by covered entities for use by their contract pharmacies.
- States must be allowed to enforce their laws to prevent pharmacy benefit managers (PBMs) and other payers from siphoning off 340B discounts by using discriminatory practices against safety-net providers.
- Congress and the agencies, not drug companies or courts, should guide program integrity for the 340B program.

VIEWS ON KEY ISSUES IN THE RFI

CV340B is a non-profit 501(c)(3) organization and therefore does not comment on specific legislative proposals. It would like to take this opportunity, however, to share the following

information and data to ensure that the 340B Working Group is properly informed about key issues addressed in the RFI.

Contract Pharmacies

The "bill to/ship to" arrangement underlying covered entities' use of contract pharmacies is a long-established mechanism used by safety net providers to help patients access prescription drugs. Such use facilitates the intent of the 340B program – "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Any limitation, geographic or otherwise, to covered entities' ability to utilize contract pharmacy arrangements harms patient care and public health.

For nearly 30 years, the drug industry honored the use of contract pharmacy arrangements to help underserved populations. In 2020, when America's healthcare safety-net was facing a multitude of challenges associated with the COVID pandemic, drug companies one-by-one began blocking the delivery of 340B medications to contract pharmacies, leaving millions of Americans in the lurch. Patients have endured real harm due to these unilateral and unlawful restrictions. Some have been forced to change prescriptions to drugs that are less effective and/or more expensive. Others have endured the inconvenience of searching for, finding, and traveling to a different pharmacy. Today, over thirty drug companies are denying covered entities access to the 340B savings they need and count on to improve public health in their services areas. This overreach by the drug industry – defying federal and state law – thwarts both Congress' intent in establishing the 340B program and the states' roles in protecting public health. Increased use of contract pharmacies is not an abuse, as the drug industry contends. Rather, it furthers the intent of the program by expanding access to affordable medications and generating more savings to underwrite the cost of uncompensated care. The drug industry clearly wants to sell its products, but not at the discount required by Congress and needed by underserved populations.

Patient Definition

The drug industry argues that savings from the 340B program should be delivered directly and exclusively to patients and that there should be a far more limited definition of patient in the 340B program. This rhetoric deceives policymakers and the public into believing that the program doesn't give drug discounts to patients or that safety net providers are not bound by rules about who are their patients. Safety net providers do provide deep discounts to patients, but they do far more than that. Further, there is a "patient definition" in the 340B program that is widely used by covered entities and part of all routine covered entity audits from the Health Services and Resources Administration (HRSA). HRSA's 1996 patient eligibility standards (61 Fed. Reg. 55156-158) have guided the 340B program for nearly 30 years. That standard

[1] 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 [1] 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.").

contains the most important elements of a patient-provider relationship – services are delivered by the 340B safety net provider who maintains responsibility and records of the care. Any limitations on patient eligibility would be completely counter to the purpose of the 340B program – providing more services to more patients.

Safety net providers are best positioned to understand their communities' needs and know who their patients are, as already reviewed by HRSA through audits or the Administrative Dispute Resolution process. 340B savings are used by safety net providers on more than drugs; they are used to help patients get other services, prevention, outreach, education, and the like. With often exorbitant drug costs, even a huge discount would be of no service to patients with little resources. Further, if the drug industry really wanted discounts to go directly to patients, they could simply do so or lower drug prices for all. Further, recasting the 340B program as a direct to patient drug discount would destroy the 340B program's ability to use savings gained from insured patients to cover drugs and services for uninsured patients and for uncompensated services.

Limiting the 340B patient definition was recently tested in the U.S. District Court in South Carolina. The court analyzed the intent of the 340B program and "patient definition," finding that, "It is evident that Congress 1) Was aware the potential issue with a broad definition for 'patient.' 2) Had the tools to limit the definition and, 3) Chose not to."[2] The broad definition of patient was not only a deliberate choice by Congress but allows covered entities to serve a wide range of patients and fulfill the intended purpose of the 340B program. As such, any changes to direct savings to patients or narrow the definition of "patient" will directly and negatively impact patient care in our healthcare safety net.

Transparency

Safety net providers should not be subjected to a new regulatory burden for choosing to enroll in a program that is intended to mitigate the high cost of drugs caused by publicly traded for-profit, multi-national companies. Requiring covered entities to itemize their use of the program only serves to increase the administrative burden on covered entities and divert resources away from covered entities' ability to care for their patients. Even more troubling are the anticipated consequences of forcing covered entities to disclose valuable pharmacy-related financial data. Requiring safety net providers to share drug cost and charge data, patient demographics, the amount and use of 340B savings and similar information would arm drug companies with new data that they can manipulate to support their decade-long campaign to criticize the program.

The same concerns about high drug prices that led Congress to create the 340B program thirty years ago still exist today. The drug industry has long decried a lack of covered entity transparency in the program to conceal its true goal, namely, to regain the profits that manufacturers have lost by having to sell their drugs at the 340B discounted price. Meanwhile, drug companies enjoy a lack of transparency applicable to their own prices because of federal Medicaid laws protecting the confidentiality of a manufacturer's "best price" and "average manufacturer price." It defies reason to impose greater transparency standards on covered entities' drug prices when manufacturers' drug prices are shielded from disclosure.

[2] https://cv340b.org/wp-content/uploads/2023/12/U.S.-District-Court-of-South-Carolina-upholds-fundamental-patient-definition-for-340B-covered-entities.pdf.

Enhancing Program Integrity

Any conversation about enhancing program integrity is incomplete without addressing the obvious shortcomings in how manufacturers comply with their discount obligations. Below is a chart listing the number of overcharge notices manufacturers have issued to covered entities, the number of NDC overcharges committed and the number of audits to which they have been subjected. These statistics reveal a significant lack of compliance by the drug industry.

Manufacturer	Notices	Number of NDC Overcharges	Audits Since 2015
Alcon	1	22	0
Amgen	2	84	0
Amneal	1	699	0
Amring Pharmaceuticals	1	14	0
Chartwell RX	1	43	0
Daiichi Sankyo	1	3	0
Dermavent	1	1	0
Eli Lilly and Company	2	10	0
Granules	1	94	0
GSK	4	44	0
J&J	4	31	1
Jazz	1	2	0
Lifestar Pharma	1	4	0
Meitheal	1	11	0
Merck	3	25	0
Neurocrine Biosciences	1	1	0
Noven	1	21	0
Novo Nordisk	4	9	0
Purdue	1	15	0
SK Life Science	1	8	0
SpecGx	1	118	0
Tolmar	1	7	0
Vertex	1	1	0
VistaPharm	1	245	1
WG Critical Care	1	1	0
Zydus	1	60	0
Total	39	1573	2

https://www.hrsa.gov/opa/manufacturer-notices

Covered entities know the value of the 340B program and invest significant resources to comply with program requirements. They are regularly audited by HRSA and audit results show that covered entities' compliance status is consistently improving. CV340B determined – through analysis of publicly-available HRSA audit reports – that covered entity compliance has improved

by 41% over the past five years. The percentage of covered entity audits in which HRSA issued no findings increased from 47% in 2018 to 75% in 2021.[3]

These statistics indicate that, while covered entities were fighting on the front lines of the COVID pandemic, struggling with staffing and drug shortages, and navigating ever-changing contract pharmacy restrictions, they were still able to meet their 340B compliance responsibilities. Yet, covered entities are being audited at nearly forty times the rate of manufacturers. It is the drug industry that should be audited more frequently. In 2023, 26 manufacturers issued 39 individual overcharge notices to covered entities offering repayment on 1,573 distinct NDCs.[4] In the past nine years, only two of those 26 manufacturers were audited by HRSA.[3] This year Genentech issued a notice to covered entities detailing a ***ten-year*** period (2011 to 2021) in which it overcharged covered entities for the orphan drug Klonopin (clonazepam). Yet, Genentech has not been audited by HRSA in the past nine years.

User Fee Program

It is internally inconsistent to impose a user fee on participants of a program that is designed to reduce costs for the participants. That inconsistency is even more pronounced for a proposed user fee within the 340B program since the purpose of reducing drug costs for covered entities is to expand access and services for the most medically vulnerable population in our country. Holding the public health safety net financially responsible for funding HRSA's 340B oversight is also inconsistent with the 501(c)(3) tax status of non-profit covered entities. The user fee would effectively impose a federal tax on their participation in the 340B program. CV340B feels strongly that covered entities should be able to use all their 340B savings to care for the medically underserved, i.e., to stretch scarce federal resources to serve more patients and provide more comprehensive services as the law intends.

* * * * *

The 340B program is at a critical juncture. Data shows that covered entities are fulfilling their obligation to comply with 340B program requirements while using program savings to benefit their patients and communities. The drug industry, by contrast, is taking advantage of lax enforcement within the program and going to court to challenge policies that they dislike. The 340B program faces serious risks as a direct result of drug industry's efforts to shrink the program, to increase revenues, and to avoid regulation. Greater drug industry oversight is therefore needed to protect the program.

Community Voices for 340B appreciates the Working Group's effort to review and protect the 340B program. Please consider CV340B a resource if questions arise about the role of the 340B program in supporting public health within local communities across our nation.

For further information, contact Rhiannon Marshall Klein at rhiannon.marshall@cv340b.org.

[3] https://www.hrsa.gov/opa/program-integrity.
[4] https://www.hrsa.gov/opa/manufacturer-notices.