Ryan White Clinics for 340B Access

August 24, 2023

Via email: **drugshortages@mail.house.gov**

The Honorable Cathy McMorris Rodgers
Chair, Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Re: Opposition to Draft Legislation on Drug Shortages

Dear Chair McMorris Rodgers:

Ryan White Clinics for 340B Access ("RWC-340B") strongly opposes Title II of the draft legislation you released on July 28, 2023 (the "Discussion Draft"), which excludes certain drugs from discounts under the federal 340B drug pricing program ("340B Program") and infers that the 340B Program is the cause of drug shortages. These provisions are a thinly veiled drug industry attempt to scapegoat the 340B Program for drug shortages that its own greedy tactics have created. The industry has failed to convince Congress to restrict the 340B Program according to its terms, so it is now trying a different tactic: blame the 340B Program for shortages that it fosters and for its failure to manage its own supply chain. While RWC-340B shares and appreciate your commitment to addressing drug shortages and ensuring patients can access needed medications, we strongly disagree with the approach set forth in Title II of the Discussion Draft.

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, which enables them to expand and support care. Ryan White clinics—like many other safety-net providers—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.

340B Program Overview

The 340B Program was created by Section 602 the Veterans Health Care Act of 1992, which added section 340B to the Public Health Service Act ("PHS Act"). The 340B Program requires drug manufacturers to enter into a Pharmaceutical Pricing Agreement ("PPA") with the Department of Health and Human Services ("HHS") Secretary as a condition having their drugs

covered under Medicaid and Medicare Part B. Under the PPA, manufacturers agree to provide front-end discounts on "covered outpatient drugs" purchased by "covered entities," which includes several categories of statutorily-defined providers like Ryan White clinics that serve the nation's most vulnerable patients. The 340B Program strengthens the U.S. public health infrastructure by providing discounted drugs to safety net providers without use of taxpayer dollars. The Energy and Commerce Committee's report on the bill introducing the 340B Program stated that the program is intended to allow covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

Most covered entities, including Ryan White clinics, use a virtual inventory system to manage their 340B inventory. A virtual inventory system allows covered entities to keep small amounts of a drug on hand and then restock with drugs purchased under the 340B program after the drugs is dispensed to a patient. Most HIV medications come in a 30 day supply, resulting in very small and predictable quantities needed for each patient. Covered entities, therefore, are not stockpiling 340B drugs. They are at the end of the supply chain – not the ones causing issues at the beginning of the supply chain. Given the high cost of HIV medications and rudimentary pharmacy operations practices, no pharmacy would willingly choose to increase its inventory levels.

As we noted in our July 7, 2023 response to your request for information ("RFI") on drug shortages, in over thirty years of the 340B Program's existence, critics have failed to provide any evidence that the 340B Program creates pressures to reduce generic drug prices to unsustainable levels or otherwise contributes to the problem of drug shortages.[2] Actions taken by the pharmaceutical industry and drug manufacturers are at the root of nearly all drug shortages, yet this Discussion Draft shifts the blame to 340B safety net providers. Title II would negatively affect the 340B Program and patients and we urge the Committee to reconsider its approach.

Restricting 340B-Eligible Drugs Only Serves to Harm Patients

Title II, Section 201 ("Exempting Generic, Sterile Injectable Drugs from the 340B Drug Discount Program") of the Discussion Draft would exempt drug companies from providing 340B discounts on generic, sterile injectable drugs with at least one indication for a serious disease or condition that are made by more than one manufacturer. Narrowing the scope of 340B eligible drugs, as this provision would do, would unduly harm patients, while increasing pharmaceutical companies' profits by reducing their obligation to provide discounts through the 340B Program.

[1] H.R. Rep. No. 102-384(II), at 12 (1992).
[2] RWC 340-B, Response to Drug Shortages RFI (Jul. 7, 2023).

Any support from the drug industry for this provision is simply a ruse to attack the 340B Program and abandon any commitment to underserved patients.

Ryan White clinics—and all other 340B covered entities—deliver essential care to their patients and communities. If Congress began limiting the drugs eligible for 340B discounts, covered entities would be left with fewer resources to provide care to patients who are uninsured, underinsured, or dependent upon public health programs like Medicaid. For these reasons, we strongly oppose the removal of any eligible drugs from the 340B Program.

340B Penny Pricing Is Not a Cause of Drug Shortages

Title II, Section 202 ("Study on Penny Pricing and Other Price Setting Policies") would task the Government Accountability Office ("GAO") with investigating possible links between drug shortages and products that are that are subject to 340B penny pricing.

To participate in the 340B Program, drug manufacturers must abide by the "penny pricing rule," which requires them to charge no more than a penny for a drug when the ceiling price formula yields a lower price because of manufacturers raising the price of their drugs faster than the rate of inflation. This rule deters multinational drug companies from inflating their prices to increase profits within the U.S. drug market and thereby provides patients with essential protections.

As we noted in our July 7 response, 340B Program critics allege, with little to no supporting evidence, that 340B covered entities stockpile 340B drugs that are subject to penny pricing which, in turn, causes drug shortages.[3] We reiterate here that such a claim is entirely false, and HHS has unequivocally refuted it. In 2011, HHS' Health Resources and Services Administration ("HRSA") issued a 340B program notice stating that "when a 340B price drops to a penny price, a manufacturer may anticipate challenges with *equitable* market distribution of the drug, and should develop a plan for *non-discriminatory,* restricted distribution to all purchasers, *including 340B covered entities*."[4] This limited distribution mechanism dissociates 340B utilization from the potential of drug shortages. The GAO study proposed in the Discussion Draft is inappropriate and unnecessary and once again unfairly places blame for drug shortages on 340B covered entities, rather than on drug companies. Inflation penalties result in lower drug prices for patients and should not be treated as a cause of drug shortages.

[3] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1216 (Jan. 5, 2017).
[4] 340B Drug Pricing Program Notice Release No. 2011-2.

Congress Must Focus on Drug Manufacturers, Not Covered Entities

Finally, Title II, Section 203 "Guidance on Preventing Diversion During Shortages" would task HRSA with issuing guidance to covered entities on permissible ways to share drugs during shortages without violating prohibitions on drug diversion. This language inappropriately shifts blame to covered entities when drug shortages are manufacturer driven.

RWC-340B members acknowledge a drug shortage problem is imminent, but that problem is attributable solely to manufacturer misconduct. Manufacturers have announced that, of the few HIV/AIDS treatment options currently available in the U.S., several will be discontinued this year. Specifically, formulations of Epzicom (abacavir sulfate, lamivudine), Lexiva (fosamprenavir calcium), Selzentry (maraviroc), Tivicay (dolutegravir), Trizivir (abacavir sulfate, lamivudine, zidovudine), and Ziagen (abacavir sulfate) will be discontinued on January 1, 2024.[5] People living with HIV will therefore face limited treatment options, increasing health risks for those patients who may not tolerate medications still on the market. The unavailability of these medications will set back this nation's fight against the AIDS epidemic.

Congress must take action to prevent drug shortages, but targeting the 340B Program and safety net providers is not the answer. HRSA does not need to issue guidance to covered entities on permissible ways to share drugs during shortages. Nor does Congress need to take any other action outlined in the Discussion Draft. Rather, it needs to address the manufacturer-driven root causes of drug shortages, summarized below (as previously stated in our July 7 RFI response):

- Lack of incentive for manufacturers to produce less profitable drugs;
- Lack of incentive for manufacturers to maintain "mature quality systems" for drug production to improve and detect supply chain quality issues;
- Market consolidation among manufacturers of a given category of drugs, thereby limiting their supply;
- Disruption in complex constituent supply chains for manufacturers seeking to lower production costs by relying on unreliable outside entities to produce active pharmaceutical ingredients and finished dosage forms;
- Regulatory hurdles – such as compliance with FDA requirements for safe and effective drugs – that slow the entry of new drugs into the market and/or reduce drug production because of quality concerns;
- Manufacturer limited supply distribution restrictions that allow the manufacturer to proactively control the distribution of a drug, causing disruption to patients and safety

[5] Diana Ernst, Discontinuation of Several HIV Medications Reported to FDA (Jan 4, 2023), https://www.empr.com/home/news/discontinuationof-several-hiv-medications-reported-to-fda/.

net providers because the manufacturer proactively controls the distribution of the drug[6]; and

- Manufacturers' underproduction simply due to failure to anticipate spikes in demand caused by natural disasters and public health emergencies, such as Hurricane Maria in Puerto Rico and the global COVID-19 pandemic.[7]

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As detailed in this letter, RWC-340B has significant concerns about the Discussion Draft's proposal to remove certain 340B drugs from eligibility for discounted prices, contemplating the suspension of inflation penalties that are proven to result in lower drug prices, and unfairly shifting blame to 340B covered entities for drug shortages. RWC-340B urges the Energy and Commerce Committee to delete all of these provisions before introducing any legislation to address drugs shortages.

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

Sincerely,

Shannon Burger, MBA, CPA
President
Ryan White Clinics for 340B Access

[6] For example, the manufacturer of Mytesi® has implemented a limited distribution plan that allows only three specified pharmacies to dispense the drug. Mytesi® is used to treat diarrhea in adult patients with HIV/AIDs on anti-retroviral therapy, so limiting access to this medication directly impacts the patients of Ryan White clinics, particularly those with pharmacies that manage all of the other medications, and interactions of those medications, for Ryan White patients.

[7] American Society of Health-System Pharmacists, https://www.ashp.org/drug-shortages/shortage-resources/drug-shortagesstatistics?loginreturnUrl=SSOCheckOnly.