Ryan White Clinics 340B for 340B Access

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April 1, 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
170 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:

On behalf Ryan White Clinics for 340B Access (RWC-340B), thank you for proposing a legislative framework to protect and improve the federal 340B drug pricing program (340B program). The 340B program, as you know, has become a vital source of support for the safety net providers that serve as the backbone of this nation's public health system.

RWC-340B has carefully reviewed the draft legislation, explanatory statement, and supplemental request for information (RFI) that the Bipartisan 340B Senate Working Group (Working Group) shared with 340B stakeholders on February 2, 2024, in connection to its draft bill called the "SUSTAIN 340B Act". We submit the attached chart in response to the Working Group's proposed changes to the 340B program as reflected in those documents.

RWC-340B is a national association of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program. Ryan White clinics (RWCs) 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 including primary care, case management, dental and behavioral health, and other support services.
The attached chart builds on the comments that RWC-340B submitted on July 28, 2023, in response to the Working Group's initial RFI. In those comments, RWC-340B articulated a series

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of principles to help guide Congress in strengthening the 340B program for RWCs and people living with HIV. The purpose of the chart is to provide feedback on the SUSTAIN 340B Act discussion draft (Discussion Draft) based on the principles that RWC-340B previously furnished to the Working Group.

In our submission for the initial RFI, we asked that any resulting legislation incorporate certain key protections and improvements that are summarized below.

- The legislative intent of the 340B program should not be reinterpreted any differently than how Congress stated it in the conference report that accompanied the original statute. That intent has guided the program to support the nation's public health system for over thirty years. Congress intended the program to broadly support safety net providers, enabling them to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]
  - The 340B program should not be restructured into a patient drug assistance program. Safety net providers should continue to derive 340B savings from insurance reimbursement from people who are not low income and to reinvest those savings broadly, without limitation to low-income and uninsured services. This broad support will continue to enable RWCs to provide more comprehensive care to all people living with HIV/AIDS and to curb the spread of HIV.[2,3]
  - Taxpayers should not bear any burden for an untested new vision for the 340B program to relieve highly profitable drug companies of their responsibility to provide discounted medications to safety net providers. Drugmakers already reap nearly three times more profit on US taxpayers compared to other developed countries.[4]

[1] Congress was clear regarding its wise decision for 340B to provide broad support to strengthen our Nation's public health system. Congress stated that it intended 340B to "enable these [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 96 (emphasis added). Congress also stated that the 340B statute "*does not authorize the Secretary [of HHS] to limit in any way the volume of purchases* that can be made at the" 340B price. *Id.* at 16.

[2] Peer reviewed studies show that merely eliminating cost-sharing requirements, without a broader system of support, has a negligible impact on patient outcomes and overall health care costs and may even reduce compliance with medication regimens. Niteesh K Choudhry et al., Full Coverage for Preventive Medications after Myocardial Infraction, 365 New Engl. J. Med. 2088 (2011); Francois Despres et al., Impact of Patient Reimbursement Timing and Patient Out-of-Pocket Expenses on Medication Adherence in Patients Covered by Private Drug Insurance Plans, 22 J. Manag. Care Pharm. 539 (2016).

[3] According to peer-reviewed literature, drug costs *are only one relevant factor* among many for addressing patient health outcomes, quality of care, and care costs. To lower health care costs and improve patient outcomes, interventions must address patient knowledge, attitudes, complexity of prescription regimens, and other difficulties in accessing medications, which are all services provided by covered entities. Carole W. Cranor et al., *The Asheville Project: Long-Term Clinical and Economic Outcomes of Community Pharmacy Diabetes Care Program*, 43 J. Am. Pharm. Ass'n 173 (2003).

[4] In 2022, U.S. prices across all drugs (brands and generics) were nearly three times as high as prices in 33 developed countries. For every dollar paid in other countries for drugs, consumers in the U.S. pay $2.78. The gap is widening over time as U.S. drug prices grow faster than drug prices in other countries and the mix of drugs changes. Assistant Secretary for Planning and Evaluation, *Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability,* ASPE HHS (Jan. 31, 2024), https://aspe.hhs.gov/sites/default/files/documents/d5541b529a379d1f908ed2f9c00a9255/aspe-cover-idr-pricing-availability.pdf.

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- Narrowly defined limits on access to 340B drugs, by disease state or condition, are unacceptable and will weaken the U.S. public health infrastructure.
- Policymakers and/or the courts must stop manufacturers from dictating the rules for the 340B contract pharmacy program.
- Onerous reporting requirements are unnecessary and will force RWCs to take time away from patient care and countless community services.
- Pharmacy benefit managers must be prohibited from siphoning off 340B savings.
- A national clearinghouse should be established to reduce the risk of duplicate discounts on Medicaid drugs, but it should not protect commercial rebate arrangements.
- Congress should not nullify state laws that are protective of the 340B program.

RWC-340B also asked that the Working Group consider the following policy requests as it charts a path forward for improving and protecting the 340B program.

- Require HRSA to finalize, implement 340B administrative dispute resolution (ADR) program;
- Clarify HRSA's regulatory authority to audit manufacturers and expand manufacturer audits;
- Codify covered entities' right to use contract pharmacies and states' rights to regulate their use; and
- Enact the PROTECT Act, H.R. 2534, to protect against payer's predatory contracting practices.

We structured the attached chart to facilitate evaluation of the Discussion Draft according to our previously submitted principles. The first two columns describe, respectively, the general topic area covered by the Discussion Draft and what the Working Group proposed on that topic. The third column summarizes RWC-340B's position on that topic as expressed in its response to the Working Group's initial RFI. The fourth column lists RWC-340B's comments to the Discussion Draft, and requested changes thereto, based on its previous feedback reflected in column three.

We deeply appreciate this opportunity to comment on the Discussion Draft and the Working Group's willingness to consider our input. Please contact Michael Thompson, michael@rwc340b.org, or Peggy Tighe at Peggy.Tighe@PowersLaw.com if you have any questions or need additional information.

Sincerely,

Shannon Burger
President, RWC-340B

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TOPIC	DISCUSSION DRAFT ON TOPIC	RWC-340B RESPONSE TO PREVIOUS RFI	COMMENTS OR CHANGES REQUESTED TO DISCUSSION DRAFT
LEGISLATIVE INTENT	Section 2 of the Discussion Draft seeks to memorialize the original purpose of the 340B program but could be interpreted as limiting the program.	The legislative intent of the 340B program should not be reinterpreted, re-envisioned, or stated any differently than it already is: "The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."	• RWC-340B generally supports the Discussion Draft's "Sense of Congress," which memorializes Congress' intent for the 340B program. • RWC-340B is concerned, however, that the current language could be interpreted to narrow the program's purpose. It suggests broadening the language to mirror Congress' original intent by: (1) incorporating Congress' statement from the statute's 1992 conference report that "the 340B program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services". (2) ensuring that it covers all safety net services, not just "health care services"; and (3) codifying that the statute "does not authorize the Secretary [of HHS] to limit in any way the volume of purchases that can be made at the" 340B price. • Shifting from states to covered entities the obligation to repay manufacturers for Medicaid managed care duplicate discounts is contrary to Congressional intent when Congress expanded both the 340B and Medicaid drug rebate programs under the Affordable Care Act (ACA). Congress added section 1927(j)(1) to the Social Security Act to clarify that expansion of the Medicaid drug rebate program to Medicaid managed care drugs did not apply to those drugs purchased through the 340B program. Section 8 of the Discussion Draft should be amended to honor that intent. • The legislative history of the 340B statute reveals Congress' decision not to disturb existing drug distribution arrangements used by covered entities, including contract pharmacy arrangements. Congress' intent to allow covered entities to continue using contract pharmacy and

			other drug distribution arrangements should be memorialized in Section 8.
FLEXIBILITY IN USE OF 340B SAVINGS	The Discussion Draft appears to preserve covered entities' discretion in using 340B savings and revenue to meet the unique public health needs of their patients and community.	• RWCs provide comprehensive services that range from free or discounted medications to critical wrap-around support services for people living with HIV including case management, medical transportation, linkage to other providers, and housing assistance. Because RWCs often receive no insurance payments for these services, they depend on 340B program savings and revenue to underwrite the cost of providing this care to their patients. The 340B program enables RWCs to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication	• Flexibility in use of 340B savings is critical for RWCs because it enables them to test and treat hard-to-reach populations and to provide other necessary services that are generally not covered and reimbursed by payers. Limiting use of the 340B program to drug discounts is completely unhelpful for untested patients who are unaware of their HIV status or patients who are not in treatment. Such limits would undermine our nation's fight against the AIDS epidemic. Fortunately, the Discussion Draft appears to protect how covered entities use their savings. • RWC-340B does not support imposing user fees on safety net providers. ○ Imposing user fees on covered entities will reduce 340B savings and revenue for RWCs. Further, the use of wholesale acquisition cost to calculate the user fees will inflate their size. ○ RWC-340B appreciates that the 340B program needs funding and that establishing a user fee program would satisfy that need. If Congress adopts a user fee program over covered entity objections, the fees should be used by HRSA to improve manufacturer compliance. For example, they should pay for HHS audits of manufacturers' calculation and reporting of best price, average manufacturer price, and inflationary penalty to ensure they are not manipulating those calculations to reduce their 340B and Medicaid rebate liabilities. • RWCs use 340B savings to fund contract pharmacy patient assistance programs to ensure their HIV patients have access to affordable medications. However, mandating such use could undermine patient care by steering 340B savings and income aware from more important patient and community needs.

		adherence and viral suppression. • The 340B program should not be restructured as only a patient drug assistance program or focus only on low-income and uninsured patients because doing so would mean that RWCs no longer have the resources to provide more comprehensive care to all patients. • RWCs already ensure that each of their patients receive the drugs that they need, often at no cost to the patient, because RWC grant requirements currently require RWCs to provide care to low-income patients.	• RWC-340B hopes to work with the Senators to ensure that some of the Discussion Draft's transparency provisions do not unintentionally undermine grantees' use of 340B savings. • Covered entities should be permitted to continue to contract with for-profit vendors because those vendors help covered entities utilize the 340B program and comply with its requirements.
CONTRACT PHARMACIES	Discussion Draft codifies the requirement that drugmakers deliver 340B	• Policymakers and/or the courts must stop manufacturers from dictating the rules for the 340B contract	• The Discussion Draft is strong on this point. RWC-340B applauds the Working Group for protecting 340B contract pharmacy arrangements because RWCs and their patients are highly dependent on them. • The requirement for a written contract pharmacy agreement is

	drugs to locations where patients can access them.	pharmacy program. • Contract pharmacy arrangements must <u>not</u> be limited in number, by geography or to certain service areas or populations. • Because many RWC's serve large rural service areas, these restrictions force patients to travel long distances where they could be using their local pharmacy. • Many RWC patients need drugs that are only available through specialty pharmacies located far from the RWC, but also need other drugs that they can pick up from their local pharmacy. • Arbitrary limitations set by drug manufacturers on access to 340B drugs only benefit the manufacturers and deny access to life saving medications to patients.	consistent with existing HRSA requirements, which RWC-340B strongly supports. • To avoid the burden on safety net providers of requiring them to modify existing agreements, consider replacing the "standard contract provisions" with the "essential compliance elements" terms found in HRSA's 2010 contract pharmacy guidelines (75 Fed. Reg. 10272-279), with the inclusion of a new term to effectuate the clearinghouse data collection requirement. ○ Contract pharmacy agreements are privately negotiated and contain nuanced, proprietary information. Such contract terms should not be subject to government specification, and proprietary terms should be redacted and/or held in confidence if submission is required. ○ Contract pharmacy registration should occur throughout the year, at the convenience of the safety net provider. Limiting registration to annual or quarterly registration windows significantly impedes pharmaceutical access to underserved patient populations and places significant burden on safety net providers. ○ Covered entities and contract pharmacies use a myriad of drug inventory accounting mechanisms, which should be explicitly permitted under the bill language to avoid disputes with drugmakers that seek to limit contract pharmacy arrangements. • Contract pharmacy contract review and oversight requirements should be achieved through a process that is less burdensome to safety net providers given their limited resources and the underprivileged communities they serve. • The Discussion Draft should set a federal "floor" that mandates that manufacturers do not condition 340B pricing on authorized delivery location or inventory accounting systems used by covered entities and their pharmacies.

			• Protections of contract pharmacy arrangements must not supplant state laws that are more restrictive on drugmakers.
TRANSPARENCY AND OTHER NEW REGULATORY REQUIREMENTS	Would impose new reporting requirements on covered entities, increase HRSA regulatory authority in other areas, some to manufacturer oversight, others to covered entities.	• As a condition of receiving a federal grant, RWCs must report on funds and uses from the grants. • Proposals requiring additional, onerous reporting requirements are unnecessary, will force RWCs to take time away from patient care and community service.	• Needs clarification that new transparency requirements only apply to hospitals. Requirements could be construed as applying to RWCs/other grantees, creating unnecessary burden. • If the Senators intend to apply the new accounting and reporting practices to grantees, such requirements will divert resources from patient care, thereby undermining the purpose of the 340B program. ○ Congress chose only certain categories of health care grantees as 340B-eligible because of other already granted federal designations, serving as a proxy for entities deserving savings. ○ Federal grantees are already subject to reporting requirements on their program operations, use of grant funds, and use of program income derived from grant-related activities.
PHARM'AL BENEFIT MANAGERS (PBMs), CLEARINGHOUSE	The Discussion Draft would provide timely and critical protections against predatory PBM contracting practices that threaten safety net savings and services. It would also establish a national clearinghouse to protect manufact-urers	• PBMs must be prohibited from siphoning off 340B savings by reducing payments for 340B drugs or creating network barriers that funnel HIV patients away from RWCs to unrelated and ill-quipped pharmacies participating in the PBM system. • A national clearinghouse should be established to	• The Discussion Draft would prohibit discriminatory reimbursement and other discriminating contracting practices by PBMs. It would also establish a national clearinghouse to prevent duplicate discounts. We applaud both measures and hope to help the Senate Working Group make improvements to the draft language. • RWC-340B strongly supports the provisions that prohibit payer discrimination and pickpocketing. ○ The 340B program has helped RWCs make enormous strides in the fight against HIV because it allows RWCs to reinvest program savings into programs that work to treat HIV and prevent its spread. ○ When PBMs and payers block RWCs from receiving those benefits by under-reimbursing RWCs for 340B drugs or imposing other restrictions, patients are directly harmed. ○ The prohibition against PBM reimbursement discrimination is critical for preserving the intent of the 340B program. The

	from duplicate discounts.	reduce duplicate discounts, but the clearinghouse should be narrowly targeted to prohibit duplicate discounts on Medicaid claims only, as prohibited in the 340B statute, not expanded to commercial claims.	benefit of the 340B discount should accrue to covered entities, including RWCs, so that they can be reinvested into patient care. The savings should not be taken by payers or PBMs. • The clearinghouse provisions are too broad and should prevent duplicate discounts before they occur rather than after manufacturer rebates are paid. • Pricing and reimbursement data submitted to the clearinghouse by covered entities should be limited to Medicaid claims and should not be shared with manufacturers due to their proprietary nature and the risk that manufacturers will use such information to the detriment of covered entities, patients, and the 340B program generally. • Responsibility for preventing duplicate discounts should be assigned to the neutral third party operating the clearinghouse, not manufacturers and states that have significant conflicts of interest.
ACCOUNTABILITY	The Discussion Draft adds new sections to the 340B law to enhance program integrity, to ensure equitable treatment of covered entities and pharmacies, and to provide additional resources for	• HRSA should be supported in ensuring program integrity through proper monitoring of 340B eligibility.	• RWC-340B supports the requirement that HRSA audits must follow audit standards established by the Comptroller General. ○ The Discussion Draft would increase the number of audits for covered entities that are found to be in violation of certain compliance requirements. ○ Because a diversion or duplicate discount finding can result from even one drug being dispensed improperly, increased audits should be limited to covered entities with significant compliance problems. ○ Manufacturers should also be subject to increased audits for significant non-compliance. ○ The requirement for further sanctions by HRSA if a covered

	program oversight.		entity fails to "implement" a corrective action plan within six months should be clarified to state that implementation does not mean negotiations with manufacturers over repayment obligations must be completed within six months because covered entities lack control over manufacturers' response to repayment offers. • RWC-340B strongly supports language imposing civil monetary penalties on manufacturers that prohibit or limit delivery of 340B drugs to contract pharmacies. ○ We recommend clarifying that such penalties be imposed on manufacturers that "limit, prohibit, or interfere with, either directly or indirectly, the delivery of" covered outpatient drugs. ○ Doing so will ensure that workarounds, such as refusals to pay 340B-based chargebacks to wholesalers or conditioning delivery on 340B claims data submission, are subject to civil monetary penalties.
COVERED ENTITY ELIGIBILITY	The Discussion Draft clarifies and imposes new covered entity eligibility requirements, especially with respect to offsite locations.	• Any proposal to limit 340B eligibility should be weighed carefully against the detrimental impact on underserved communities that will result from reducing resources to safety net providers. • The Ryan White program is divided into various parts, some for grantees and others for subgrantees through the states. Proposals	• The Discussion Draft does not appear to threaten the 340B eligibility of RWCs, but the relevant language needs to be tightened up. • RWC-340B also believes the Working Group has an opportunity to correct some eligibility-related inefficiencies by making some modest changes to the statute's current language. • RWC-340B suggests clarifying that a "child site" is unique to hospital covered entities. ○ Grantees have "associated sites" or "affiliated sites" that are co-equal with all other sites operating under the same grant. ○ Consider defining "affiliated sites" to describe all sites other than the primary sites, with "child site" as a specific hospital-type affiliated site. • All RWCs operating under a single grant should be treated as a single covered entity with a primary site and other "associated" sites.

		should not undermine subgrantee uses of the 340B program. • Compliance with the prohibition against diversion and duplicate discounts should not be a condition of eligibility for 340B. Covered entities are already required to make repayments to manufacturers if they discover any issue of non-compliance, often a result of simple errors or misunderstanding of complex HRSA guidance.	○ HRSA has historically treated each individual location of an RWC (and grantees other than federally qualified health centers) as a separate covered entity. ○ Treating offsite locations of RWCs as separate covered entities unfairly fragments RWCs into multiple 340B programs.
NULLIFICATION OF STATE LAW	The Discussion Draft does not contain protections for state laws that fill	• In no instance should Congress nullify state laws on 340B. More than 25 states have passed laws to prevent	• States and the federal government have clear rights to regulate 340B on issues under their control. The draft bill should be stronger on this point. • The Discussion Draft mandates that a manufacturer deliver or allow delivery of 340B drugs. State laws that govern drug distribution, the

	in gaps within the 340B statute and/or impose higher standards on 340B stakeholders.	discriminatory reimbursement and one state passed a law to regulate manufacturers' distribution of 340B drugs to contract pharmacies within state boundaries.	practice of pharmacy, contracting (indemnification, unconscionability, equitable remedies, etc.), unfair trade practices, and other nuanced matters must not be supplanted by the 340B statute. • RWC-340B strongly recommends including a "savings clause" to preserve state laws that fill in statutory gaps and impose higher standards on covered entities and manufacturers.
PATIENT DEFINITION	The Discussion Draft requests comment on a workable patient definition. This provides an opportunity to strengthen the nation's public health system through clarity without disrupting established norms and professional health care practices.	• Any proposals that create narrowly defined limits on access to 340B drugs, by disease state or condition, would seriously undermine the ability of safety net providers to use 340B savings to care for patients' comprehensive needs which, in turn, would threaten our nation's efforts to end the HIV epidemic. • Medical best practices and terms of our grants require that RWCs provide comprehensive, holistic care.	• RWC-340B commends the Working Group's request for information relating to 340B patient eligibility. We support codifying standards consistent with Congress's original intent for the program, to provide broad support to safety net providers serving as the backbone of the nation's public health system. ○ RWC-340B strongly recommends codifying HRSA's 1996 patient eligibility standards (61 Fed. Reg. 55156-158), which have guided the 340B program for nearly 30 years. ○ The existing standards touch on each of the key hallmarks of a provider-patient relationship – a health care service delivered by a covered entity health care professional such that the covered entity maintains responsibility and records of the care. ○ Grantees must deliver a service that is consistent with the scope of the award that earned them 340B program eligibility. ○ Neither the 340B statute nor the 1996 guidelines describe the duration of a patient-provider relationship, which is appropriate. • RWC-340B recommends specifying that a covered entity be required to maintain auditable records of the health care service rendered to the patient, and each drug purchased by the covered entity, including whether it was dispensed or administered to a patient, returned, or destroyed. • The focus should remain on the word "patient" and the relationship

		• The patient definition guidance published by HRSA in 1996 works well for RWCs. RWCs provide core medical services, including ambulatory, mental health, dental, home- and community-based and outpatient substance abuse care. • Determining a rigid timeframe for "patient definition" could be very harmful to the patients we serve. There is no cure for HIV, so many persons living with HIV receive care on an "as needed" basis for their entire lives.	between the patient and covered entity. The test should not focus on individual prescriptions which would disrupt established health care professional norms and practice. • RWC-340B does not believe that the patient definition should be established by regulations. Whether an individual is a "patient" is inherently a fact-specific determination. Interpretation of the standard is best left to the audit and administrative dispute resolution process as Congress intended under the ACA. • RWC-340B recommends revising the statutory diversion prohibition (42 U.S.C. § 256b(a)(5)(B)) to state that "a covered entity shall not resell, *dispense or administer* the drug to a person who is not a patient of the entity." ○ This language clarifies that the mere physical transfer of drugs without a change in title does not implicate the anti-diversion requirement. ○ A transfer of title occurs with the reselling, dispensing and administration of a drug. It does not occur when, for example, a contract pharmacy or patient representative merely takes physical custody of the drug.