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Chantelle Britton  
Director  
Office of Pharmacy Affairs  
Office of Special Health Initiatives  
Health Resources and Services Administration  
5600 Fishers Lane, Mail Stop 10W29  
Rockville, MD 20857

**RE: HHS Docket No. HRSA-2026-03042: Ryan White Clinics for 340B Access Comments in Response to Request for Information: 340B Rebate Model Pilot Program**

Dear Director Britton:

Ryan White Clinics for 340B Access (RWC-340B) appreciates the opportunity to submit comments to the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) in response to the Request for Information (RFI) regarding a 340B Rebate Model Pilot Program (Rebate Model Pilot). We strongly oppose any Rebate Model Pilot or any other proposal that would limit covered entities' access to upfront 340B discounts.

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) are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS. Our members are on the frontlines of the battle against the HIV/AIDS epidemic, supporting patients living with HIV/AIDS by providing primary care, case management, testing and behavioral health, and other support services that are proven to keep medically vulnerable individuals engaged in their healthcare. The 340B program allows RWCs to stretch their scarce resources to support the full continuum of care that their patients require, including testing, linkage to care, treatment, retention, case management, and medication adherence. Services funded by 340B savings enable RWCs to achieve high viral suppression rates for their patients, helping to improve their health, reduce costs and protect against new incidence of HIV.

RWCs have made tremendous strides towards controlling the AIDS epidemic in the U.S. Their success is due in large part to the support they receive from the 340B program. However, such progress would be seriously jeopardized and potentially reversed if HRSA capitulates to industry

pressure to allow manufacturers to offer 340B pricing in the form of a post-purchase rebate instead of an upfront discount. Because a rebate model would cause RWCs and their patients significant harm, we respectfully request that HRSA abstain from implementing a Rebate Model Pilot and collaborate with the Centers for Medicare & Medicaid Services (CMS) to establish a neutral 340B clearinghouse as an alternative approach to protect manufacturers from providing both the 340B ceiling price and a maximum fair price (MFP) rebate on the same drug claim.

#### **I. A Rebate Model Pilot Would Harm RWCs' Ability to Care for Their Patients**

The comprehensive services that RWCs provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and food and housing assistance. Because RWCs often receive no insurance payments for these services and given that Congress has kept funding for such programs through the Ryan White program flat, they depend on the 340B program to underwrite the cost of providing these critical services to their patients. Importantly, the 340B program allows RWCs to provide these expanded services without any cost to taxpayers. 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 adherence and viral suppression.

RWCs rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating RWCs' access to 340B discounts, the Rebate Model Pilot would erode the 340B savings available to RWCs to cover the cost of care to the uninsured and underinsured. A Rebate Model Pilot would make the comprehensive care that RWCs' patients need less accessible and more expensive, an outcome that is completely contrary to congressional intent in enacting the 340B program. Increased financial and administrative costs to RWCs from the Rebate Model Pilot would reduce the resources on which RWCs rely, both to care for existing patients and to identify additional patients in need of care. These burdens directly contradict the purpose of the 340B program – to enable covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>1</sup>

Additionally, contract pharmacies may be less willing to distribute 340B drugs to patients on behalf of covered entities due to the cumbersome and financially challenging rebate process. If contract pharmacies refuse to enter into agreements with RWCs, access to medications will be limited for Ryan White patients, many of whom are already difficult to reach due to barriers such as housing instability, food insecurity, unemployment, and mental health conditions for RWCs, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and RWCs' efforts to encourage patient adherence are significantly compromised if individuals living with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. Simply put, implementation of a Rebate Model Pilot would set back this nation's fight to end the AIDS epidemic.

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<sup>1</sup> H.R. Rep. No. 102-384, pt. 2, at 12.

## **II. A Rebate Model Pilot Would Increase RWCs' Drug Acquisition Costs**

A Rebate Model Pilot would increase RWCs' drug acquisition costs because they will lose the upfront 340B price reductions and subceiling discounts that they receive at the time of purchase. RWCs would be forced to pay wholesale acquisition cost for drugs at the point of sale and face the uncertainty of obtaining a rebate in the future. This process would place a cash flow strain on already under-resourced RWCs and would threaten their ability to pass through upfront discounts to patients at the point of sale.

HIV medications are among the most expensive drugs in the nation. Most RWCs lack the funds to buy their drugs at retail prices, which are often thousands of dollars above the drugs' 340B price. RWCs are non-profit community-based organizations that are required by law to invest their savings and revenue into patient care. They do not have the margins to float what is essentially an interest-free loan to drug companies and to wait to receive their 340B rebates.

## **III. A Rebate Model Would Place a Tremendous Administrative Burden on RWCs**

For the last 30 years, RWCs and their vendor partners have developed sophisticated technologies and workflows to manage the complexities of 340B compliance and operations. These carefully crafted systems have been built on the premise that RWCs receive 340B ceiling prices as upfront discounts. Converting 340B into a rebate program would completely upend these systems, pose substantial implementation and management costs, and do nothing to improve 340B compliance or operations. RWCs would have to make significant upfront and ongoing financial investments in technology, staff, and workflow redesign to accommodate a Rebate Model Pilot. Importantly, these investments would diminish RWCs' ability to care for their patients.

Some RWCs are also federally qualified health centers (FQHCs) and participate in 340B as FQHCs. The administrative burden of a Rebate Model Pilot would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when uploading data to manufacturer platforms. If HRSA advanced its Rebate Model Pilot, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

## **IV. A Rebate Model Pilot Would Further Manufacturer Efforts to Shrink the 340B Program**

A Rebate Model Pilot would be a "gift" to manufacturers. Even a narrowly constructed pilot would provide the foundation and blueprint for more restrictive manufacturer rebate models in the future. For years, manufacturers have attempted to shrink the size and scope of the 340B program, first through contract pharmacy restrictions and most recently through manufacturer-initiated rebate programs. The Rebate Model Pilot would give credibility to manufacturers' unfounded claims that the 340B program is flawed and in need of reform. The Rebate Model Pilot would inappropriately shift decision-making power into the hands of manufacturers to decide whether a covered entity purchase is eligible for the statutorily mandated 340B ceiling

price. Giving manufacturers control over whether 340B discounts are paid will lead to fewer 340B discounts because these discounts come directly from manufacturers' bottom lines.

For many years, covered entities have contended with pharmacy benefit managers (PBMs) using 340B claims data and knowledge of entities' program participation to target them for lower, discriminatory reimbursement rates. These payment policies erode covered entities' 340B savings and, in turn, undermine their ability to care for patients. Covered entities have had to fight for dozens of state laws prohibiting such policies and blocking requirements that entities share 340B claims data with PBMs. HRSA should not recreate this same problem by ceding control over 340B discounts to manufacturers or granting them access to data to which they are not entitled.

Pharmacy claims data is proprietary information. Manufacturers can use such data to fuel their marketing campaigns, whether directed at patients, providers, or both. Even worse, they can use the data to support their advocacy efforts to attack and shrink the 340B program. Manufacturers have a long history of publishing pseudo-scientific studies that allegedly document misuse of the 340B program. The Rebate Model Pilot would give them new data to expand their misinformation campaigns.

#### **V. HRSA Should Pursue a Neutral 340B Clearinghouse Instead of a Rebate Model Pilot**

Instead of proceeding with a Rebate Model Pilot, RWC-340B respectfully asks that HRSA work with CMS to develop a neutral clearinghouse run by the federal government or a government contractor, to which covered entities, third-party administrators, and/or contract pharmacies retrospectively submit 340B claims data to prevent 340B-MFP duplicate discounts.

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a clearinghouse-like model that the agency is calling a "340B repository" to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

In RWCs' experience, submitting 340B claims data to manufacturers or their vendors has been a nightmare full of problems. Our members have reported endless challenges when reporting 340B claims data to comply with manufacturers' contract pharmacy restrictions or to address issues related to MFP-340B duplicate discount prevention or payment of MFP rebates. Manufacturers fail to provide required discounts, correct errors, communicate with covered entities, or understand how covered entities use drugs. Additionally, manufacturers have demonstrated they do not understand how federal grant programs work. These problems are why we need a neutral clearinghouse run by the federal government or a contractor, rather than a Rebate Model Pilot requiring RWCs to submit 340B claims data to manufacturers or their vendors.

We believe a clearinghouse with the following elements would benefit manufacturers by preventing duplicate discounts, and covered entities and contract pharmacies by using an impartial process that is not unnecessarily costly or burdensome:

- prevents duplicate discounts before they occur,
- Prohibits manufacturers from having their own individual 340B-MFP deduplication requirements,
- Requires covered entities to submit the minimum necessary 340B claims data, while also providing entities an opportunity to submit supplemental data (e.g., indicating a claim previously identified as 340B is non-340B or a vice versa),
- Limits data elements provided to manufacturers to only an indicator that a particular claim was 340B,
- Prohibits manufacturers from deciding whether 340B is used for a 340B-eligible patient,
- Run by a conflict-free vendor that would be accountable to the government rather than the drug industry, and
- In instances where a drug's MFP is lower than its 340B ceiling price, provides a way for a covered entity to receive from the manufacturer a payment for the difference between the MFP and the 340B ceiling price.

A 340B clearinghouse model represents the ideal solution for all stakeholders - covered entities, contract pharmacies, manufacturers, and the government – by providing an efficient and coordinated framework that streamlines and enhances compliance, data exchange, and program integrity.

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We appreciate HRSA's consideration of our comments. For further information, please contact me at [ceo@cempa.org](mailto:ceo@cempa.org) or 423-648-9911.

Sincerely,



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