Howard Brown Health

September 8, 2025

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program
(HHS-2025-14619)

Dear Director Britton:

Howard Brown Health is one of the largest health centers in the Midwest, serving more than 40,000 patients across seven clinic locations in Chicago. Howard Brown serves adults and youth in its diverse health and social service delivery system focused around seven major programmatic divisions: primary medical care, behavioral health, research, HIV/STI prevention, youth services, elder services, and community initiatives. As a federally qualified community health center (CHC), Howard Brown provides services regardless of a patient's ability to pay or insurance status. Around 20% of Howard Brown's patients are uninsured and we serve vulnerable patients from all over Illinois including rural and low-income areas.

As you know, CHCs are an essential part of our nation's health system. For sixty years, CHCs have provided high-quality, comprehensive, affordable primary and preventive care. In addition to medical services, CHCs provide integrated dental, behavioral health, pharmacy, vision, and other health services to America's most vulnerable, medically underserved communities in rural, urban, suburban, frontier, mountain, and island communities. Today, CHCs serve nearly 34 million people at over 17,000 locations, ensuring patients receive the care they need and pay what they can based on a sliding fee scale.[1]

The 340B Program was never intended to function as a rebate program, and attempting to shift it to a rebate-based model is both unsustainable and harmful to CHCs and our patients.[2] For several years now, pharmaceutical companies have been pushing to replace the upfront discounts from the 340B Program with back-end rebates, a change that undermines longstanding federal policy and puts patients' access to essential

[1] 2025 UDA Data, HRSA. (hrsa.gov)
[2] American Hospital Association. "Fact Sheet: The 340B Drug Pricing Program | AHA." *Www.aha.org*, Jan. 2025, www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program.

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medications at risk. Moreover, some rebate models attempt to bypass Health Resources and Services Administration's (HRSA) authority by imposing restrictive, subjective standards around patient eligibility and other aspects of the 340B program.

Overall, this will further jeopardize the financial sustainability of CHCs across the country, and it undermines the program's intent to serve vulnerable populations. We urge Health and Human Services (HHS) to exempt FQHCs from the 340B rebate pilot. Howard Brown Health Strongly Urges HRSA To Exempt Community Health Centers from the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program is a direct threat to the core mission of CHCs and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has allowed health centers to purchase outpatient medications at significantly reduced costs, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The cost of 340B discounted medication accounts for less than 5% of drug companies' global revenues but is a vital source of revenue to fund our nation's safety-net providers. The proposed rebate model places an immense financial burden on health centers and creates obstacles to medication access for under- and uninsured patients. At Howard Brown, we pass on our 340B savings to under- and uninsured patients by providing medication vouchers for patients who do not have the ability to pay for their medications.

By requiring health centers to purchase medications at full price and wait for a rebate, this model would cause significant financial turmoil and directly impact our ability to serve our patients. The National Association for Community Health Centers (NACHC) data indicates that without discounted or free medications, a substantial portion of CHC patients—up to 3 million or more—would lose access to essential treatments.[3] These patients often have chronic conditions like diabetes, heart disease, and behavioral health needs. At Howard Brown, many of our patients are people living with or vulnerable to HIV, in addition to other chronic conditions.

A change of this nature will have an immediate and direct impact on patients at the pharmacy counter. It would limit the range and volume of drugs health centers can afford to stock, directly contradicting the program's goal of increasing access to affordable medications. Since 90% of health center patients are at or below 200% of the federal poverty level, they rely on discounted medications from their local health

[3]National Association of Community Health Centers. *Summary of NACHC's Report on 340B: A Critical Program for Health Centers*. https://www.hcadvocacy.org/wp-content/uploads/2023/02/NACHC-340B-Report-Summary-June-2022.pdf

center.[4] We strongly urge HRSA to exempt Community Health Centers from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

Howard Brown Health Has Significant Concerns That a Rebate Model Would Create Administrative Complexities and Financial Challenges for Health Centers.

Under the proposed 340B Rebate Model Pilot, health centers would be required to purchase drugs at full retail price, also known as Wholesale Acquisition Cost (WAC). This departure from over 30 years of precedent would drastically impact our ability to purchase drugs due to the uncertainty of waiting for a manufacturer to approve a rebate, thereby constraining cash flow. Health centers will have to wait to receive their rebate payment *after* providing medications to their patients. This rebate will force CHCs to restructure their budgets to account for new upfront medication costs and rebate tracking and management, which in turn will require significant resources to develop the necessary systems to track, process, and manage rebates.

Health centers do not have the financial flexibility or resources to take on the task of implementing this pilot program. Recent data suggests that the median cash-on-hand for CHCs is 100 days, and a quarter of CHCs have -4% operating margins. Furthermore, we anticipate additional financial challenges for health centers due to future changes in Medicaid eligibility and Marketplace insurance, which will likely increase uncompensated care costs. If health centers are required to participate in the 340B Rebate Model Pilot Program, this will significantly impact our ability to fulfill our mission to serve all patients, regardless of ability to pay. Health centers will have to make difficult decisions on how to utilize their limited financial resources, which could result in cutting essential health services, reducing operating hours, or discontinuing services that support improved health outcomes.

While we appreciate HRSA's requirement for a 10-day timeframe for rebate payments, we have concerns about the lack of details regarding enforcement and consequences for manufacturers. While rebates are expected to arrive within 10 days, there may be delays in receiving the full rebate, such as denials, which could create financial strain on health centers. Furthermore, if the rebate is denied, the health center takes a net loss on the transaction. We urge HRSA to establish clear penalties and accountability procedures for drug companies that fail to adhere to HRSA requirements.

The pilot also lacks an official and effective communication channel for covered entities. The 340B statute and historical guidance require a formal dispute resolution process, with HRSA playing a central, decision-making role. To address these critical issues, we

[4] Ibid.

recommend that OPA establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed. This panel should include pharmacists with the necessary subject matter expertise to understand the complexities of pharmacy software, billing, and data components. Without these clear protections, the pilot program risks becoming a mechanism that benefits manufacturers at the expense of the safety-net providers it was created to support.

The proposed 340B Rebate Model Pilot Program is not only a financial threat to health centers but also a duplicative and unnecessary administrative burden. In an attempt to address manufacturers' "concerns" about duplicate discounts, the Pilot Program would force health centers to divert even more scarce resources away from patient care. Health centers have already absorbed significant administrative and technology costs over the past four years to comply with manufacturers' burdensome and unnecessary contract pharmacy restrictions by submitting data to 340B ESP.

Similar to navigating manufacturers' existing contract pharmacy restrictions, health centers will need to hire, redirect and/or reassign existing staff and resources to untangle all of the complexities related to varying data submission requirements, timelines, and systems. The lack of standardization and varying requirements from each manufacturer will likely force health centers to use multiple systems to manage and report the same data, thereby increasing both costs and operational burdens. Howard Brown urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates. We also urge HRSA to establish a centralized, third-party platform for all data submissions. Critically, we believe that the drug manufacturers should be required to cover the full range of costs associated with the increased administrative burden of implementing this pilot program, as discussed above.

Howard Brown Health Has Concerns Regarding the Pilot Program's Design and Scope.

We believe that the Pilot Program's scope is overly broad, which would result in unnecessary financial and administrative burden for CHCs. This ultimately harms our patients, and as such, we recommend that HRSA implement the following limitations and safeguards:

- Limit the scope of manufacturer data requests: We urge OPA not to include Bank Identification Number (BIN) and Processor Control Number (PCN) as permitted data elements for the pilot's pharmacy claim submissions. Requiring this data would create an unnecessary administrative burden for health centers without providing any enhanced program integrity. BIN/PCN data are frequently unavailable to us, creating an operational barrier for a model intended to be transparent and comprehensive. BIN/PCN fields are also not used for clinic-administered or

physician-dispensed medications, further limiting their applicability. We also recommend that manufacturers be prohibited from requesting purchasing data, as this presents a significant and unnecessary administrative burden on CHCs.

- Limit the 340B Rebate Model Pilot to retail pharmacy claims only: We strongly urge OPA to reconsider applying the pilot program to all areas of 340B. The decision to apply the pilot to all outpatient settings, including physician- and clinic-administered drugs, is a significant overreach for an untested pilot program. This broad approach is fundamentally at odds with the current statutory landscape. Until 2028, the Medicare Drug Price Negotiation Program (MDPNP) Maximum Fair Prices (MFP) only apply to the retail claim setting.[5] This means there is no risk of duplicate discounts with MFPs outside of the retail setting for at least the next two years. Extending the pilot program to non-retail claims where no duplicate discount risk currently exists would create a major disruption to health centers and their patients for no clear benefit.

- Preserve purchasing model flexibility: Historically, the 340B Program has been intentionally flexible to accommodate the significant variance in covered entity types and organizational structures. With manufacturers now able to define rebate models within the 340B Rebate Model Pilot Program, we anticipate that covered entities will lose much of this flexibility, including the ability to choose the purchasing model that best fits their needs. This shift represents a significant departure from the program's history and poses a threat to the health centers' ability to participate successfully. Covered entities should be able to choose either unit-level or package-level accumulation and rebating dependent on which approach works better for the covered entity as this can vary. Any approved model must also include safeguards to minimize waste and financial burden on health centers. OPA should not approve models with limited timeframes for covered entities to accumulate toward a full package size.

- Extend the unreasonable compliance timeline: Providing health centers with only 60 days to comply with a manufacturer's rebate plan creates extreme administrative burden and operational challenges. A core principle of the 340B program is that any anti-fraud efforts must "minimize the administrative and financial burdens" on covered entities. This short timeline is destined to create a variety of challenges that will directly impact patients' access to affordable medications.

Conclusion

[5] Health Resources and Services Administration. "340B Rebate Model Pilot Program | HRSA." *Hrsa.gov*, 14 Aug. 2025, www.hrsa.gov/opa/340b-model-pilot-program.

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Howard Brown Health strongly urges HRSA to exempt Community Health Centers from the 340B Rebate Model Pilot Program. This pilot, as currently proposed, represents a fundamental departure from the original intent of the 340B program to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. The retrospective rebate model would impose immense administrative, financial, and operational burdens on health centers, hindering our ability to provide essential services to the 34 million Americans who rely on them.

Given the existing, robust compliance and oversight framework already in place for health centers, we believe this pilot would cause disproportionate harm to the very providers the program was designed to support. Instead of enhancing program integrity, the pilot's lack of clear enforcement, conflicting statutory requirements, and burdensome data demands will only create an untenable system that puts patient access at risk. We urge HRSA to reconsider its approach and ensure that the future of 340B protects, rather than harms, the most vulnerable patients.

We appreciate the opportunity to respond to this 340B rebate model pilot program and look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Tim Wang, Director of Policy and Advocacy, at timothyw@howardbrown.org.

Sincerely,

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