Howard Brown Health

April 20, 2026

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

RE: Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042)

Dear Director Britton:

On behalf of Howard Brown Health**,** I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to covered entities' ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide.

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 health center (FQHC), 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.

I. We strongly urge HRSA to halt the 340B Rebate Model Pilot Program for covered entities, including CHCs.

The proposed 340B Rebate Model Pilot Program is a direct threat to CHCs' core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has enabled CHCs to purchase outpatient medications with upfront significantly reduced prices. At Howard Brown Health, we pass these savings to 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 proposed rebate model undermines this by placing an immense financial burden on CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us. For Howard Brown Heath, this will impact:

- Patient Care: All our patients benefit from the increased medication access and expanded services that are available through the 340B program. Switching to a rebate model would threaten the health of the 42, 984 patients we saw in 2025.
- Administrative Burden: Switching to a rebate model would increase our current 340B current administrative costs by 1 FTE in a time when the healthcare sector is already burdened with funding cuts and workforce shortages.
- Programs and Services: Howard Brown reinvests our 340B savings to help fund and maintain a wide variety of critical services that our patients rely on. Many of these services are unique to Howard Brown and are otherwise poorly funded and reimbursed for. Some of these programs and services include: comprehensive healthcare and social services for unhoused youth at our Broadway Youth Center, case management and insurance navigation for people living with HIV, and free and subsidized full service dental care at our 63rd Street dental clinic.

We strongly urge HRSA to halt the rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

II. Patient Impact

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally impossible. T**his model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

We have significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, are used to manage chronic conditions prevalent in primary care settings, meaning CHC patients will be disproportionately affected. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[1] This patient population relies on access to affordable medications to manage these long-term conditions.

We are deeply concerned that implementing a rebate model would cause CHC patients to lose access to essential, life-sustaining therapies. For instance, direct oral anticoagulants (DOACs) such as Xarelto® and Eliquis® are vital for patients with deep vein thrombosis, pulmonary embolism, and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives. This is not an optional therapy but a critical tool for survival, as one study showed

[1] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.

that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[2]

Similarly, the impact on patients requiring SGLT2 inhibitors, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[3] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

The United States is in the midst of an alarming mental health crisis. Nearly one in four (23.4%) Americans live with a mental illness.[4] Starting in 2027, the MDPNP will include some behavioral health drugs. Vraylar ® is an atypical antipsychotic; atypical antipsychotics are the mainstay of treatment for Schizophrenia. A rebate model could create regulatory barriers for CHCs seeking to provide this drug to uninsured and underinsured patients. Additionally, the 2027 list includes Austedo®, a drug used to treat Tardive Dyskinesia, a common side effect of antipsychotics. Studies have shown that 73% of patients treated with Austedo® achieved treatment success, resulting in improved quality of life.[5] Impairing access to these drugs could result in exacerbation of the mental health crisis.

The impact on insulin access is particularly alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[6] affordability of insulin is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin that reflects the 340B price. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full WAC rather than the discounted 340B price. This makes the price unattainable for the patient and precludes CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

A 340B Rebate Model poses a direct and serious threat to medication access for the vulnerable patients that CHCs serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model will render critical medications financially out of reach since upfront 340B pricing will not be available. Consequently, due to cost, patients may be forced to make tough decisions, including switching to other medications. These therapeutic interchanges

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[2] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.

[3] Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure. Circulation. https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748

[4] Substance Abuse and Mental Health Services Administration. (2025). Key substance use and mental health indicators in the United States: Results from the 2024 National Survey on Drug Use and Health (HHS Publication No. PEP25-07-007, NSDUH Series H-60). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/data-we-collect/nsduh-national-surveydrug-use-and-health/national-releases

[5] Hauser RA, et al. Long-Term Deutetrabenazine Treatment for Tardive Dyskinesia Is Associated With Sustained Benefits and Safety: A 3-Year, Open-Label Extension Study. Front Neurol. 2022 Feb 23;13:773999. doi: 10.3389/fneur.2022.773999. PMID: 35280262; PMCID: PMC8906841.

[6] 2025 UDA Data, HRSA (hrsa.gov)

introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by.

III. Administrative Complexities and Financial Challenges for CHCs

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHCs but also a duplicative and unnecessary administrative burden. The implementation of the 340B Rebate Model Pilot will cause covered entities to incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NACHC assessment illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative burden in monitoring rebate claims and payments.

If we were to use the manufacturer restriction platform as a proxy to what comes with the Rebate Model, then we are worried about the useability and support of the platform. We spent many hours per week on issues related to restrictions and have scheduled biweekly meetings to review setups and notices.

- Routine maintenance is equivalent to two to four hours per week
- Because of the complexity of the system, when an unexpected event occurs, the expected workload can increase five-fold as a team troubleshoots through:
    - A manufacturer platform representing:
        - Two dozen manufacturers,
    - Alongside the platforms representing:
        - Multiple wholesalers,
        - Multiple third-party administrators,
        - Multiple contract pharmacy arrangements.

<u>340B Rebate Model Operational & Administrative Cost Calculator Description</u>

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an Operational & Administrative Cost Calculator. The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support operational cost forecasting.

CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, which have now been extended to clinic-administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Staffing Impact**: To account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model, Howard Brown Health anticipates 1.5 FTEs in the beginning and then goes down to 1 FTE.
- **External Vendor Costs**: Given increased complexity, Howard Brown Health anticipates costs related to external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, and reconciliation services.

Workforce Impact

Below are specific data on the administrative costs that CHCs anticipate, based on thorough planning, review of current business practices, and the costs of implementing new systems and processes.

- According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.[7] Howard Brown Health has factored 1.5 FTE in for the first 6–8-month period and then drops down to 1 FTE.
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities. Howard Brown Health created a new position in anticipation of the model.
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. Howard Brown Health's experience with the current platform used for manufacturer restrictions informed estimates during the initial planning for the rebate model. It will require pulling data from different vendors and conforming to the required standards. We estimate 10-15 hours will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans. The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **Howard Brown Health urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than just staff; it requires significant changes to pharmacy software and Third-Party Administrator (TPA) workflows. We encourage HRSA to consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers are allowed to select different software platforms, as they currently do with contract pharmacy policies, the administrative burden on CHCs would increase substantially.

[7] Internal NACHC assessment (99 responses).
[8] Ibid.

- **Initial Implementation Operational Impact** The rebate model will require new workflows, including submission, reporting, and tracking. There will be a high upfront cost to adapt and modify current procedures to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. We work with several different TPAs and pharmacies, including independents pharmacies that provide a point of access in vulnerable communities.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our team must track claims with different pharmacy partners to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative burden, this may leave patients living in pharmacy desert areas of Chicago with limited affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed in a cost-effective manner that reflects the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[11]

- **Bundled Payments:** Most clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Inventory Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper.
- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then

[9] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network

[10] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff

[11] Internal NACHC survey data

expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.

- **HRSA should explicitly exclude CADs from any 340B Rebate Model pilot. By including both Retail and CAD, CHCs will have to create two very different workflows.** At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

A. Financial Challenges

Under the proposed 340B Rebate Model Pilot, CHCs would be required to purchase drugs at full retail price, also known as the Wholesale Acquisition Cost (WAC). The uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow and is a departure from over 30 years of precedent. CHCs will have to wait to receive their rebate payment after providing medications to their patients. This change will force CHCs to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

The proposed 340B Rebate Model Pilot would directly impact CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to purchase at full WAC pricing upfront. CHCs' pharmacies, as well as entity-owned and contract pharmacies, will not have access to the 340B price when the patient needs medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC. The rebate model creates confusion about its impact on a CHC's ability to offer sliding-fee discounts at the point of purchase.

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[12] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[13] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Up front access to 340B pricing at Howard Brown Health, means patients who are under/uninsured have access to affordable medications. Additionally, for patients with less resources, we provide medication vouchers directly to the patients.

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to

[12] HRSA FAQ

[13] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. The financial impact is further compounded when CHCs have entity-owned pharmacies with physical inventories and must stock their shelves with purchases at WAC. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[14] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

There may be other delays in receiving the full rebate, such as denials, which could create financial strain on CHCs. We appreciate HRSA's requirement for a 10-day timeframe for rebate payments; however, we have concerns about the lack of details regarding enforcement if manufacturers fail to meet this requirement. Based on experience with manufacturer denials related to the current MFP to 340B de-duplication processes, once an entity has contested a denied rebate and the issue is resolved so the CHC can receive the rebate, manufacturers and their vendors have failed to pay the rebate within the MFP standard of 14 days from when the status is corrected. We are concerned that in a 340B rebate pilot, manufacturers and their vendor(s) will continue to provide corrected contested rebates for an undefined and unlimited time. Complicatedly, the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must estimate the rebate amount and may undercharge or overcharge patients due to confusion. Furthermore, if the rebate is denied, the CHC takes a net loss on the transaction. **We respectfully request that, if a rebate pilot is implemented, manufacturers are required to pay rebates within 10 days of both initial and corrected determinations.**

340B Rebate Drug Cost Impact Calculator Description

To support CHCs in assessing the financial impact of purchasing drugs at the full WAC price, NACHC worked with its consultant, FQHC 340B Compliance, to create another calculator for all CHCs. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC-specific purchasing data, 340B[15] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[16] For individual MDPNP Price Applicability Years, the calculator evaluates:

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for

[14] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review
[15] https://340bpricing.hrsa.gov/
[16] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.

- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).
- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHCs must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate the purchase of these ten drugs under the proposed 340B Rebate Model would increase our upfront cost by 1,278% (equal to the difference between WAC minus 340B cost, divided by the 340B cost).

The 340B Rebate Model makes it more difficult for Howard Brown Health to expand services.

- It would create a barrier to implementing new programs/services that are important to our patients but may not be billable.
- Our ability to provide medications at "zero-pay" or deeply discounted rates under our sliding fee scale will be compromised.

B. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted.

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHCs are unable to disclose their exact prompt-pay discount.
- Howard Brown Health estimates that purchasing the 2026, 2027, and 2028 MFP selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by 56% (equal to the difference between WAC minus 340B cost, divided by the 340B cost).

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. The long-term impact is if the 340B Rebate

Model expands, then the "trickle-down" effect is longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 34 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

Howard Brown Health urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of a CHC's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHCs need to understand or contest those decisions.[17]

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative 10% denial rate would result in an annual drug cost increase by 5%. This is a sum our CHC cannot absorb year after year, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

The financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHCs to "estimate" rebate amounts, creating unpredictable financial losses and the potential to undercharge or overcharge patients. Additionally, the lack of real-time 340B pricing presents challenges for compliance with 340B actual acquisition cost (AAC) billing in fee-for-service Medicaid. This may lead to increased Medicaid costs and potential state-level claw-backs, creating a second layer of financial liability for the CHC. Without a standardized, transparent, and neutral dispute resolution process, the 340B Rebate Model Pilot functions as an interest-free loan from safety-net providers to multi-billion-dollar manufacturers. These unpredictable denials and delays create serious cash flow issues for CHCs operating on thin margins, which depend on timely reimbursement to sustain services for medically underserved populations.

IV. Reconciliation and Rebate Denials Operational Challenges

If HRSA proceeds with a rebate-based pricing model, the program must include clear, enforceable operational guardrails to prevent the systematic shifting of financial and administrative risk to covered entities. **HRSA must require that any rebate model operates under uniform national standards that limit manufacturer discretion, hold manufacturers accountable, and protect covered entities from financial harm.** Recommendations around guardrails include:

[17] Application Process for the 340B Rebate Model Pilot Program, 2025-14619 (90 FR 36163) https://www.federalregister.gov/documents/2025/08/01/2025-14619/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;
- Rebate payment timing requirements must apply to both initial and corrected determinations. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism;
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers;
- Manufacturers must bear the burden of establishing that a rebate is not owed;
- Rebate determinations must align with statutory patient definition: HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.
- OPA should 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.

V. Existing CHC Compliance Actions

CHCs already operate under a comprehensive regulatory framework established through the Health Center Program and the 340B statute to make medications affordable for patients.

- In alignment with Section 330 of the Public Health Service Act, they utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay.
- CHCs also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These services would not be possible without the savings generated from the 340B program.
- CHCs participate in regular Operational Site Visits (OSVs) to verify Health Center Program compliance, and also follow strict 340B compliance protocols, including internal audits, training, and external oversight.
- CHCs participating in the 340B program are required to report 340B-related information annually through the Uniform Data System (UDS). This includes data on 340B-purchased drugs, associated costs and revenues, and detailed information about the patients served by the program.

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

VI. Establishing a National, Neutral Claims Clearinghouse

We recommend OPA use a Neutral Claims Clearinghouse (NCC), which would produce more accurate deduplication at a tiny fraction of the cost and administrative burden of a rebate model. Compared to HRSA's proposed rebate model, the NCC approach would:

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**
- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.
- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHCs' participation in the program.
- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHCs to stop purchasing or dispensing MFP drugs altogether.
- **Identify Medicaid Duplicate discounts in Medicaid.** An NCC could provide a standardized national approach to prevent duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states.

Given the major disruption the 340B rebate program is anticipated to have on CHCs, a system that forces CHCs to provide data that is already accurately and readily available to manufacturers is not only redundant but also adds additional administrative burdens on safety-net providers. It is imperative that HRSA require manufacturers to leverage existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

Conclusion

Howard Brown Health strongly urges HRSA to halt the 340B Rebate Model Pilot Program. A 340B Rebate Model represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. Howard Brown Health believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Howard Brown Health appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **[YOUR POLICY DIRECTOR'S/VP'S NAME AND EMAIL ADDRESS.]**

Sincerely,

CEO NAME
ORGANIZATION'S NAME