



Community Health Development, Inc.
The Heart of the Community

April 27, 2026

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

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Community Health Development, Inc. (CHDI)**, I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, CHDI again requests that CHCs be exempted from the pilot program.**

CHDI was founded in 1983 in Uvalde, Texas, with the mission of increasing access to high-quality healthcare services for uninsured and underserved populations. Since its inception, CHDI has remained committed to improving the health and well-being of the communities it serves.

CHDI began delivering medical care in 1984 with a staff of four, operating out of an 800-square-foot trailer on the east side of Uvalde. Today, CHDI has grown into a comprehensive, multi-site healthcare organization that:

- Operates seven service delivery sites across Uvalde and Real counties, including a School-Based Health Center;
- Provides integrated medical, dental, behavioral health, pharmacy, laboratory, and radiology (X-ray) services;
- Employs more than 140 staff members, making CHDI one of the major employers in our area; and
- In 2025, CHDI served 13,005 patients. Of those served, 86% have incomes at or below 200% of the Federal Poverty Level. Additionally, 34% of patients are uninsured, while 12% are covered by Medicaid, 18% by Medicare, and 36% by private insurance.

Since 2021, **CHDI** has been recognized by the HRSA as a Health Center Quality Leader, reflecting its commitment to delivering high-quality, patient-centered care. In 2025, **CHDI** earned its first National Quality Leader Badges for excellence in Diabetes and Behavioral Health, further demonstrating its strong clinical outcomes and dedication to addressing critical health needs in its service area.

The 340B program is foundational to CHC's 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. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

I. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **13005** patients who rely on us. We operate on razor-thin margins, and these additional costs are not an option for many entities. 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. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with its consultant, FQHC 340B Compliance, to create an Operational & Administrative Cost Calculator.¹ The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact:** **CHDI** anticipates needing at least 4.0 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **CHDI** will face an increased administrative burden to monitor rebate claims and payments. 16 hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs:** **CHDI** anticipates an additional \$55,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

¹ <https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/>

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. At least \$25,000 will be required simply 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 of \$55,000 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves over 13,000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **\$2,302,584** annually.

The In-House Pharmacy: The Burden of IT Integration

CHDI operates four (4). The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. **CHDI** will have to manually compute costs and sliding fee discounts unless we can contract with companies that understand the process and can program an interface between the pharmacy software and EHR systems.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **CHDI** has not been able to identify a software vendor that fully understands how the rebate model should operate, while also understanding **CHDI** workflow, and estimates of at least \$20,000 and may be up to \$55,000 or more.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 20 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with one pharmacy to increase access to affordable medications.

- **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 staff must monitor claims at one location to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Uvalde and Real Counties, this would leave patients with no

affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.²

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect 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.³ CHDI estimates it will take at least 20 hours and cost \$36,000 to upload records related to CADs.

Most CADs 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. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

CHDI has 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, manage chronic conditions prevalent in primary care settings. 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.⁴ This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,⁵ insulin affordability 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. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

² [Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network](#)

³ Internal NACHC survey data

⁴ 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.

⁵ 2025 UDA Data, HRSA (hrsa.gov)

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand and one in four reporting negative 5% operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model 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 project.⁶ In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.⁷ A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. At **CHDI**, it has been our longstanding practice to provide medications at acquisition cost plus a minimal dispensing fee, scaled according to income, thereby directly passing 340B savings on to patients.

Requiring **CHDI** to purchase medications at full cost under a rebate model would undermine this approach and create a significant financial barrier for patients. This shift would directly impact medication adherence and access to care for the low-income populations we serve, contradicting the intent of the 340B program and CHCs' statutory obligation to provide affordable services.

Conclusion

COMMUNITY HEALTH DEVELOPMENT, INC. strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program 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 upfront 340B discount, making it operationally impossible to provide the sliding fee scale and steeply

⁶ HRSA FAQ

⁷ Such discounts are subject to potential legal and contractual restrictions. <https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10>

discounted medications required by law. **CHDI** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

CHDI appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please do not hesitate to contact me at mcastanon@chdi4health.org or call me at 830-278-5604 ext. 3104.

Sincerely,



Mayela Castanon
Chief Executive Officer
Community Health Development, Inc.

Serving Uvalde, Real, Edwards, and Zavala counties since 1983

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