HealthLinc
YOUR COMMUNITY HEALTH CENTER®

April 22nd, 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 **HealthLinc,** 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, HealthLinc again requests that CHCs be exempted from the pilot program.**

HealthLinc, Inc. is a Federally Qualified Health Center (FQHC) serving six counties in northern Indiana: Porter, LaPorte, St. Joseph, Lake, Newton, and Starke. We started as a free clinic in 1996 and achieved full FQHC designation in 2006. HealthLinc's model ensures a patient-centered medical home that contributes to the creation of healthy communities. In 2025, HealthLinc cared for 56,557 patients through 219,756 visits. Our network includes 14 clinics and one corporate headquarters. According to NIH data, 34% of HealthLinc's service area population is low-income, and access to health care continues to be challenging, with 8.9% of Indiana residents uninsured in 2024. As of April 2026, HealthLinc's service area population represents 16% of Indiana's total population and spans two time zones and two rural counties.

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 **56,557** 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 their 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**: **HealthLinc** anticipates needing **1.5 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, **HealthLinc** will face an increased administrative burden to monitor rebate claims and payments. For 2026 alone, HealthLinc anticipates that reporting rebate claims to the third-party platform will require **more than 20 hours per week—**assuming full compliance with all nine manufacturers' requirements—with additional time needed for claims reconciliation. 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.
- **External Vendor Costs**: **HealthLinc** anticipates an additional **$250,000 annually in expenses** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

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

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

different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **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.
- **Total Cost:** For our CHC, which serves **56,557** patients, the total projected additional increase in expenses—including labor, IT, and carrying costs—is estimated at **6.7 million annually.**

The In-House Pharmacy: The Burden of IT Integration

HealthLinc operates four in-house pharmacies located across four different counties and services patients in all six counties in northern Indiana. 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 Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.

  HealthLinc pharmacies do not utilize a TPA to manage in-house pharmacy claims, meaning there is no automated infrastructure in place to support rebate processing under the proposed model. As a result, implementation would impose a substantial and ongoing operational burden, requiring manual extraction, validation, and reconciliation of pharmacy data from the PMS across all four pharmacy locations.

  This process would need to be repeated independently for each of nine manufacturers, each of which may impose distinct and evolving reporting requirements. The absence of system integration or standardized reporting pathways would create a highly fragmented, labor-intensive workflow, significantly increasing the risk of errors, delays, and administrative inefficiencies.

  To meet these requirements, HealthLinc estimates the need for additional staffing capacity and expanded time commitments from existing personnel, resulting in approximately **$140,000 in annual costs**. This reflects not only incremental staffing needs but also the diversion of current pharmacy and operational staff away from direct patient care and essential clinical services.

  Taken together, the lack of automation, increased reporting complexity, and added staffing burden represent a structural operational challenge that would materially strain HealthLinc's pharmacy operations and limit the organization's ability to efficiently deliver care within existing resource constraints

- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **10** 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. HealthLinc currently partners with several contract pharmacies, including Walgreens, CVS, Walmart, etc., to expand 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 across all our different contract pharmacy locations 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 **northern Indiana**, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

II. Patient Impact

HealthLinc 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.[3] 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,[4] 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.

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 five percent 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

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

[3] 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.

[4] 2025 UDA Data, HRSA (hrsa.gov)

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.[5] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

  HealthLinc is committed to ensuring that all qualifying patients have access to affordable medications through its sliding fee discount program. Consistent with its mission and HRSA requirements, HealthLinc applies sliding-scale discounts to prescription drugs, enabling patients to access medications at reduced cost. These affordability measures are implemented across all four in-house pharmacy locations and extend to contract pharmacy partners, ensuring equitable access to medications throughout the six counties HealthLinc services in northern Indiana.

  The introduction of a 340B rebate model would create significant uncertainty and financial strain around HealthLinc's ability to sustain these discounts at the point of sale. Increased upfront drug acquisition costs and delayed rebate recovery would place additional pressure on already limited resources, directly impacting the organization's cash flow and operating capacity.

  As a result, HealthLinc would face difficult operational decisions that could ultimately limit its ability to extend sliding fee discounts consistently across all dispensing sites. Any reduction in this program would disproportionately affect low-income patients, increasing out-of-pocket medication costs and creating barriers to medication adherence and continuity of care.

Conclusion

HealthLinc 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 up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law.

[5] HRSA FAQ

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

HealthLinc believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

HealthLinc 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 contact Broxton Davis, Director of Pharmacy, at bdavis@healthlincchc.org.

Sincerely,

DocuSigned by:
Melissa Mitchell
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Melissa D. Mitchell, CEO
HealthLinc