



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:

For the past 55 years, the National Association of Community Health Centers (NACHC) has been the leading national, nonpartisan organization dedicated to supporting CHCs (also known as Federally Qualified Health Centers), our committed 326,000 primary care workforce, and the nearly 34 million patients we serve annually. As our nation's largest primary care system, CHCs save lives and money across 17,000 locations that serve as an affordable, comprehensive, effective primary care home for 52 million, or 1 in 7, including 1 in 3 in rural America.

For 60 years, CHCs have provided high-quality, affordable, comprehensive care – including primary, preventive, dental, behavioral health, pharmacy, vision, and other essential health services at over 17,000 locations across rural and nonrural communities. This includes 1 in 3 rural residents and 1 in 2 in poverty. As our nation's largest primary care system, there is strong evidence, including from the Congressional Budget Office, that our work saves lives and also saves Medicaid and Medicare billions annually by reducing costly emergency, inpatient, and specialty care.<sup>1</sup> Research shows that every dollar invested in primary care yields a 13-to-1 return in overall health system savings.<sup>2</sup>

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 information from CHCs, the hours and dollars spent complying with a rebate program would be staggering.

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

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<sup>1</sup> Volerman A, Carlson B, Wan W, Murugesan M, Asfour N, Bolton J, Chin MH, Sripipatana A, Nocon RS. Utilization, quality, and spending for pediatric Medicaid enrollees with primary care in health centers vs non-health centers. *BMC Pediatr.* 2024 Feb 8;24(1):100. doi: 10.1186/s12887-024-04547-y. PMID: 38331758; PMCID: PMC10851548.  
<https://pubmed.ncbi.nlm.nih.gov/38331758/>

<sup>2</sup> <https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf>

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 their patients. They 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 FQHC 340B Compliance to create an Operational & Administrative Cost Calculator.<sup>3</sup> 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:** 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.<sup>4</sup>
  - Additionally, several CHCs estimate the cost to hire additional staff to be between \$30,000 to \$200,000 annually.<sup>5</sup> 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.
  - For IT needs specifically, one mid-sized CHC in Alaska stated that the administrative time required to set up new IT processes to establish data feeds, run financial reports, and decipher Beacon claims will result in at least one FTE employee at \$120,000 and another \$100,000 for investment in IT systems. For another large health center in Alabama, the estimated logistics will require an additional one to two FTE if the program grows to manage the reconciliation and continued burden.
- **Number of Hours:** 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. Thirty-nine percent of CHCs estimate it will take their staff more than 20 hours to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans; another 38% estimate between 15 to 20 hours, and 23%

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<sup>3</sup> <https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/>

<sup>4</sup> Internal NACHC assessment (99 responses).

<sup>5</sup> Ibid.

believe it will take 5 to 10 hours to meet reporting requirements with this pilot program.<sup>6</sup> 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.

### **Pharmacy Software & Third-Party Administration Changes**

Navigating this pilot requires both staff and changes to the 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, the CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** CHCs anticipate high upfront costs to adapt their pharmacy software, pay for custom dashboard modifications, and design new internal workflows, all of which will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees:** Beyond implementation, CHC TPAs 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 In-House Pharmacy: The Burden of IT Integration**

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

- **System Interoperability Challenges:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), CHC with in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. This creates new technical dependencies and increases the risk of workflow disruptions at the pharmacy counter.
- **High Upfront Integration Costs:** NACHC anticipates CHC would face significant upfront costs to modify existing systems, including building custom APIs and implementing “Price File” reconciliation tools to meet rebate model data submissions and claims validation requirements.
- **Ongoing Administrative Burden and Cost:** Reporting requirements alone are expected to be resource intensive. Thirty-nine percent of CHCs estimate it will take their staff more than 20 hours to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers’ plans; another 38% estimate between 15 to 20 hours, and 23% believe it will take 5 to 10 hours to meet reporting requirements with this rebate model.<sup>7</sup> Additionally, several CHCs estimate the cost to hire additional staff to be between \$30,000 to \$200,000 annually.<sup>8</sup>

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<sup>6</sup> Internal NACHC assessment (out of 101 responses).

<sup>7</sup> Internal NACHC assessment (out of 101 responses).

<sup>8</sup> Internal NACHC assessment (99 responses).

## **The Contract Pharmacy: The Burden of Network Coordination**

Nationwide, **more than 65% of CHCs utilize a contract pharmacy** to expand medication access, maintain affordability, and meet patients where they are.<sup>9</sup> For contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these partnerships.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. CHCs anticipate that 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. CHC staff will have to monitor claims in their entity-owned pharmacies, if applicable, and work with their different contract pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, many CHCs fear their contract partners will opt out of the 340B program entirely rather than manage the administrative headache. This would leave patients in our area with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,<sup>10</sup> 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.<sup>11</sup>

## **Clinic Administered Drugs: The Burden of New Systems Required**

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed to be cost-effective and 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.<sup>12</sup>

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**

**NACHC 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

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<sup>9</sup> [https://www.nachc.org/wp-content/uploads/2026/01/Pharmacy-Survey\\_Expanding-Access\\_V2.pdf](https://www.nachc.org/wp-content/uploads/2026/01/Pharmacy-Survey_Expanding-Access_V2.pdf)

<sup>10</sup> [Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network](https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff)

<sup>11</sup> <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff>

<sup>12</sup> Internal NACHC survey data

higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.<sup>13</sup> 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,<sup>14</sup> 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 of CHCs operating with fewer than 90 days of cash on hand, and one in four reporting approximately negative five percent (-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.<sup>15</sup> In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.<sup>16</sup> A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

### Conclusion

**NACHC 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

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<sup>13</sup> 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.

<sup>14</sup> 2025 UDA Data, HRSA (hrsa.gov)

<sup>15</sup> HRSA FAQ

<sup>16</sup> Such discounts are subject to potential legal and contractual restrictions. <https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10>

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

NACHC appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and looks forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Elizabeth Linderbaum, Director of Regulatory Affairs, at [elinderbaum@nachc.org](mailto:elinderbaum@nachc.org)

Sincerely,

A handwritten signature in black ink that reads "Joe Dunn". The signature is written in a cursive, flowing style.

Joe Dunn  
Chief Policy Officer