HOPEWELL
HEALTH CENTERS

Access to Affordable, High Quality,
Integrated Health Care for All

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April 24, 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:

As the CEO of Hopewell Health Centers, I would like to thank the Health Resources and Services Administration (HRSA) for the extended opportunity to provide comments on the proposed 340B Rebate program. The 340B program is essential to our agency's ability to serve as a community safety net for our most vulnerable residents. The proposed change to a rebate model, will cause a significant shift of administrative and fiscal responsibility from manufacturers to Community Health Centers, like Hopewell, who are already working on thin margins and would greatly detract from the ability to remain focused on quality patient care. I am deeply concerned that the burden created by this change will not only destabilize our pharmacy operations but will also threaten the existence of many of our programs designed to address the health disparities in our Appalachian region.

Hopewell Health Centers serves nine counties in the rural, Appalachian southeast corner of Ohio (Athens, Gallia, Hocking, Jackson, Meigs, Perry, Ross, Vinton, and Washington). Residents in our counties face the same health disparities as other parts of Appalachia. Most of our counties are in the bottom 25% for Health Outcomes and the bottom 50% for Health Factors (http://www.countyhealthrankings.org). Rates of depression, suicide, and substance use disorders exceed national and state averages. All counties are HRSA designated Workforce Shortage Areas for Mental Health and Dental Health, as well as contain medically underserved areas for Primary Care (www.datawarehouse.hrsa.gov/tools/analyzers/hpsafind). Pharmacy deserts, defined as areas with limited access to pharmacies (often 10+ miles away), are expanding in Southeast Ohio due to closures. Recent data indicate that over 130 Ohio census tracts are deserts. These closures, often driven by chain store reductions, create significant health access challenges for rural residents (Ohio State University, 2024).

Hopewell has already faced financial challenges due to drug manufacturers' restrictions on contract pharmacies that have been implemented over the past two years. These led to agency lay-offs and significantly impacted our agency's ability to serve our patients. Based on our team's calculations, we have become quite alarmed about the additional negative impacts that may result from the implementation of a rebate model. These negative impacts include:

- **Financial Losses:** Hopewell Health Centers anticipates **an average loss of one million dollars a year from our pharmacy operations** because of the administrative hurdles of manual reconciliation and potential claims denials involved with a rebate model.
- **Projected Cost Increases:** Our agency anticipates a significant increase in operational costs related to converting our program into a rebate model. We anticipate we will need to hire an additional 4.5 FTE across our financial and pharmacy departments to manage the oversight of this type of model (approximately $650,000). We also anticipate an additional $350,000 in increased costs for external contractors who assist us with the legal and compliance aspects of the program. **This translates into one million dollars in additional new costs.**
- **Risks to our agency's financial well-being and elimination of core services:** The conservative estimates outlined above translate into an overall reduction of two million dollars a year from Hopewell's annual budget of $80 million. On first glance, this may seem insignificant, but we operate on a very tight margin. Our agency ended 2025 with a modest surplus of $2.2 million for the first time in four years--which aligns with the time period when manufacturer restrictions began to significantly impact our 340B program revenue. This small surplus was gained through downsizing operations, decreasing staff levels, eliminating innovative programming, invoking salary freezes, and overworking our determined, dedicated staff. As outlined above, this hard-won surplus will be virtually eliminated if the rebate model is implemented. We will not be able to sustain current operations if we have an additional $2,000,000 removed from our annual budget. There is nothing left for us to cut to manage the shortfall except for essential clinical staff and core services to our patients.

**I Strongly Urge HRSA To Exempt Community Health Centers (CHC's) from the 340B Rebate Model Pilot Program.**

The proposed 340B Rebate Model Pilot Program is a direct threat to our 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 our agency to purchase outpatient medications at significantly reduced prices, enabling us to provide affordable and sometimes free medications to our 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 32 million patients who rely on us.

**For Hopewell Health Centers in particular, the impact will include:**

- **300,000 annual prescriptions that flow through our pharmacy program.**

- **Reduced core services for 39,963 patients served by our agency. 64% (25,577), who are especially vulnerable due to their financial circumstances and are uninsured, Medicaid, or Medicare patients**
- **700 staff who may once again face freezes to their salaries and benefits**
- **Increased workforce shortages in our region as clinical staff find it difficult to stay with our agency and move on to more lucrative opportunities in the metropolitan areas.**
- **15,000 behavioral health patients who will face reduced access to Hopewell's robust psychiatry services, crisis services, and case management which are all partially supported by 340B funds.**
- **Nearly 2,000 patients who are relying on our enabling services (such as transportation) to access care since these are partially supported by our 340B funds.**

Due to the severe negative impacts, I strongly urge HRSA to exempt CHCs like Hopewell from any rebate model to protect the financial stability of safety-net providers like ours and ensure continued access to care for our most vulnerable patients.

**Hopewell Health Centers** 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 me at **mark.bridenbaugh @hopewellhealth.org.**

Sincerely,

Mark Bridenbaugh

**Mark Bridenbaugh, CEO**
**Hopewell Health Centers**

April 24, 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 the Michigan Primary Care Association (MPCA), we appreciate the opportunity to provide comments on the proposed Information Collection Request (ICR) for the 340B Rebate Model Pilot Program.

The Michigan Primary Care Association represents 48 community health centers, including Federally Qualified Health Centers (FQHCs), Tribal Health Centers, and an Urban Indian Health Program, operating more than 400 sites across Michigan and serving approximately 690,000 patients—nearly 1 in every 15 Michigan residents.

As the statewide Primary Care Association, MPCA provides technical assistance, operational support, and policy leadership across Michigan's safety-net system. This perspective allows us to assess not only individual health center impact, but also the aggregate, system-wide implications of federal policy changes on access to care, financial stability, and service delivery.

**The Michigan Primary Care Association strongly urges HRSA and OMB to exempt community health centers from participation in any 340B rebate model pilot.**

From a statewide perspective, the proposed shift from an upfront discount to a post-purchase rebate represents a fundamental restructuring of the 340B program. This model transfers financial and administrative burden from manufacturers to safety-net providers and introduces instability into a program that health centers rely on to deliver care to underserved populations.
The 340B program is foundational to the ability of Michigan health centers to provide comprehensive, affordable care. Savings generated through upfront discounts are reinvested into enabling services, expanded clinical capacity, medication access programs, and care coordination. A rebate model disrupts this structure by requiring health centers to purchase drugs at Wholesale Acquisition Cost (WAC) and wait for reimbursement.

Across Michigan, where many health centers operate on narrow margins, this shift introduces significant financial risk and undermines the predictability of 340B savings. At scale, this creates a systemic threat to the stability of the safety-net delivery system.

The Michigan Primary Care Association's analysis, informed by national tools and direct engagement with member health centers, indicates that the rebate model would create a substantial increase in administrative burden across the network.

**Health centers would be required to:**

- Submit detailed claims data across multiple manufacturers and platforms.
- Track and reconcile rebate payments.
- Manage claim denials and dispute processes.
- Monitor compliance with varying manufacturer requirements.

These responsibilities represent a new, ongoing operational function that does not exist under the current 340B model.

**At a statewide level, the Michigan Primary Care Association anticipates:**

- Significant increases in full-time equivalent (FTE) staffing needs across member organizations.
- Reallocation of clinical and pharmacy staff time away from patient care.
- Significant one-time implementation costs for software customization and workflow redesign, as well as ongoing vendor fees for new rebate tracking and reporting functionality.
- Increased reliance on external consultants, with new associated costs.

In addition, based on monitoring frameworks being developed to track rebate activity, health centers will need to dedicate substantial weekly administrative time to claim tracking, reconciliation, and issue resolution, further compounding workforce strain.

Another critical concern from MPCA's perspective is the lack of standardization across manufacturers and rebate platforms. **Health centers would be required to interface with multiple systems, each with unique:**

- Data submission requirements.
- File formats.
- Timelines.
- Reconciliation processes.

This fragmentation creates inefficiencies across the network and significantly increases the risk of data errors, delayed or denied rebates, and/or compliance challenges.

In-house pharmacy operations will require extensive system integration between electronic health records, pharmacy management systems, and rebate platforms. This includes costly customization and ongoing manual verification processes.

The rebate model introduces new financial and administrative risk for contract pharmacy partners. Increased complexity, delayed payments, and reliance on third-party administrators may lead pharmacies to reconsider participation in 340B arrangements.

**From a statewide access perspective, the Michigan Primary Care Association is concerned this could lead to:**

- Reduction in contract pharmacy participation, impacting medication accessibility.
- Further expansion of pharmacy deserts, particularly in rural communities.

**Clinic-administered drugs present a significant operational challenge under a rebate model. Currently, many Michigan health centers:**

- Operate under Prospective Payment System (PPS) billing.
- Do not separately bill for medications.
- Maintain documentation in non-standardized or manual formats.

**Transitioning to a rebate model would require:**

- New software systems.
- Manual conversion of existing documentation into electronic data.

These requirements represent a significant unfunded mandate across the health center network and would disproportionately impact smaller and rural providers. The proposed rebate model directly threatens patient access to affordable medications.

**Michigan health centers serve a population with**:

- Higher rates of chronic conditions such as diabetes and hypertension.
- Greater reliance on sliding fee discounts.
- Limited financial resources.

**Under a rebate model:**

- Health centers will face significant difficulties in providing discounted medications at the point of sale.
- Patients may face higher upfront costs or delays in access.
- Health centers may be unable to maintain an adequate inventory of high-cost drugs.

For health center patients, affordability is critical, and immediate access is essential to patient health outcomes.

Health centers across Michigan are already navigating **c**hanges in Medicaid policy and reimbursement, fluctuations in patient health insurance coverage, workforce shortages, rising operational costs, and more. Layering a rebate model on top of these pressures would significantly destabilize operations.

**The Michigan Primary Care Association anticipates that health centers may be forced to:**

- Delay hiring or reduce workforce capacity.
- Scale back pharmacy services or operating hours.

- Reduce enabling services such as transportation and care coordination.
- Rely on lines of credit to manage cash flow gaps.
- Limit access to high-cost medications.

While widespread reductions have not yet occurred, health centers report that a rebate model would necessitate these actions. The 340B program was established to allow safety-net providers to "stretch scarce Federal resources" to serve vulnerable populations and a 340B rebate model would make it very difficult to achieve the purpose of the program.

**Specifically, a rebate model undermines this intent by:**

- Eliminating upfront savings.
- Introducing financial uncertainty.
- Increasing administrative burden.
- Reducing the ability to reinvest in patient care.

As outlined in federal policy discussions, requiring health centers to pay more than the 340B ceiling price upfront—even temporarily—runs counter to the foundational purpose of the program.

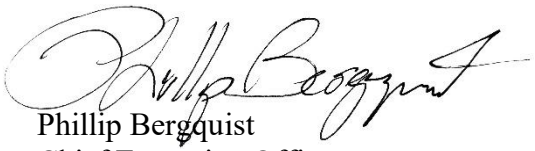
**Simply put, the 340B rebate model is not a viable or sustainable approach for community health centers. The model introduces significant financial risk, administrative burden, operational complexity, and threats to patient access.**

**The Michigan Primary Care Association strongly urges HRSA and OMB to exempt community health centers from participation in any 340B rebate model pilot program.**

We remain committed to working collaboratively with federal partners to identify solutions that preserve the integrity of the 340B program while minimizing burden on providers and ensuring continued access to care for the patients who depend on it.

Thank you for the opportunity to provide input on this important issue. If you have any questions, please contact Frank Waters, Senior Director of Government Affairs at fwaters@mpca.net

Sincerely,



Phillip Bergquist
Chief Executive Officer
Michigan Primary Care Association

CHANGE, Inc.
Community Action Agency & Community Health Center
Administrative Office: 3158 West Street ▪ Weirton, WV 26062
304.797.7733 ▪ www.changeinc.org

April 24, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
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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 CHANGE, Inc., 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, CHANGE, Inc. again requests that CHCs be exempted from the pilot program.**

CHANGE, Inc. is a Community Action and Community Health Center that offers a wide range of health, housing, victim advocacy and supportive services designed to support and empower individuals throughout the Ohio Valley to build a better future for themselves and their families.

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 over 18,000 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**: CHANGE, Inc. anticipates needing 1.0 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, CHANGE, Inc. will face an increased administrative burden to monitor rebate claims and payments. An additional five hours per month will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: CHANGE, Inc. anticipates an additional **$70,000** 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 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. Upwards of **$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 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 18,450 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $10,000 annually.

**The In-House Pharmacy: The Burden of IT Integration**

**CHANGE, Inc. operates one inhouse pharmacy.** The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy

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

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.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. CHANGE, Inc. estimates a one time integration cost for its Pharmacy software system of $20,000.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **5** 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 11 independent and 16 chain and specialty pharmacies 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 across **27** different 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 the Ohio Valley**,** 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] CHANGE, Inc. estimates it will take **10 hours and cost $25,000 (to purchase scanning equipment)** 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),

[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

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

**CHANGE, Inc. 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.

## 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 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

[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)
[6] HRSA FAQ

individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

**Conclusion**

**CHANGE, 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 up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **CHANGE, Inc.** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

**CHANGE, Inc.** 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 us at 304-797-7733.

Sincerely,

**Lisa Mowry, CEO**
**CHANGE, Inc.**

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

April 24, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
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5600 Fishers Lane
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**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 **Sadler Health Center,** 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, Sadler Health Center again requests that CHCs be exempted from the pilot program.**

**Sadler Health Center's mission is to advance the health of our community by providing inclusive, high-quality and compassionate care. As a federally qualified health center, Sadler offers comprehensive and affordable services to all patients – including those who are uninsured or underinsured – through a patient-centered medical home model. Across its Cumberland County locations in Carlisle and Mechanicsburg, PA, Sadler provides a broad range of services including medical, dental, vision, behavioral health, addiction recovery, pharmacy, express care, lab testing, nutrition, insurance enrollment and community resource connections. The organization also offers dental services in Perry County at its Loysville, PA location. Together, Sadler served nearly 14,000 patients last year.**

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 **13,973** 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**: **Sadler Health Center** anticipates needing **1.25** 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, **Sadler Health Center** will face an increased administrative burden to monitor rebate claims and payments. **15 hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Sadler Health Center** anticipates an additional **$80,000** 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 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. **$60,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.

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

- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees **$213,208** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **13,973** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$1 million** annually.

**The In-House Pharmacy: The Burden of IT Integration**

**Sadler Health Center operates two In-House pharmacies**. 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. Sadler Health Center has 2 entity-owned pharmacies, that use 2 different PMS's. This will not only impact on the amount of time taken to compile date but also to format it so they can be compared on an organization-wide scale.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools **Sadler Health Center estimates its one-time integration cost at $75,000.**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **10-15** 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 53 pharmacies 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 across **53** different 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 Central Pennsylvania**,** 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

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

software.[3] **Sadler Health Center** estimates it will take 10 hours and cost $238,808 to upload records related to CADs due to needing additional EHR modules and additional vendor services we currently are able to manage in-house.

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

**Sadler Health Center 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.

## 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

[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)

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.

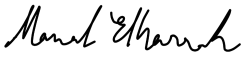
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of 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. **Sadler Health Center offers patients a sliding fee for medications and services. This allows patients to maintain their health even if they are experiencing hardship. Without this assistance, the community burden would be tremendous.**

**Conclusion**

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

**Sadler Health Center** 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 **Samantha Imbraguglio Edenfield at sedenfield@sadlerhealth.org.**

Sincerely,



**Manal El Harrak**
**Sadler Health Center**

[6] HRSA FAQ

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

| Topic Number | Topic | HRSA Estimate | CentraCare Estimate |
|---|---|---|---|
| 1 | # CE's impacted | 14,600 | 9 |
| 2 | # Annual Submissions | Weekly (52/year) | Daily (~260/year) |
| 3 | Required hours per submission | 5 | 24 (3 FTEs) |
| 4 | Total hours required per entity annually | 260 | 693 |
| 5 | Financial Impact | Not estimated | $21.4M in delayed 340B rebates for current medication list, 3 FTEs required |

1. This graph displays the differences between HRSA's estimate of the burden the 340B rebate model would cause covered entities compared against our estimate for CentraCare's 9 hospitals.
2. We believe the best way to maintain compliance and timeliness of rebates with the 340B rebate program requires us to submit daily instead of weekly.
3. We believe that three full-time employees we be required to maintain compliance and timeliness of rebates. Implementing a rebate model would require no fewer than three additional full-time employees to operate effectively. Before these full-time employees can begin their tasks, at least 6 months of training is required to educate the new staff on the 340B program and the 340B rebate model requirements. At best, one employee could support pre-submission activities such as data extraction, validation, formatting, and transmission. However, the operational burden does not end with claim submission. Substantial, ongoing effort is required to track rebate payments from multiple manufacturers, accurately match those payments to submitted claims, and complete detailed reconciliation. We estimate that two of the three full-time employees would need to be dedicated to rebate monitoring and reconciliation. These labor-intensive activities are unavoidable and continuous, not episodic. They are also additive to existing operational requirements, including ongoing claim submissions through platforms such as 340B ESP. Under a rebate model, these workflows become meaningfully more complex, as staff must simultaneously manage medications subject to 340B price restoration and those requiring rebate submission, often under different rules and timelines.
4. The total hours required per entity annually is calculated by the 24 hours required each daily submission (~260/year) divided by the 9 covered entities.
5. Over the course of one year, we believe our hospital would be required to front to drug manufacturers approximately $21.4 million by having to purchase these medications on WAC instead of getting the up front 340B discount. This figure is based on our 2025 purchases of IPAY 2026 and IPAY 2027 NDCs. This estimate will change dependent on the drugs chosen for the rebate pilot and how it will expand over time. This impact disrupts decades of business practices built around 340B upfront discounts.

AFFINIA HEALTHCARE™

Inspired by the Patients We Serve

April 22, 2025

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**

Dear Director Britton:

On behalf of **Affinia Healthcare,** 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, Affinia Healthcare again requests that CHCs be exempted from the pilot program.**

**Affinia Healthcare is an award-winning, nationally accredited health center, providing affordable primary and preventive health care for St. Louis, Missouri, area residents. Affinia Healthcare is a community health center, 501(c)(3) non-profit organization, and is accredited through The Joint Commission and National Committee of Quality Assurance organizations. Established in 1906 as the Holy Cross Dispensary, Affinia Healthcare today serves over 43,700 people per year, of whom more than 90 percent have incomes under 100 percent of the federal poverty level. Approximately 70 percent of patients served are Black or African American, 11 percent are Hispanic/Latinx, and over 4,000 are un-housed.**
**The Affinia Healthcare Development Team helps support the mission of our community health center by providing funding to serve the unmet healthcare needs of the most vulnerable and disenfranchised in our community. The Development team depends on a wide array of funding sources and individual donor contributions to fund the care for these communities.**

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 **600** patients who rely on us for prescriptions. 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**: **Affinia Healthcare** anticipates needing **at least one** additional FTE 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, **Affinia Healthcare** will face an increased administrative burden to monitor rebate claims and payments. **An estimate of twenty hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Affinia Healthcare** anticipates an additional **$250 per month** 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**

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

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. **$5,000** 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 $500 per month to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **43,700** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$200,000** annually.

**The In-House Pharmacy: The Burden of IT Integration**

**Affinia Healthcare operates its in-house pharmacies**. 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.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools of approximately $10,000.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **twenty** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

**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.[2]

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),

[2] Internal NACHC survey data

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

**Affinia Healthcare 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 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

[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)
[5] HRSA FAQ

individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

**Conclusion**

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

**Affinia Healthcare** 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, don't hesitate to contact Dr. David Miller **at dmiller@affiniahealthcare.org.**

Sincerely,

Kenyatta Johnson, RPh
Director of Pharmacy Services
Affinia Healthcare

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

PrimeCareHealth
COMMUNITY HEALTH CENTERS

April 24, 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 PrimeCare Community Health, Inc., 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, PrimeCare Community Health, Inc. again requests that CHCs be exempted from the pilot program.**

PrimeCare Community Health, Inc. is a nonprofit, Federally Qualified Health Center (FQHC) that served almost 32,000 patients across 82 zip codes in the Chicagoland Area in 2025. Our mission is to provide accessible, high-quality, and affordable healthcare to underserved populations, regardless of their ability to pay. As a safety-net provider, many of our patients are uninsured, underinsured, or living with chronic conditions that require consistent access to affordable medications. Because of this, the 340B Drug Pricing Program is an essential resource that allows us to stretch limited resources and provide life-saving medications to those most in need.

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 31,859 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**: PrimeCare Community Health, Inc. anticipates needing 2.0 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, PrimeCare Community Health, Inc. will face an increased administrative burden to monitor rebate claims and payments. More than 12 hours per week will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: PrimeCare Community Health, Inc**.** anticipates an additional $25,000 for external vendors, including consultants, legal counsel, program coordination, and third-party administrators (TPAs).

**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.

- **Ongoing Operational Fees**: Our TPA will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.

**Total Cost:** For our CHC, which serves 31,859 patients, the total projected increase in expenses, including labor~~, IT~~, and carrying costs, is estimated at $165,000 annually.

**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 83 pharmacies 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.

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

- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across many different pharmacy locations and chains to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners (i.e., Walgreens) to opt out of the 340B program entirely rather than manage the administrative headache. In Chicagoland**,** 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

**PrimeCare Community Health, Inc. 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.

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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 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

[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)

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. PrimeCare Community Health, Inc. is committed to ensuring medications remain affordable and accessible for all patients. We extend 340B pricing to all eligible health center patients, regardless of insurance status, and actively promote this benefit to individuals who are uninsured, underinsured, or experiencing financial barriers to accessing their prescriptions. We do not restrict access to 340B pricing based on payer type or other criteria beyond patient eligibility, as our goal is to remove cost as a barrier to care. As PrimeCare Community Health, Inc. does not operate an entity-owned pharmacy, we rely on our contract pharmacy partners to dispense medications at 340B prices with no markup. However, manufacturer imposed contract pharmacy restrictions beginning in July 2020 have made it increasingly challenging to consistently provide these discounts. Despite these limitations, our clinical and care teams remain deeply committed to working with patients to secure medications at the lowest possible cost, often at the 340B price, while also prioritizing convenience and access at pharmacy locations that best meet patients' needs.

**Conclusion**

**PrimeCare Community Health, 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 up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. PrimeCare Community Health, Inc. believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

PrimeCare Community Health, Inc. 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 Kenzie Keisler, 340B Administrator, at Kenzie.Keisler@primecarechi.org.

Sincerely,

Lynn Hopkins
PrimeCare Community Health Inc.

[5] HRSA FAQ

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

Southwest Mississippi Regional Medical Center
Southwest Health

April 27, 2026

HRSA Information Collection Clearance Officer
paperwork@hrsa.gov

Re: Information Collection Request – 340B Rebate Model Pilot Program (OMB No. 0906–NEW)

Dear Sir or Madam:

On behalf of Southwest Mississippi Regional Medical Center (SMRMC), I am submitting these comments in response to HRSA's Information Collection Request (ICR) associated with the proposed 340B Rebate Model Pilot Program. These comments supplement our previously submitted response to the Request for Information (RFI).

Our comments are focused specifically on the burden estimates and operational realities associated with the proposed data collection requirements, as required under the Paperwork Reduction Act.

**1. HRSA's Estimated Burden is Materially Understated**

*HRSA estimates that covered entities would require approximately 5 hours per week to submit claims-level data.*

Based on our direct operational experience with existing platforms (including ESP and Beacon-related workflows), **this estimate is not reflective of real-world conditions**.

At SMRMC, we estimate the following ongoing burden under a rebate model:

- Pharmacy (data validation, claim integrity, resubmissions): 10–15 hours/week
- Finance (rebate tracking, reconciliation, variance analysis): 8–12 hours/week
- IT/Reporting (data extraction, formatting, system interfacing): 6–10 hours/week
- Vendor coordination and dispute resolution: 5–8 hours/week

**SMRMC Total Estimated Burden***: 29–45 hours per week (1.5–2.5 FTEs minimum)
*This estimate does not include initial build costs, system configuration, or implementation-phase workload, which would be substantial. Accordingly, SMRMC does not agree with HRSA's assertion that the proposed data collection burden is minimal or comparable to existing practices.

**2. Data Required is Not "Readily Available" or Standardized**

*The ICR assumes that required data elements are comparable to data already maintained or submitted through existing processes.*
**This assumption is inaccurate**.

At SMRMC:

- Required data elements reside across multiple non-integrated systems (EHR, pharmacy systems, billing, contract pharmacy platforms)
- These systems are subject to ongoing vendor-driven updates and changes in data structure, often without advance notice to the CE, requiring continuous revalidation and reconciliation of reporting outputs.
- Data must be manually extracted, normalized, and reformatted
- There is no standardized format across manufacturers or third-party platforms
- Significant manual intervention is required to ensure claim eligibility

We do not currently submit complete claims-level data sets to all manufacturers across all dispensing channels, and doing so would require new infrastructure, workflows, and staffing.

**3. Ongoing Operational Burden Extends Far Beyond Initial Submission**

**The burden associated with the proposed model is not limited to initial data submission. It includes continuous, iterative processes:**

- Manual claim review and eligibility validation
- Correction and resubmission of rejected claims
- Monitoring of platform errors and system logic discrepancies
- Coordination with multiple TPAs and manufacturers
- Tracking and managing 45-day submission windows
- Reconciliation of expected vs. received rebate payments
- Initiation and tracking of credit/rebill processes

Our experience demonstrates that even when claims are submitted correctly, system-level errors and opaque adjudication processes can delay or prevent reimbursement. To date, despite significant resource investment, SMRMC has not successfully resolved a single denied claim through existing rebate-related infrastructure.

**4. Financial Burden and Cash Flow Impact**

**The rebate model introduces a material financial burden tied directly to the data collection process.**

SMRMC projects:

- $1.25 million increase in upfront drug spend (2026)
- Up to $6 million annual exposure by 2028

In addition:

- Delays in rebate payment create cash flow strain
- Denied or disputed claims result in permanent financial loss
- Additional administrative burden requires new staffing and/or vendor contracts

Southwest Mississippi Regional Medical Center
Southwest Health

These financial risks are inseparable from the data submission requirements and must be considered part of the total burden under the PRA. These financial exposures are directly contingent upon successful data submission, validation, and adjudication, and therefore are inseparable from the information collection burden itself.

**5. Response to PRA Evaluation Criteria**

**Under the Paperwork Reduction Act, agencies are required to ensure that information collection burdens are accurately estimated and minimized to the extent practicable.**

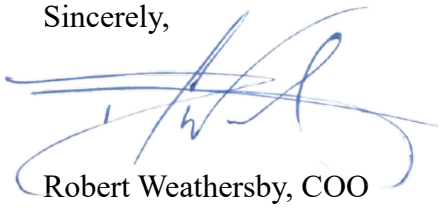
- (1) Necessity and Utility
  The proposed data collection is duplicative of existing processes and does not justify the operational burden imposed.
- (2) Accuracy of Burden Estimate
  HRSA's estimate of 5 hours/week is significantly understated. Based on real-world experience, the burden is 6–9 times higher.
- (3) Quality and Clarity of Data Collection
  Current systems lack standardization, transparency, and reliability, limiting the utility of collected data.
- (4) Use of Automation
  Automation is not feasible given:
  - Fragmented data sources
  - Lack of standardized formats
  - Dependence on external vendor platforms

In conclusion, based on our operational experience, the data collection requirements associated with the proposed rebate model would impose a substantial and ongoing administrative burden that is not accurately reflected in the ICR.

We respectfully request that HRSA revise its burden estimates to reflect real-world conditions and reconsider the feasibility of the proposed data collection framework.

Thank you for the opportunity to provide these comments.

Sincerely,



Robert Weathersby, COO
Southwest Mississippi Regional Medical Center

community health
northwest florida
HealthcareWithinReach.org

April 24, 2025

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 **Escambia Community Clinics D/B/A Community Health Northwest Florida (CHNWF),** 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, CHNWF again requests that CHCs be exempted from the pilot program.

CHNWF serves a geographic foot in Escambia and Santa Rosa Counties in Florida through our seventeen (17) clinic sites (three of which are mobile). CHNWF serves approximately 49,000 unduplicated patients 83% of whom are 200% or more below the poverty line.

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 **49,000** 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**: CHNWF anticipates needing two 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, CHNWF will face an increased administrative burden to monitor rebate claims and payments.Twenty work hours weekly will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: CHNWF anticipates an additional $300,000 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 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. $250,000 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 $50,000 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 49,000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $3,000,000 annually.

**The In-House Pharmacy: The Burden of IT Integration**

CHNWF operates four (4) in-house pharmacies. 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.

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

- **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.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. The estimated costs are $300,000 for these changes.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend twenty 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 multiple pharmacies 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 across numerous different 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 Northwest Florida and Lower Alabama, 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] CHNWF estimates it will take twenty hours and cost tens of thousands of dollars 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.

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[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

## II. Patient Impact

CHNWF 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.

## 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 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.

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[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)

[6] HRSA FAQ

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

**Conclusion**

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

CHNWF 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 Walter Arrington, Director of Grants & Development warrington@chnwf.org .

Sincerely,

Chandra Smiley, MSW
CEO
Community Health Northwest Florida

April 22, 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 APLA Health, 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, APLA Health again requests that CHCs be exempted from the pilot program.**

**APLA Health is a federally qualified health center serving some 13,438 patients annually at eight sites in Los Angeles County, California.** Our clinics provide primary, oral and behavioral health care, as well as STD and HIV testing and treatment. 70 percent of our patients are covered through Medi-Cal, the California Medicaid program. These patients live at 138 percent of the federal poverty level or below. We see 2300 patients living with HIV; another 2100 are administered PrEP (pre-exposure prophylaxis). As of 2024, we administered over 16,000 STD tests. APLA Health contracts for pharmacy services with 101 contract pharmacies; we also operate one in-house pharmacy.

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 **13,438** 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**: APLA Health anticipates needing 3.2 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, APLA Health will face an increased administrative burden to monitor rebate claims and payments. 15 additional hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: APLA Health anticipates an additional $166,000 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 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. $40,000 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 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 13,428 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $686,625 million annually and a 15% loss in savings for contract pharmacy arrangements annually.



**The In-House Pharmacy: The Burden of IT Integration**

**APLA Health operates one in house pharmacy**. 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. 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. In anticipation for a possible rebate model, our in-house pharmacy has moved to a TPA coordinated virtual inventory. The additional cost of this was $50,000 per year

- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. APLA Health expects to incur integration costs of $10,000.

- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 60 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 101 pharmacies 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 across 101 different 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 Los Angeles County**,** 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

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

**APLA Health 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.

## 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 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.

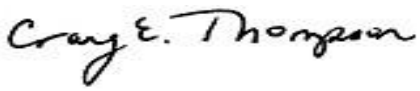
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of 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. APLA Health provided $1,221,324 in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.

**Conclusion**

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

**APLA Health** 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 Philip Curtis, Director of Government Affairs at PCurtis@aplahealth.org

Sincerely,



Craig E. Thompson
Chief Executive Officer

MOUNTAIN LAUREL
MEDICAL CENTER

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April, 23 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 Western Maryland Health Care Corporation, doing business as Mountain Laurel Medical Center (MLMC), we appreciate the opportunity to provide comments regarding the anticipated administrative and operational burden associated with the proposed 340B Rebate Model Pilot Program. Given the significant administrative, financial, and operational impact, MLMC again requests that Community Health Centers (CHCs) be exempted from participation in the pilot.

MLMC is a rural Federally Qualified Health Center serving approximately 12,000 patients annually across Western Maryland and adjacent West Virginia counties. We provide integrated primary care, behavioral health, and pharmacy services, processing over 125,000 prescriptions annually, with more than 90% attributable to the 340B program. The program is foundational to our ability to provide affordable medications and support over $3 million annually in charity care and patient services.

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 over 12,000 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:** MLMC anticipates the need for at least 2 additional full-time equivalents (FTEs) to support the increased operational, administrative, and compliance burden associated with rebate tracking, reporting, reconciliation, and dispute resolution.
- **Number of Hours:** MLMC estimates that approximately 10–15 hours per week will be required to monitor and report rebate claims due to the complexity and variability of manufacturer-specific requirements.
- **External Vendor Costs:** MLMC anticipates annual costs of $50,000–$150,000, including third-party administrators (TPAs), pharmacy system updates, EMR modifications, and compliance support 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 different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** MLMC estimates one-time implementation costs of approximately **$50,000–$100,000** to modify pharmacy systems, build reporting capabilities, and redesign workflows necessary for rebate compliance.
- **Ongoing Operational Fees:** Ongoing vendor and system-related costs are expected to increase due to the need for continuous rebate tracking, reporting, and reconciliation.
- **Total Cost:** In total, MLMC estimates the rebate model will result in more than $500,000 annually in additional operational costs, including labor, IT infrastructure, and carrying costs.

**The In-House Pharmacy: The Burden of IT Integration**

MLMC operates several in-house pharmacies that requires direct integration between our Electronic Health Record (EHR), pharmacy management system, and purchasing workflows. The rebate model is not a simple accounting change; it is a significant technological disruption.

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

To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** The rebate model introduces additional complexity by requiring alignment between dispensing data, purchasing records, and manufacturer rebate requirements across multiple systems.
- **One-Time Integration Costs:** MLMC estimates integration costs to exceed $75,000 for API development and reconciliation tools.
- **Ongoing Resource Diversion:** Pharmacy and administrative staff will need to dedicate approximately 10–15 hours per week to manual reconciliation, diverting resources from patient-facing services.

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

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. MLMC partners with a network of contract pharmacies across Western Maryland and neighboring West Virginia communities to ensure access to medications in rural areas.

- **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 that requires ongoing monitoring across multiple contract pharmacy partners and dispensing locations. MLMC staff must track and validate claims across this network to ensure rebates are processed accurately and in a timely manner, significantly increasing the administrative burden.
- **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 headache. In our region, this would leave patients in our tri-county area of Garrett, Allegany, and Preston counties in Maryland and West Virginia 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] Implementation of a rebate model for clinic-administered drugs would require new tracking systems, workflow changes, and staff training.

MLMC anticipates additional administrative burden and costs associated with converting existing documentation into electronic formats and ensuring compliance with rebate submission requirements.

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

[2] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Networto be cost-effective and k

[3] Internal NACHC survey datto be cost-effective and a

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

MLMC 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.

## 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.

[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)

- **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.
- MLMC applies sliding fee discounts, co-sliding adjustments, pharmacy-specific sliding programs, and fee waivers to ensure patients can access medications regardless of their ability to pay.
- These programs depend on predictable, upfront 340B pricing. A rebate model introduces uncertainty in reimbursement timing and amounts, making it operationally difficult to determine patient pricing at the point of care and limiting our ability to provide discounted medications.

**Conclusion**

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

MLMC 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 James Mou, CFO @ jwmou@mtnlaurel.org.

Sincerely,

Michelle Dixon

**Michelle Dixon, CEO**
**Mountain Laurel Medical Center**
**mdixon@mtnlaurel.org**
**4/23/2026**

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

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April 23, 2025

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 **The Pit River Health Service,** which serves approximately **4085 patients** across **7 PRHS facilities** we appreciate the opportunity to comment on HRSA's Information Collection Request (ICR) for the 340B Rebate Model Pilot Program.

**The Pit River Health Service strongly opposes** any transition from the current upfront discount structure to a rebate-based model under the 340B Program. Our program relies on 340B to stretch limited resources and maintain access to essential medications for American Indian and Alaska Native patients. A rebate model would fundamentally undermine this purpose by requiring us to absorb significant upfront drug costs, while navigating delayed reimbursement, creating serious financial and operational challenges.

For our program, the proposed rebate model would impose a substantial administrative and financial burden. We estimate this will increase the number of staff hours per week/month dedicated to claims-level data submission, rebate tracking, and reconciliation, and may require additional staff/FTEs. These requirements exceed our current capacity and are not accurately reflected in HRSA's burden estimates.
The proposed information collection requirements, including claims-level data submission, tracking, and reconciliation, would significantly increase administrative complexity and divert limited staff from patient care. Additional reporting, data validation, and coordination with third-party vendors would further strain our operations.

Most importantly, the rebate model would negatively impact patient access. Our patients rely on affordable medications to manage chronic conditions and any disruption to 340B savings could affect our community.

**If HRSA proceeds with a rebate model despite these concerns, the Pit River Health Service strongly urges that Tribal Health Programs be exempt from participation.** This exemption is necessary to prevent further administrative burden, protect access to care, and avoid exacerbating longstanding federal funding inequities. It is also critical to uphold the federal trust responsibility to Tribal Nations. Congress has declared that it is the policy of this Nation, "in fulfillment of its special trust responsibilities and legal obligations to Indians… to

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ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy."[1]

The 340B program is essential to our ability to provide care. A rebate model would destabilize our operations and reduce access to essential medications for the patients we serve.

Thank you for the opportunity to comment. If you have any questions, please contact Loren Ellery at 530-335-5090.

Sincerely,
Loren Ellery, CEO
Pit River Health Service
36977 Park Ave
Burney, CA, 96013
530-335-5090
Loren.Ellery@pitriverhealthservice.org

[1] Indian Health Care Improvement Act, 25 U.S.C. § 1602(1), 25 USC 1602: Declaration of national Indian health policy; see also Snyder Act, 25 U.S.C. § 13, 25 USC 13: Expenditure of appropriations by Bureau

TUG RIVER
HEALTH ASSOCIATION

April 24, 2025

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 Tug River Health Association, Inc, 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, Tug River Health Association, Inc. again requests that CHCs be exempted from the pilot program.

Opening its doors in 1976, Tug River Health Association, Inc. has provided medical services to persons in McDowell County, West Virginia, meeting the high standards of a Federally Qualified Health Center. TRHA has expanded throughout its 50-year history and now operates five practice sites in McDowell and Wyoming Counties. With a patient population of over 6,400 and 24,000+ annual encounters, the organization provides affordable healthcare to our rural population which has over 36% living in poverty. Ninety-eight percent (98%) of our patients live in a household at or below 200% Federal Poverty level.

Meeting the needs of the community, TRHA has multiple in-service and outreach programs. TRHA provides behavioral health services both on site and via tele-psychiatry. TRHA also offers prenatal services utilizing contracted obstetricians for labor and delivery services and is a WV Perinatal Partnership designated Drug Free Mom and Babies site, offering Medication Assistant Treatment, Behavioral Counseling and Peer Recovery Coaching to identified patients. Hep C/HIV patient navigation is also provided to identified patients, predominantly via our Medication Assistance Program for Substance Use Disorder.

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 6,400 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.

<u>Workforce Impact:</u>

- Staffing Impact: Tug River Health Association, Inc. anticipates needing 1.5 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, Tug River Health Association will face an increased administrative burden to monitor rebate claims and payments. 15 hours will be required to report 340B rebate claims to a third-party platform.
- External Vendor Costs: Tug River Health Association, Inc.anticipates an additional $120,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

<u>Pharmacy Software & Third-Party Administration Changes</u>

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.

- One-Time Implementation Costs: We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. $80,000 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 $25,000 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- Total Cost: For our CHC, which serves 6,400 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at 175,000 annually.

The In-House Pharmacy: The Burden of IT Integration

Tug River Health Association, Inc. operates one in-house pharmacy . 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.
- One-Time Integration Costs: We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- 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. My CHC currently partners with 12 pharmacies 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 across 12 different 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 McDowell County, West Virginia, 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

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

would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3]

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

Tug River Health Association, Inc. 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.

**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

[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)

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. Tug River Health Association, Inc. provides medication assistance to uninsured/underinsured patients often at the expense of the organization.

Conclusion

Tug River Health Association, 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 up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. Tug River Health Association, Inc. believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Tug River Health Association, Inc. 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 Cheryl Mitchem, Chief Development Officer at chmitchem@tugroivermedical.org

Sincerely,

Andrea Thornton

Andrea Thornton, CEO
Tug River Health Association, Inc.

[6] HRSA FAQ

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

MONONGAHELA VALLEY ASSOCIATION OF HEALTH CENTERS
MVA Health Center - Fairmont | P.O. Box 1112 | Fairmont, W.V. 26555 - 1112 | (304) 366-0700

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

**RE: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW**

*Submitted via paperwork@hrsa.gov*

Dear Director Britton:

Please add this letter regarding the estimated burden on HRSA on compliance with the 340B rebate model programs and consider this a request that all federally qualified health centers be exempt from the pilot program. Monongahela Valley Association of Health Centers, Inc. (MVA) was established in 1958 as the first non for profit group practice in northern West Virginia. Pharmacy services were initiated in 1965. Since that time, MVA has provided high quality care to all residents of the service area. By the mid-1980s, early community health funding from DHHS was converted to the present model of CHCs, now under the purview of HRSA. MVA's mission is to provide quality primary care services to vulnerable members of the community. Thus, the 340B program is foundational.

However, MVA requests HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden:

1. This model would cause significant financial turmoil and directly affect our ability to serve the 8000 registered patients who received services here.
2. Navigating manufacturers' existing contract pharmacy restrictions are cumbersome and increased our administrative costs. This requires IT infrastructure upgrades (which are currently an issue given our present EMR system) in addition to incurring outsourced consultants including one on a monthly basis to manage complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates.
3. The increased administrative burden in monitoring rebate claims and payments for this added $37,000 in additional contracting for annual audits and monthly assistance for submission of claims/pricing under the 340B program. A rebate model will require a significant increase in already-strained operational capabilities.

4. In addition to the above, the workforce impact is up to 30 percent of the chief pharmacist's time as well as 30 percent of an administrative director's time is over $100,000 in salary and benefits, not to mention a reduction in productive time needed elsewhere. In addition, upgrades to IT infrastructure for interfaces needed has proved to be time consuming.
5. In short, Pharmacy revenue for FY2025 was $710,000 less than FY2024 related to issues with the current 340B program implementation as well as planning for a complex new rebate infrastructure. Currently for FY2026, MVA is still $211,000 below budget through March, 2026.

- 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. 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. This will be additional expense as we anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. MVA currently partners with many local pharmacies to increase access to affordable medications, especially for patients who utilize two rural satellite locations.

From a patient care standpoint, 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. MVA has a documented user profile with a higher burden of chronic conditions compared to private practices. Approximately one out of every four patients qualified for discounted services as the incomes are below 100 percent of the poverty level. One in nine have no insurance. One out of every 100 is homeless. This patient population relies on affordable medications to manage these long-term conditions associated with socio-economic levels and related population health risks.

MVA urges HRSA to exempt CHCs as their stories have to be similar to our experience in North Central West Virginia. The rebate model would create even more significant cash flow challenges, forcing difficult decisions about staffing, services, and whether or not a pharmacy program can be based on site.

Thank you for consideration of the points in this letter.

Sincerely,

Dr. Raymond Alvarez, DHA, MPA, FACHE
President and CEO

Email: Raymond.alvarez@mvahealth.org

April 24, 2025

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 **Ingham County,** 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, Ingham Community Health Centers again requests that CHCs be exempted from the pilot program.**

Ingham Community Health Centers offer a range of services from adult and pediatric primary care, including; behavioral health, adolescent school-based/linked care, women's specialty services, dentistry, and pharmacy services, ensuring the provision of comprehensive, high quality primary care to underserved, low income populations, regardless of their ability to pay. Community Health Centers (CHCs) are the best, most innovative, and resilient part of our nation's health system. For sixty years, CHCs have provided high-quality, comprehensive, affordable primary and preventive care. Ingham Community Health Centers maintains its role as the national voice for CHCs and believes high-quality primary health care is essential in creating healthy communities and preventing chronic conditions. The collective mission and mandate of Ingham Community Health Centers and the 1,512 CHCs nationwide are to close the primary care gap and provide high-quality, cost-effective primary and preventive medical care to communities across this country. When we improve patients' health, we help people to go back to work, and we lower health care costs, and we support local economies.

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 **19,775** 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**: **Ingham Community Health Centers** anticipates needing **two (2)** 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, **Ingham Community Health Centers** will face an increased administrative burden to monitor rebate claims and payments. **An estimated 80 additional hours weekly** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Ingham Community Health Centers** anticipates an additional **$250,000.00** 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 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. An

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

estimated one time cost **$50,000.00** 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 **$35,000.00** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **19,775** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$525,000.00** annually.

**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 12 pharmacies 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 across **75** different 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 Ingham County**,** 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] **Ingham Community Health Centers** estimates it will take ten (10) **hours weekly and cost $75,000 annually** to upload records related to CADs due to the addition and implementation of technology.

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

[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

**Ingham Community Health Centers 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.

## 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 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. Ingham Community Health Centers helps make prescription medications affordable by using a sliding fee scale, which adjusts costs based on a patient's income and household size. This ensures that individuals and families with limited financial resources can still access

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

essential medications without facing prohibitive expenses. By evaluating each patient's ability to pay, Ingham Community Health Center's reduce or cap out-of-pocket drug costs, in combination with the 340B Program, to keep medications accessible and equitable for the entire community.

**Conclusion**

**Ingham Community Health Centers 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. **Ingham Community Health Centers** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

**Ingham Community Health Centers** 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 **Elizabeth Linder, RPh ACE Pharmacy Services and 340B Program Manager, elinder@ingham.org**

Sincerely,

Brittany Moore, RN, MSN-PH
Executive Director/Deputy Health Officer
Ingham Community Health Centers

*Elizabeth Linder, RPh, ACE*

Elizabeth Linder, RPh, ACE
Pharmacy Services and 340B Program Manager
Ingham Community Health Centers

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Community Healthcare Network

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 Healthcare Network, Inc**,** 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, Community Healthcare Network, Inc. again requests that CHCs be exempted from the pilot program.**

Community Healthcare Network is comprised of 14 healthcare sites in medically underserved areas across Brooklyn, the Bronx, Manhattan, and Queens, along with a fleet of medical mobile vans. The organization provides primary and behavioral health care, dental, nutrition, and needed support services for patients of all ages, regardless of their ability to pay. No one is turned away.

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 **38,635** 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.

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**Workforce Impact:**

- **Staffing Impact**: **Community Healthcare Network, Inc.** anticipates needing **one to three** 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, Community Healthcare Network, Inc. will face an increased administrative burden to monitor rebate claims and payments. 18 hours per month will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Community Healthcare Network, Inc. anticipates an additional cost between $480,000 to $1,210,000 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 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. $385,000 to $935,000 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 $480,000 to $1,210,000 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 38,635 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $480,000 to $1,210,000 annually.

**The In-House Pharmacy: The Burden of IT Integration**

**Community Healthcare Network, Inc. operates 2 in house pharmacies**. 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.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **Community Healthcare Network's estimated one-time costs are $385,000 - $935,000**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend 140-240 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

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- **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.[1] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[1] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

## Conclusion

**Community Healthcare Network, 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 up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **Community Healthcare Network, Inc.** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

**Community Healthcare Network, Inc.** 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 Alan Wengrofsky, CFO/EVP, awengrofsky@chnnyc.org.

Sincerely,

**Alan Wengrofsky**
**Community Healthcare Network, Inc.**

Bucksport Regional
Health Center

April 24, 2025

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 **Bucksport Regional Health Center,** 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, Bucksport Regional Health Center again requests that CHCs be exempted from the pilot program.**

**Bucksport Regional Health Center is an FQHC that has serving Hancock, Penobscot and Waldo County Maine for 52 years. We serve 9000 residents with 2 primary care sites and 5 school-based health services. We provide primary care, behavioral health, dental, laboratory, x-ray and pharmacy services through our organization.**

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 **9000** 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**: **Bucksport Regional Health Center** anticipates needing **2** 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, **Bucksport Regional Health Center** will face an increased administrative burden to monitor rebate claims and payments. **We are anticipating 10 hours per week to report claims** to 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Bucksport Regional Health Center** anticipates an additional **$75,000** 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 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. **$50,000** 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 **$35,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.

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

- **Total Cost:** For our CHC, which serves **9000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$35,384** annually.

**The In-House Pharmacy: The Burden of IT Integration**

**Bucksport Regional Health Center operates one pharmacy**. 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. BRHC hires an pharmacy vendor to manage our program and anticipate an increase in administrative costs if the rebate program is implemented for community health centers.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **We estimate that cost of $75,000.**
- **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. My CHC currently partners with 17 pharmacies 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 across **17** different 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 Hancock and Waldo County Maine and the surrounding area 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

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

would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3]

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

**Bucksport Regional Health Center 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.

## 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

[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)

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 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.

**Conclusion**

**Bucksport Regional Health Center 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. **Bucksport Regional Health Center** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

**Bucksport Regional Health Center** 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 **Carol Carew, CEO at ccarew@brhcme.org.**

Sincerely,

**Carol Carew, CEO**

[6] HRSA FAQ

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

NJCRI
NORTH JERSEY COMMUNITY RESEARCH INITIATIVE
Seeking Cures for Tomorrow, Providing Support for Today.

April 24, 2026

Samantha Miller
Director of Division of Oversight, Reporting, and Regulatory Compliance
Office of Planning Analysis and Evaluation
Health Resources and Services Administration
5600 Fishers Lane, Room 13N82
Rockville, MD 20857
*Submitted electronically via PAPERWORK@HRSA.GOV*

**RE: "340B Rebate Model Pilot Program Application, Implementation, and Evaluation" Information Collection Request Federal Register Notice**

Dear Director Miller:

North Jersey Community Research Initiative (NJCRI) appreciates the opportunity to submit feedback to the Health Resources and Services Administration (HRSA) in response to the information collection request (ICR) Federal Register Notice (FRN) dated February 26, 2026[1] referenced above. NJCRI is concerned about the proposal to transition the 340B program to a rebate model due to both the administrative and financial burdens that will be placed on our non-profit organization as well as many other similar organizations and hospitals across the country.

NJCRI was founded in 1988, and it is one of New Jersey's longest-standing community-based health organizations. Each year, NJCRI provides confidential primary care, behavioral health support, chronic illness education, and community services to more than 20,000 individuals residing in urban and rural areas throughout New Jersey. Through its vital and unique 340B program, the organization has numerous programs designed to promote equitable access to healthcare, reduce health disparities, and strengthen the overall community wellbeing. The potential impacts of significantly increasing NJCRI's administrative and financial burdens would be detrimental for the organization, and the Newark, New Jersey community, as well as the entire state, would be negatively affected by this change.

## I. A Rebate Model Would Harm NJCRI's Ability to Care for Our Patients

In 2024–2025, NJCRI delivered a broad range of healthcare services across its programs. A total of 841 new patients were enrolled in primary medical care, while 4,302 clients received medical

[1] 91 Fed. Reg. 9632 (Feb. 26, 2026).

case management services. Preventive and diagnostic efforts included 6,913 screenings for sexually transmitted infections and 5,381 HIV tests, along with 3,459 referrals for HIV prevention (PrEP). NJCRI also conducted 1,146 rapid Hepatitis C tests and completed 702 full laboratory workups to support treatment, resulting in 1,272 individuals receiving Hepatitis C treatment. In addition, vaccination efforts reached thousands of community members, with 5,943 COVID-19 vaccines administered, 2,802 Mpox vaccines provided, and 180 RSV vaccines delivered.

Most of the services listed above are provided to all clients, even though many do not generate revenue for the organization and they are often not covered under state or federal grants. It often costs more to deliver these services than the organization can recover from them. Thanks to 340B, NJCRI can provide holistic medical care, including general PCP services, access to specialists, dentistry, behavioral health and more to New Jerseyans in urban and rural areas across the entire state.

With support from the 340B program, NJCRI has treated more than 2,000 patients for Hepatitis C and cured over 1,880, achieving a 90 to 92 percent adherence rate that exceeds national averages. In partnership with the New Jersey Department of Health and aligned with WHO elimination goals, the agency delivers care through mobile clinics serving all 21 counties, including rural areas, and provides rapid access to specialists, on-site diagnostics, and comprehensive support services such as transportation, lab work, and medication assistance. Its network now spans more than 75 mobile treatment sites across 53 cities and several rural counties. This statewide model operates without reliance on federal funding and minimal state support, instead sustained by 340B savings. Fully transparent and accountable, it demonstrates that Hepatitis C can be eliminated in a way that is cost-effective, equitable, and community driven, with the 340B program serving as its foundation.

Community Pride Pharmacy, located on the first floor of NJCRI, serves both our patients and individuals from across the state and is a key component of our 340B program. A shift to a rebate model would increase costs and reduce access to medications, as Medicaid reimbursement rates already fall below the cost of Hepatitis C treatment, creating financial losses without 340B eligibility. This uncertainty may lead contract pharmacies to withdrawal, further limiting patient access. Additionally, delays or denials of 340B savings would make it difficult to continue providing financial assistance at the point of dispensing.

If these administrative and financial pressures become too great, NJCRI and its pharmacy partners may be unable to sustain operations. This would not only undermine efforts to end the HIV epidemic by limiting access to testing, treatment, and case management, but also disrupt the agency's nationally recognized Hepatitis C elimination work, including its mobile care model, high cure rates, and statewide reach. The loss of these services would significantly

reduce access to life-saving care and increase reliance on state-funded Medicaid programs in New Jersey.

**Direct Patient Service Reductions**: If 340B savings are delayed, reduced, or threatened due to a rebate model, the following patient services at NJCRI would be at the highest risk of reduction:

- Statewide (Urban & Rural) Mobile Hep C Clinic and HIV Testing
- Street Medicine
- Patient Diagnostic/Chronic Illness Lab Fees and Health Screenings
- FibroScan Machine & Medical Equipment
- Patient Insurance Premium, Medication Copays and Medical Transportation
- Behavioral Health Services
- Outside Auditing & Ongoing Quality Assurance

## II. A Rebate Model Would Increase NJCRI's Drug Acquisition Costs and Place a Financial Burden on the Organization

During the 2024-2025 fiscal year, NJCRI's 340B program served an average of 341 patients per month who were living with HIV, Hepatitis C, and/or were receiving HIV prevention services and $147,454.54 in savings resulting from 4043 qualified 340B claims were passed directly to patients. If the 340B program were transitioned to a Rebate Model, NJCRI, a non-profit organization, would be required to pay Wholesale Acquisition Cost (WAC) pricing for all medications associated with potentially eligible 340B claims, and then await reimbursement from the manufacturer ~45 days later to make up the difference between the 340B price and the WAC price. NJCRI's 340B program has experienced consistent and significant growth each year since 2020, and this upward trend continues. However, if the 340B program is transitioned into a Rebate Model, the organization will be forced to reduce both the scope of its services and the number of clients served, due to the loss of critical 340B savings that currently enable the effective extension of limited federal and state resources. Under a 340B Rebate Model, NJCRI's average monthly cost of medications, calculated at the extended WAC price, would be $1,964,192.99. The annual 340B medication estimated upfront cost would be $9,278,943.60 (Table 1). The estimated potential cash flow impact of this model is projected to be between $3,000,000 and $4,000,000 on average during a 60 to 90-day waiting period.

NJCRI anticipates that its services and programs would begin to experience significant impacts within two weeks to one month after the implementation of a 340B rebate model. In the event that 340B savings were delayed for a period of 60 to 90 days, some patients could

be forced to go without essential treatment for the same duration. This situation would likely require reductions in salaries and personnel, as well as a careful reevaluation of budgets across the organization. In addition, any rebates that are potentially denied or delayed could create further financial strain, placing additional pressure on NJCRI's ability to maintain its full range of services and support for the community it serves.

**Table 1: NJCRI's Medication Replenishment Report (2024-2025)**

| **2024-2025 NJCRI Medication Replenishment Report:** | Average Monthly 340B Patients | Total 340B Patient Qualified Claims | Total 340B Medications Delivered | Extended WAC Price | Invoiced 340B Price | Amount NJCRI must pay for medications upfront under a 340B Rebate Model |
|---|---|---|---|---|---|---|
| | **341** | **4091** | **4398** | **$23,570,315.93** | **$14,291,372.33** | **$9,278,943.60** |

NJCRI's other funding sources are primarily grants, many of which have delayed payments, creating ongoing cash flow challenges for the overall budget. As a result, there is little to no cash available to cover the projected costs under a 340B Rebate Model, which could impact $3-4 million during the anticipated 60–90-day period. Delays in payouts from local government-funded grants have already strained cash flow, meaning the organization's emergency savings would likely need to cover upfront medication costs at WAC pricing. Over the past 25 years, increases in Ryan White grants have been minimal and 340B has been critical in filling gaps for essential services such as medical supplies, transportation, and bringing tailored clinics to provide specialized care. This potential change could significantly limit the organization's ability to continue addressing these gaps and meeting patient needs (Table 2).

**Table 2: Expenses At-Risk with 340B Rebate Model**

| **Cost Category** | **Estimated Annual Cost Funded by 340B Savings** |
|---|---|
| 340B Patient Medications | $13,641,000 |
| 340B Program Fees (Pharmacy Dispense Fees & TPA Fees) | $1,551,000 |
| 340B Program Staff Salaries & Fringe Benefits | $787,000 |
| 340B Savings Passed Directly to Patients | $150,000 |
| 340B Patient Copays | $51,000 |
| 340B Consultant Fees | $21,000 |
| 340B Medical Supplies | $20,000 |
| 340B Program Expenses | $15,960 |
| **Total at Risk** | **$16,236,960** |

## III. A Rebate Model Would Place a Tremendous Administrative Burden on NJCRI

If the 340B program is transitioned to a rebate model, NJCRI will take on a significant administrative burden while simultaneously dealing with an increase in labor and operational costs. Centralizing, submitting, tracking, and monitoring data to secure rebates on a timely basis will undoubtedly take time and resources away from patient care. According to Table 3 below, a 340B rebate model could increase NJCRI's administrative burden by **72** to **106** weekly hours, which is much more significant than the estimate HRSA provided. A 340B rebate model allows manufacturers to use access to Covered Entities' (CEs') claims data to deny 340B discounts and further delay the savings owed to the organization. This model puts future rebates at risk, and NJCRI, much like most other non-profit organizations, does not have the cash flow to take risks with monthly expenditures. Drug manufacturers have not released safeguards to protect patient data, and that creates serious concerns that this model could be inappropriately expanded or that Covered Entities' data will be used for improper purposes. The integrity of NJCRI's 340B program is taken very seriously, and a potential 340B rebate model directly goes against the integrity of the program.

**Table 3: NJCRI's Potential Administrative Burden**

| Process for Compliance | Key Internal Roles | External Partners | Weekly Effort Per Role | Total Weekly Hrs |
|---|---|---|---|---|
| **340B Data Extraction** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 1–2 hrs | 4–8 hrs |
| **340B Data Validation** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 3–4 hrs | 12–16 hrs |
| **340B Data Formatting** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 1–2 hrs | 4–8 hrs |
| **340B Data Transmission** | 340B Program Manager, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 4–5 hrs | 8–10 hrs |
| **Internal Sign-Off** | 340B Program Manager, CFO, Finance, Admin | — | 1–2 hrs | 4–8 hrs |
| **Rebate Payment Tracking (Manufacturer)** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 3–4 hrs | 12–16 hrs |
| **Payment-to-Claim Matching** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 3–4 hrs | 12–16 hrs |
| **Invoice Reconciliation** | 340B Program Manager, Finance | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 3–4 hrs | 6–8 hrs |
| **Exception Resolution (Unreturned Refunds)** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 1–2 hrs | 4–8 hrs |
| **Audit Trail Maintenance** | 340B Program Manager, CFO, Finance, Administration | Contract Pharmacies, TPAs, Wholesalers, Consultants/Auditors | 3–4 hrs | 12–16 hrs |

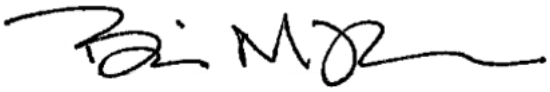
## IV. HRSA Should Pursue a Neutral 340B Clearinghouse Instead of a Rebate Model

Rather than moving forward with a rebate model, we believe a more practical solution is for HRSA and CMS to establish a neutral, government-run clearinghouse to manage 340B claims data. Covered entities, third-party administrators, and contract pharmacies could submit claims retrospectively, allowing 340B claims to be separated from Medicare drug claims before any manufacturer rebates are issued. This would prevent duplicate discounts by ensuring manufacturers only pay rebates on non-340B claims. CMS has already signaled interest in this type of approach through its proposed "340B repository," and a similar model could also be applied to Medicaid.

* * *

We appreciate HRSA's consideration of our comments. For further information, please contact me at b.mcgovern@njcri.org.

Sincerely,



Brian McGovern, CEO
North Jersey Community Research Initiative (NJCRI)

April 24, 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 **Blue Ridge Community Health Services,** 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, Blue Ridge Community Health Services again requests that CHCs be exempted from the pilot program.**

Blue Ridge Community Health Services, Inc. (BRCHS) has provided more than 60 years of health center services in Western North Carolina (NC), serving as the medical home for those most in need in Buncombe, Haywood, Henderson, Jackson, Macon, Polk, Rutherford, Swain, and Transylvania counties. BRCHS provides care from more than 70 service delivery locations, including freestanding comprehensive integrated primary care sites, general pediatric locations that also provide specialty pediatric services (neurology, endocrinology, and pulmonology), a shelter-based location, freestanding dental-only centers, behavioral health sites, mobile medical and dental unit/vans, and school-based health centers (SBHC). Directly provided services include general primary care, diagnostic lab, diagnostic radiology, screenings, emergency and after-hours coverage, voluntary family planning, immunizations, well child care, gynecology, prenatal care, intrapartum services, postpartum care, preventive dental, pharmaceutical services, case management, eligibility assistance, health education, outreach, transportation, translation, additional dental services, mental health services, substance use disorder services, optometry, nutrition, psychiatry, and specialty pediatric services - endocrinology, pulmonology, and neurology. Contractual and referral relationships are also in place to expand access to additional specialty services. In 2024, BRCHS served 87,821 patients with 214,704 medical clinic visits, 10,071 medical virtual visits, 16,583 dental clinic visits, 33,761 mental health clinic visits, and 11,488 mental health virtual visits. As an existing health center with over six decades of experience

caring for medically underserved populations, BRCHS is well-positioned to address the escalating needs in this rural region of the state.

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 **87,000 unique** 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**: **Blue Ridge Community Health Services** anticipates needing additional two FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model at an estimated cost of **$270,400 annually**.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Blue Ridge Community Health Services** will face an increased administrative burden to monitor rebate claims and payments. We estimate that 10 hours weekly will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Blue Ridge Community Health Services** anticipates an additional **$12,000** for external vendors, including consultants, legal counsel, program coordination,

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

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 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. We anticipate **$50,000** 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 **$12,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Administrative Cost:** For our CHC, which serves **87,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$332,400** annually.

**The In-House Pharmacy: The Burden of IT Integration**

**Blue Ridge Community Health Services operates three entity owned pharmacies and is working on adding two more this year**. 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. **Blue Ridge Community Health Services** utilizes PioneerRx as a pharmacy management system. The system will require significant adaptations and customizations to help us manage the data components necessary to identify the rebate model drugs. Additionally, we have to consider and plan for the patient impacts and how we price their medications which undoubtedly will require significant modifications to our systems and staff resources on an ongoing basis.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **20-25** 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 three contract pharmacies to increase access to affordable medications with a total network of 80 contract pharmacies. We utilize five different TPAs to administer our contract pharmacy network.

- **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 **80** different 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 two of our nine counties in Western North Carolina, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2] We anticipate NOT being able to offer discounted medications in these two counties since the 340B price will not be available from the wholesaler in a pricing file at the time of purchase, which is how the TPA systems are designed to work. The fact that the 340B cost is not the purchase price on the front side of the drug adjudication translates to the patients not being able to receive an affordable 340B cost when they present at the pharmacy to pick up their medications. This will likely lead to prescription abandonment and worsened health outcomes costing our healthcare system more money in the form of emergency room visits and hospital stays.

## II. Patient Impact

**Blue Ridge Community Health Services 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:

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[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)

- **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.[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. **Blue Ridge Community Health Services** administers a sliding scale discount for our income qualified patients. We pass through the 340B drug cost plus a nominal dispensing fee to ensure patients can afford and access their medications to improve their overall health. This pricing system is reliant on the upfront 340B purchase price being available and passing into our system on daily EDI files that we receive from our wholesaler. The pricing plans in our pharmacy management system are built on actual acquisition cost at the time of dispensing. In a rebate model in which the 340B cost would only be recognized after the drug purchase, these pricing models are in jeopardy as is patient health and medication access.

**Conclusion**

**Blue Ridge Community Health Services 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. **Blue Ridge Community Health Services** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

**Blue Ridge Community Health Services** 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 Gwen Ernesty, Chief Pharmacy Officer at gernesty@brchs.com.

[5] HRSA FAQ

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

Sincerely,

**Tammy Greenwell**
**Blue Ridge Community Health Services**

TACHC
TEXAS ASSOCIATION OF COMMUNITY HEALTH CENTERS

April 24, 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 **the Texas Association of Community Health Centers (TACHC),** 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, TACHC again requests that CHCs be exempted from the pilot program.**

Texas health centers utilize the 340B program to better serve almost 2 million Texans annually across the state. The 79 health centers in Texas operate over 700 clinic sites across 131 counties, providing medical, dental, behavioral health, pharmacy, vision, and other health services to Texas' most hard-to-reach, medically underserved communities. In Texas, about 34% of health center patients are uninsured and 92% live below 200% of the poverty level, making 340B a critical lifeline to ensure health centers can offer low-cost drugs and services to their patients.

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 the ability of Texas health centers [illegible] patients who rely on their services. These community focused

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organizations operate on razor-thin margins (**Texas CHCs had an average operating margin of -2%, with two-thirds having a negative margin and one-third having 30 days or less of cash on hand**) 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**: TACHC anticipates Texas health centers needing at least one additional FTE, and likely more for larger organizations, 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, Texas CHCs will face an increased administrative burden to monitor rebate claims and payments.
- **External Vendor Costs**: TACHC anticipates an additional expense 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 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. Large investments will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, CHC TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.

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

## The In-House Pharmacy: The Burden of IT Integration

**Texas CHCs operate over 150 pharmacies across the state.** 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.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend extensive hours 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. Texas CHCs currently partners with hundreds of pharmacies 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 across different 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 some areas, 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]

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

[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

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

**TACHC 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.

## 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 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

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[5] 2025 UDA Data, HRSA (hrsa.gov)
[6] HRSA FAQ

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.

**Conclusion**

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

TACHC 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 Preston Poole, Policy and Research Director at ppoole@tachc.org

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