Multnomah County
Health Department
Community Health Center

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 **Multnomah County Community Health Center (MCCHC),** 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, MCCHC again requests that Community Health Centers (CHC) be exempted from the pilot program.**

Through the provision of community health services in seven integrated primary care and dental clinics, nine Student Health Centers, and care tailored for people living with HIV in our Health Services Center, the MCCHC is the largest public entity federally qualified health center in Oregon. Pharmacy services are a critical component of the care that we provide, as our eight pharmacy locations and pharmacy staff serve patients across the most populous county in the state - dispensing approximately 350,000 prescriptions per year to health center patients (regardless of ability to pay). All eight of the MCCHC pharmacies are recognized as critical access pharmacies by the Oregon Health Authority as they serve as crucial low-barrier locations for medications. Our clinical pharmacists are vital members of our multidisciplinary health care team, ensuring that our patients have access to key services that improve health outcomes and help control health care costs - including medication therapy management, individualized adherence support, and post-diagnostic disease state management.

The 340B program is foundational to our and other health center'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 **60,201** patients who rely on us each year. 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**: **MCCHC** anticipates needing a minimum of **1.0** additional FTEs and an increase in financial analyst 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, **MCCHC** will face an increased administrative burden to monitor rebate claims and payments. **100 hours per month** will be required to report, track and reconcile 340B rebate claims to a third-party platform.
- **Vendor and Total Staffing Costs**: **MCCHC** anticipates an additional **$365,000 in annual costs** directly related to the rebate model for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, new staffing, 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. **$100,000** 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 **exceeding $220,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **over 60,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$365,000** annually. These costs are the projected operational and administrative costs, and do not reflect the additional expected increases in drug prices that the health center would have to support under a rebate model - for our health center, we are projecting that we would have to **pay over $15M more in annual drug costs by 2028.**

The In-House Pharmacy: The Burden of IT Integration

MCCHC operates eight 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. **The MCCHC currently utilizes PioneerRx as the pharmacy's electronic health record system for pharmacy services, as well as OCHIN Epic for integrated primary care, behavioral health care, and dental patient care records. System interoperability remains a critical concern for ongoing administrative changes and reporting requirements.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **We estimate a one time upfront cost of over $100,000 to complete this required change.**
- **Ongoing Resource Diversion:** Staff who currently manage pharmacy services will be forced to spend a minimum of **12 hours per week (over 50 hours per month)** 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 and unnecessary complexity that threatens the existence of contractual arrangements. Our health center previously partnered with one contract pharmacy to increase access to affordable medications, but had to terminate the agreement due to overly burdensome reconciliation activities. This experience concerns us for the future of how other community health centers will have to navigate ongoing duplication in reporting, onerous reporting requirements and inconsistent data filing requirements.These challenges are particularly impactful for Oregon, where the state currently ranks 49th for retail pharmacy access.[2]

Clinic Administered Drugs: The Burden of New Systems Required

[2] Oregon Budget Broadcasting "Oregon 2nd worse in the nation for retail pharmacy access, new analysis finds". June 5, 2024.

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] The use of electronic medication administration records (e-MARs) helps our health center maintain compliance with these requirements, but comes at the significant cost of over **$10,000 a month in fees,** not including indirect fees of clinical staff time to reconcile data and account for any variances.

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

MCCHC 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. For example, our health center is currently able to directly offer patients a 90 day supply of insulin for $10; if we were

[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)

forced to distribute insulin at the WAC, the health center would be forced to carry an upfront cost of nearly $25,000 annually for Novolog alone or charge patients the difference in price.

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.
    - The availability and affordability of insulin is of particular importance to MCCHC patients - our health center dispenses 500 insulin prescriptions each month. Our underinsured and uninsured clients may receive a 28 to 90 day supply for a fee of $10 in compliance with Executive Order #14273. With a Rebate Model where we purchase at WAC and seek a Rebate later, we will no longer be able to provide insulin at such a low cost which will be detrimental to the health of our insulin-dependent patients.
    - Under the proposed rebate model, the wholesaler price file would reflect the full WAC rather than the discounted 340B price. This makes the price unattainable for patients, even on a sliding fee schedule. It would preclude Community Health Centers from fulfilling their legal obligation to offer required discounts and still meet the administration's Executive Order #14273 on affordable insulin. There is no operational model to provide discounted medications in a retrospective rebate model.

Conclusion

MCCHC 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

[6] HRSA FAQ

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

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

The MCCHC 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 Michele Koder, Pharmacy Director, at michele.koder@multco.us .

Sincerely,

Anirudh Padmala
Interim Executive Director
Multnomah County Community Health Center

Michele Koder, PharmD
Pharmacy Director
Multnomah County Community Health Center

Ritchie Longoria, PharmD
Deputy Pharmacy Director
Multnomah County Community Health Center

Adrienne Daniels, MPH
Strategy and Policy Director
Multnomah County Community Health Center

GREATER VALLEY
HEALTH CENTER

1935 3rd Avenue East, Kalispell, MT 59901 | 406-607-4900 | www.greatervalleyhealth.org

April 17, 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 **Flathead Community Health Center, 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, Flathead Community Health Center, Inc. again requests that CHCs be exempted from the pilot program.**

Flathead Community Health Center, Inc. continues to provide exceptional patient-centered care regardless of ability to pay. We strive to cultivate a healthy community with access to quality care for all. Our service areas span the Flathead Valley in Northwest Montana that includes over 10,000 patients, 3 clinic locations, and 2 pharmacies. Our patient population benefits tremendously from accessibility to quality healthcare, especially in the rural area of Hungry Horse, MT.

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 **10,000** 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**: **Flathead Community Health Center, Inc.** anticipates needing **at least 1** 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, **Flathead Community Health Center, Inc.** will face an increased administrative burden to monitor rebate claims and payments. **An estimated 5-10 hours per week** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Flathead Community Health Center, Inc.** anticipates an estimated additional **increase of $150,000** 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. **This estimated cost of about $5,000** 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 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **10,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$30,000** annually.

The In-House Pharmacy: The Burden of IT Integration

Flathead Community Health Center, Inc. operates 2 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.

- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **5-10** 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), 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

Flathead Community Health Center, 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.

---

[2] Internal NACHC survey data

[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.

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 individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **Flathead Community Health Center, Inc. reinvests its 340B program savings directly into services that support and benefit its patient population.**

Conclusion

Flathead Community Health Center, 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

[4] 2025 UDA Data, HRSA (hrsa.gov)
[5] HRSA FAQ
[6] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

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

Flathead Community Health Center, 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 **Dr. Yvonne Christow, Pharmacy Director, at ychristow@greatervalleyhealth.org.**

Sincerely,

Adam Naumann, CEO
Flathead Community Health Center, Inc.
dba Greater Valley Health Center

LOS ANGELES LGBT CENTER®

Anita May Rosenstein Campus
1118 N. McCadden Place
Los Angeles, CA 90038

T: 323-993-7400
F: 323-308-4480

lalgbtcenter.org

@lalgbtcenter
@LALGBTCenter
@lalgbtcenter

April 24, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

RE: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Information Collection Request (OMB No. 0906-NEW)

Dear Director Miller:

The Los Angeles LGBT Center takes this opportunity to comment to the Health Resources and Services Administration (HRSA) in response to the above-referenced information collection request (ICR) Federal Register Notice (FRN), dated February 26, 2026. The purpose of this comment is to express our alarm that HRSA is proposing a rebate model in the ICR that is unnecessary and highly burdensome. In the FRN, HRSA drastically underestimates the burden of such a collection, and fails to consider less burdensome alternatives that would enhance the collected information.

Since 1969, the Center has cared for, championed, and celebrated LGBT individuals and families in Los Angeles and beyond. Today the Center's over 800 employees provide services for more LGBT people than any other organization in the world. The Center is one of the few FQHCs in the nation with providers who specialize in primary care, HIV/AIDS specialty care, women's care through the Audre Lorde Health Program, and trans specific care through the Trans Wellness Center. In addition, the Center covers a broad range of other services including, but not limited to, mental health, substance abuse, and housing navigation. Across all our programs, we see over 50,000 clients per month; or, over half a million visits each year. In this moment, the need for our services has never been greater.

The 340B program is foundational to the ability of community health centers (CHCs) and Ryan White clinics (RWCs)—like the Center—to serve the most vulnerable members of our community. The proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC and RWC pharmacy operations nationwide. Any rebate model would completely upend our technology systems and workflows, pose substantial implementation and managements costs, and do nothing to improve 340B compliance or operations. Because RWCs are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS, for RWCs, in particular, a rebate model that includes HIV medications can have an outsized impact on both patient and clinic because such a large percentage of patients take each individual

drug. HRSA has not adequately accounted for the substantial burden that a rebate model would pose on covered entities.

We respectfully urge HRSA to refrain from implementing a rebate model and instead collaborate with the Centers for Medicare & Medicaid Services (CMS) to develop an alternative approach that prevents manufacturers from providing a covered entity access to both the 340B ceiling price and a maximum fair price (MFP) rebate on the same drug claim; alternatively, we urge HRSA to exempt CHCs and RWCs from the rebate model.

I. HRSA's Rebate Model Proposal Is Unnecessary and Untenable

A. Administrative Complexities and Financial Challenges

For the last 30 years, the Los Angeles LGBT Center, like all covered entities and their vendor partners, has developed sophisticated technologies and workflows to manage the complexities of 340B compliance and operations. These carefully crafted systems have been built on the premise that we receive 340B ceiling prices as upfront discounts. Converting 340B into a rebate program would completely upend these systems, pose substantial implementation and managements costs, and do nothing to improve 340B compliance or operations. We would have to make significant upfront and ongoing financial investments in technology, staff, and workflow redesign to accommodate a rebate model. Importantly, these investments would diminish our ability to care for our patients.

B. Patient Impacts

The comprehensive services that CHCs and RWCs provide range from free or discounted medications to critical wrap-around support services, including case management, dental and behavioral health, and food and housing assistance. CHCs and RWCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing that CHCs see a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity. By definition, RWCs treat a high concentration of patients for a single disease state—HIV—a disease state for which there are only a limited number of medications and therapies available for prevention and treatment. Importantly, the 340B program allows CHCs and RWCs to provide these expanded services without any cost to taxpayers.

CHCs and RWCs rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating access to 340B discounts, a rebate model would erode the 340B savings available to cover the cost of care to the uninsured and underinsured. A rebate model would make the comprehensive care that our patients need less accessible and more expensive, an outcome that is completely contrary to congressional intent in enacting the 340B program. Increased financial and administrative costs from the rebate model would reduce the resources on which we rely, both to care for our existing patients and to identify additional patients in need of care. These burdens directly contradict the purpose of the 340B program—to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

For RWC patients, in particular, a rebate model's impact on access to HIV medication would be devastating. Studies show that single tablet regimen improve patient outcomes through treatment retention and viral suppression, compared with patients taking multiple pills.[1] Biktarvy® is the only single tablet regimen

[1] Hemmige V, et al. Single tablet HIV regimens facilitate virologic suppression and retention in care among treatment naïve patients. AIDS Care. 2018 Aug;30(8):1017-1024. doi: 10.1080/09540121.2018.1442554. Epub 2018 Feb 25. PMID: 29478329; PMCID: PMC6094383. Cotte L, et al. Effectiveness and tolerance of single tablet versus once daily multiple tablet regimens as first-line antiretroviral therapy - Results from a large french multicenter cohort study. PLoS One. 2017 Feb 2;12(2):e0170661. doi: 10.1371/journal.pone.0170661. PMID: 28152047; PMCID: PMC5289500.

included among the national HIV treatment guidelines[2] list of recommended initial treatment regimens. HIV patients have limited options for treatment, and as a result, are uniquely and disproportionately impacted by any changes in accessibility for drugs and therapies. Adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and efforts to encourage patient adherence are significantly compromised if individuals living with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need.

II. HRSA's Burden Estimate Fails to Account for All Costs

A rebate model, by its very nature, will significantly increase our drug acquisition costs because we will lose the upfront 340B price reductions and subceiling discounts that we currently receive at the time of purchase. Covered entities will have to pay wholesale acquisition cost for drugs at the point of sale, with the hope of obtaining a rebate in the future. This process places a huge cash flow strain on already under-resourced CHCs and RWCs. HRSA's burden estimate has not accounted for this additional cost. Nor has the agency accounted for additional costs to implement a rebate model like additional staffing and purchasing of additional equipment to implement the model.

HRSA's burden estimates fail to appreciate the disruptive nature of the rebate model estimating that each covered entity would spend an average of 260 hours per year on complying with a rebate model requirements. In the FRN, HRSA justifies its low burden estimate for the rebate model by stating that the covered entity data:

> will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program.

HRSA's assumption that the data will be comparable to information that covered entities already collect is inaccurate and results in HRSA's low burden estimate. The only covered entity burden estimate that HRSA included in the FRN is a 5-hour per week burden for reporting claims data to a third-party platform. For ease of reference, we have reproduced that estimate in the table below.

HRSA's Estimated Annual Burden for Covered Entity Rebate Processing

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	52	5

[2] Clinicalinfo.HIV.gov, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV, Sept. 12, 2024, https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/what-start-initial-combination-regimens.

To help HRSA adequately evaluate the rebate model costs, below is our estimate of the impact that a rebate model would have on the Los Angeles LGBT Center.

Los Angeles LGBT Center's Estimated Annual Burden for Rebate Processing

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	2,158/year	6 mins each = 11hr/week
Time Spent Disbursing Rebate Payments to Correct Covered Entity	1,835/year	2 mins each = 1.2hr/week
Time Spent Disputing Rebate Claim Denials	323/year	15 mins each = 1.5hr/week

Los Angeles LGBT Center's Estimated Start-Up Cost for Rebate Model Implementation

Cash on Hand for Upfront Drug Acquisition Costs	$310k (2027) - $2.9M (2028 – HIV meds added to list)
Purchase of Additional Equipment	$11k upfront + $35k annual ($46k first year)
Hiring and Training of Additional Staff	$30,000

Los Angeles LGBT Center's Estimated Annual Lost Wages for Rebate Model Implementation

Category of Employee Acting (e.g., Executive, Administrative Assistant, Pharmacist)	**Number of Hours Spent**	**Hourly Wage Rate**	**Total Cost** (number of hours multiplied by rate)
Director of Pharmacy	2/week = 104/year	$114	$11,856
Pharmacy Operations Manager	4/week = 208/year	$57	$11,856
Associate Director Pharmacy Operations	2/week = 104/year	$74	$7,696
Financial Coordinator x 2	4 each/week = 208 each/year	$35 each	$14,560
Inventory Coordinator x 2	1 each/week = 52 each/year	$35 each	$3,640
Health Information Services (IT)	0.5/week = 26/year	$110	$2,860
Finance Department Staff	1/week = 52/year	$62	$3,224
CFO	1/week = 52/year	$135	$7,020
Total	**20.5/week x 52 = 1,170/year**		**$62,712**

III. HRSA Failed to Consider More Efficient Rebate Model Alternatives

Instead of proceeding with a rebate model, the Los Angeles LGBT Center respectfully asks that HRSA work with CMS to develop a neutral clearinghouse run by the federal government or a government contractor, to which covered entities, third-party administrators, and/or contract pharmacies retrospectively submit 340B claims data to prevent 340B-MFP duplicate discounts.

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a voluntary clearinghouse-like model that the agency is calling a "340B repository" to prevent 340B-MFP duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

IV. Conclusion

The Los Angeles LGBT Center appreciates the opportunity to respond to this Information Collection Request 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 Jennifer Chou, Health Policy Director, at jennifer.chou@lalgbtcenter.org.

Sincerely,

Terra Russell-Slavin
Chief Strategy Officer
Los Angeles LGBT Center

April 26, 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

Dear Director Britton:

On behalf of **Centerville Clinics 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, Centerville Clinics Inc. again requests that CHCs be exempted from the pilot program.**

For patients of Centerville Clinics, transportation remains a critical barrier to healthcare accessibility across Greene, Fayette, and Washington Counties. The regions rugged, rural geography lacks a cohesive public transit infrastructure, leaving a high volume of low-income residents-nearly 88% of whom live below 200% of the federal poverty level without reliable ways to reach appointments. Without consistent non-emergency medical transportation, these residents face a cycle of missed screenings and delayed treatments, directly fueling the region's high rate of chronic disease and lower life expectancy compared to the rest of Pennsylvania. The poverty rate for these rural counties averages 5% higher than the State and Federal poverty rates. Fayette and Greene Counties are two of the least healthy, least wealthy counties in Pennsylvania. For these reasons we have opened office sites in the small towns where the patients reside.

Our 340B program has given us the ability to provide a pharmacy sliding fee to those patients who are eligible. We recently opened our second in-house pharmacy, and, we expect our sliding fee adjustment to reach over 1 million dollars.

The additional expense and the loss of receipts due to the rebate program implementation will force us to reduce the amount of sliding fee assistance that we now are able to offer our patients. Centerville is concerned that many of these patients with limited incomes will not be able to pay for their medication. This will mean that this will have a negative effect on their health. We will also be forced to eliminate or curtail our services such as food banks and diaper distribution to the poor medical care for City Mission and community health workers. We will also be forced to consider closing some of our sites that depend on the 340B program.

Centerville Clinics appreciates that the Federal grant and the 340B program has enabled us to provide services to the low income, who depend upon us for their medical, specialist, behavioral health, dental, and pharmacy services. This is the reason for the last two months, the pharmacist manager, the manager of the 340B program and our senior accountant have spent most of their time addressing this issue.

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 **31,584** 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**: **Centerville Clinics Inc.** anticipates needing **2.99** 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, **Centerville Clinics Inc.** will face an increased administrative burden to monitor rebate claims and payments. **Ten to fifteen hours** will be required to report 340B rebate claims to a third-party platform.

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

- **External Vendor Costs**: **Centerville Clinics Inc.** anticipates an additional **anticipates an additional $100,000 in additional costs related to the rebate model** 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. **A $50,000 one time cost** 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 approximately $40,000 annually** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **31,584** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$372,206** annually.

The In-House Pharmacy: The Burden of IT Integration

Centerville Clinics Inc. 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. **Our currentsystem does not have the ability to handle 1 5003 the new rebate infrastructure; therefore, we have projected the cost for upgraded systems.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **Our estimate is that our costs will be between $0,000-$75,000 for integration costs.**
- **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 thirty-nine (39) 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 **thirty-nine (39)** 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 Greene, Fayette, and Washington **,** 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 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

Centerville Clinics 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

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

[3] Internal NACHC survey data

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

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

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.
- **Centerville has a board approved pharmacy assistance plan (Sliding Fee) that will assist patients in receiving their medications without creating a barriere to care.**
- **Pursuant to Centerville Clinics's sliding fee policy, Centerville assesses, and at annual intrvals, re-assesses patients' income and family size for eligibility for the Sliding Fee program.**
- **When a patient qualities for the sliding fee discount program, Centerville Clinics pharmacies will charge the patient in accordance to the structure. The Sliding Fee program is established annuall based on the Federal Poverty Levels.**

Conclusion

1 5003 Centervile Clinics 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

[6] HRSA FAQ

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

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

As a governing Board Member of Centerville Clinics Inc., and, a former long-time employee, I appreciate the chance to respond as the Advocacy Coordinator. I look forward to continuing to advocate for Centerville Clinics Inc. in such vial information for our organization.

Sincerely,

Marianne Gideon
Centerivlle Clinics Governing Board Member
and Advocacy Coordinator

FHCSO
FAMILY HEALTH CENTER OF SOUTHERN OKLAHOMA

April 25, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 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 **Family Health Center of Southern Oklahoma, Inc. (FHCSO)**, thank you for the opportunity to submit comments regarding the estimated burden associated with the proposed 340B Rebate Model Pilot Program Information Collection Request (ICR).

Given the ongoing and frequently changing requirements imposed by drug manufacturers and their contracted vendors, FHCSO believes the rebate model would impose a **severe administrative, financial, and operational burden** on Community Health Centers (CHCs). For these reasons, FHCSO respectfully reiterates its request that **Community Health Centers be exempted from participation in the 340B Rebate Pilot Program**.

FHCSO is a HRSA-funded **Section 330 grantee** and an eligible covered entity under section 340B(a)(4) of the Public Health Service Act. Since 2004, FHCSO has provided comprehensive primary care and pharmacy services to medically underserved populations, including uninsured, underinsured, and Medicaid-insured patients. While our initial service area was Johnston County, Oklahoma, FHCSO has since expanded to include Coal, Atoka, and Marshall counties.

Participation in the 340B Drug Pricing Program is essential to FHCSO's ability to stretch scarce federal resources, expand access to affordable medications, and reinvest savings into patient care, pharmacy operations, and medical services. As a long-standing 340B covered entity responsible for enrollment, annual recertification, and ongoing compliance, FHCSO offers the following comments based on **direct operational experience**.

The 340B Program is foundational to a Community Health Center's ability to serve the most vulnerable members of its community. The proposed rebate model represents a fundamental shift

of responsibility and risk from drug manufacturers to safety-net providers and would significantly impair our ability to fulfill our mission.

HRSA's Burden Assessment

Respectfully, HRSA states in the ICR that "the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant." FHCSO strongly disagrees with this assessment.

If the requested data were submitted through a **neutral, standardized clearinghouse**, the administrative impact on covered entities would be reduced—though still significant. However, under the current design, data submission is required through **manufacturer-controlled clearinghouse platforms**, which materially increases burden, complexity, and operational risk.

As a covered entity, FHCSO has experienced repeated changes to manufacturer and clearinghouse requirements that are **outside HRSA's control and subject to unilateral modification by manufacturers**. These changes make compliance unpredictable and, in some cases, operationally infeasible.

Examples from the first quarter of this year include:

- Denial of Medicare Transaction Facilitator (MTF) claims without clear attribution;
- Retroactive requirements to submit 340B invoices to address MTF denials;
- Introduction of requiring new digital clearinghouse platforms, including **TRUZO** and **ESP**, each with differing technical and documentation standards to our in-house pharmacies and medication rooms.

As covered entities attempt to comply with one set of specifications, manufacturers and their vendors continue to revise requirements mid-cycle. This results in duplicative work, stranded administrative effort, ongoing retraining, and an inability to reliably generate or validate the information HRSA seeks to collect.

Under these conditions, the information requested through this ICR cannot reasonably be characterized as low burden. The proposed approach shifts substantial administrative responsibility to covered entities without stable standards, neutral infrastructure, or assurances that requirements will remain consistent over time.

Response to HRSA Request for Comments

1. Necessity and Utility of the Proposed Data Collection

Community Health Center Perspective

From the perspective of a community health center pharmacy director, only a limited set of data elements sent to a **neutral clearinghouse** would be necessary for an MTF model to function.

The proposed data collection sent to Beacon does not meaningfully enhance program compliance and instead diverts limited staff resources away from existing compliance activities. Community health centers already operate under multiple layers of federal and state oversight, and this proposal adds administrative demands without corresponding safeguards or clarity.

Program Integrity (Diversion and Duplicate Discounts)

Our pharmacy management systems already contain embedded safeguards to prevent duplicate discounts. Prescriptions identified as Medicaid are automatically excluded from 340B eligibility. The proposed data collection does not materially improve protections beyond controls already in place.

Lack of Added HRSA Oversight Value

The proposed data would not be collected or validated by HRSA, but instead transmitted to **manufacturer-supported clearinghouse entities**. Because these entities also control claim approvals, covered entities are frequently required to produce invoices and documentation—often retroactively and outside applicable date ranges—without enhancing HRSA oversight or program integrity.

Duplication of Existing Reporting

Many proposed data elements overlap with information already reported through:

- HRSA 340B audits
- Uniform Data System (UDS) reporting
- Medicaid billing and compliance systems

This duplication does not materially advance oversight effectiveness.

Use of 340B Savings and Program Value

Community Health Centers rely on 340B savings to:

- Expand services and service areas, including rural outreach;
- Provide discounted medications to uninsured and underinsured patients;
- Sustain sliding fee scale pharmacy programs for patients at or below 200% of the Federal Poverty Level; and

- Improve health outcomes in underserved communities.

The proposed pilot and associated data requirements would not demonstrate program value and would instead reduce CHCs' ability to fulfill their statutory mission.

Anticipated impacts include:

- Reduced ability to serve patients regardless of ability to pay;
- Loss of 340B savings passed through to uninsured and underinsured patients;
- Elimination or reduction of sliding fee scale medication discounts; and
- Reductions in services, geographic coverage, and staffing.

Simply stated, it is not possible to pass along savings that are never realized.

2. Accuracy of HRSA's Estimated Burden

HRSA's burden estimate significantly understates the real-world impact on Community Health Centers.

Staffing and Expertise

Although the full scope of effort cannot be precisely quantified due to evolving manufacturer requirements, two points are clear:

1. Compliance and reporting require specialized expertise; and
2. Manufacturers continue to modify requirements, increasing uncertainty and workload.

In response, FHCSO has already:

- Engaged external consultants;
- Sought legal counsel; and
- Increased staffing and anticipates the need for approximately **1.5 additional FTEs**.

Medication Room Issues

New manufacturer requirements will certainly cause the need of a new EMR if our current software does not do an update.

Contract Pharmacy Complexity

Given already-thin margins at contract pharmacies driven by PBM practices, FHCSO may be forced to exclude MTF-related medications altogether to avoid financial loss.

In-House Pharmacy

The addition of new pharmacy software is unknown currently.

Financial Impact

Despite Federal Register language stating the burden "may not be significant," FHCSO's experience is substantially different. The primary burden is not data transmission itself, but the loss of the upfront 340B discount.

FHCSO estimates:

- **Annual financial impact exceeding $700,000**, including medication acquisition costs, software modifications, third-party administrator fees, consultants, legal review, and staffing; and
- Corresponding reductions in patient services and medication access.

(3) Ways to Enhance the Quality, Utility, and Clarity of the Information to Be Collected

A neutral clearinghouse is necessary to be fair to all parties involved. Data quality and utility would be substantially improved by establishing **clear, stable, and uniform standards** that are not subject to unilateral modification by manufacturers or their vendors.

As currently structured, manufacturer-controlled clearinghouses apply differing technical specifications, denial codes, timelines, and documentation standards that change mid-stream and, in some cases, retroactively. Under these conditions, data cannot be expected to be complete, consistent, or comparable.

HRSA should:

- Establish uniform definitions, data elements, and documentation standards;
- Require requirements to remain fixed for defined reporting periods;
- Ensure covered entities receive clear explanations of denials; and
- Avoid reliance on manufacturer or vendor discretion to define compliance criteria.

Without these safeguards, collected information will reflect operational instability rather than meaningful program performance.

(4) Use of Automated Collection Techniques to Minimize Burden

Automation reduces burden only when systems are **neutral, standardized, and interoperable**. As proposed, this collection does not meet those criteria.

Community Health Centers already operate certified EMR and pharmacy systems capable of structured reporting. However, the proposal requires extraction, reconciliation, and resubmission of data across multiple manufacturer-controlled platforms with unique formats and logic—negating the advantages of automation.

Frequent platform changes require workflow redesign, staff retraining, and manual reconciliation, none of which are reflected in HRSA's burden estimate.

To minimize burden, HRSA should consider:

- Keeping the current 340B up-front rebate model;
- Have a single, neutral clearinghouse or HRSA-managed portal for MTF;
- Direct system-to-system submission using established interoperability standards;
- Prohibiting mid-cycle requirement changes; and
- Aligning data collection with information already generated in routine operations.

Absent these changes, automation does not reduce burden but instead shifts significant administrative responsibility onto covered entities.

Respectfully submitted,
Joe Burns DPh
Pharmacy Director
Family Health Center of Southern Oklahoma, Inc.

Vandalia Health
Pharmacy

Pharmacy Administration
3200 MacCorkle Ave. SE
Charleston, WV 25304
304-388-5432
Fax: 304-388-9633

April 26, 2026

Submitted to *Federal eRulemaking Portal:* *https://www.regulations.gov*

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Request for Information: 340B Rebate Model Pilot Program, HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

On behalf of Vandalia Health, Inc., and its subsidiary hospitals ("Vandalia Health"), we appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Request for Information regarding the Health Resources & Services Administration (HRSA) proposed 340B Rebate Model Pilot Program.

Vandalia Health, Inc. is a West Virginia–based health system serving predominantly rural and underserved communities across the state. The system is comprised of 14 hospitals, with 11 hospitals participating in the 340B Program as covered entities, including disproportionate share hospitals (DSH) and critical access hospitals (CAH). Our 340B network encompasses a broad footprint across West Virginia, including Broaddus Hospital Association, Inc., CAMC Plateau Medical Center, Inc., Webster Memorial Hospital, Inc., Preston Memorial Hospital Corporation, Stonewall Jackson Memorial Hospital Company, Charleston Area Medical Center, Inc. (CAMC), and CAMC Greenbrier Valley Medical Center, Inc. (GVMC). These facilities collectively operate numerous child sites and individual contract pharmacy locations, with CAMC managing 172 child sites and 92 contract pharmacies; Stonewall Jackson overseeing 10 child sites and 36 contract pharmacies; Davis handling 9 child sites and 47 contract pharmacies; and Broaddus, Plateau, Webster, Preston, and GVMC contributing an additional combined total of over 45 child sites and 52 contract pharmacies. This extensive network

underscores Vandalia Health's vital role in ensuring healthcare access in rural and underserved communities.

At the outset, we emphasize that the answer to HRSA's central question—whether it should replace the longstanding upfront discount model with a rebate mechanism—is no.

The existing upfront discount structure has enabled Vandalia Health's hospitals to stretch scarce federal resources, expand access to care, and sustain critical services in communities that would otherwise lack them. A rebate model would fundamentally undermine these objectives by introducing substantial administrative complexity, significant financial risk, and barriers to patient access.

Administrative and Operational Costs

A rebate model would impose extensive new administrative burdens across Vandalia Health. Our system has designed its operations, staffing, and vendor relationships around the upfront discount model. Transitioning to a rebate-based system would require substantial new investments in staffing, information technology, and compliance infrastructure.

Our current 340B team consists of 3.5 pharmacist FTEs and 6 analyst FTEs. Even with this relatively lean team, we maintain robust oversight of the program. One facility is still contracted with a 340B management service, demonstrating that even modest additional administrative demands could exceed our internal capacity. To operationalize a rebate model effectively, we would require at least two additional FTEs, diverting focus from existing compliance efforts and potentially increasing short-term compliance risk.

Additional burdens include:

- Significant staffing increases for data submission, claims tracking, reconciliation, dispute resolution, and audit support.
- Vendor costs, previously quoted when the initial rebate model pilot was floated, would rise by thousands of dollars annually due to the need for additional support (exact figures under non-disclosure agreements).
- New IT infrastructure and manual processes, as pricing updates are not currently automated across all platforms, requiring additional manual effort to maintain accurate data in EMRs and billing systems.

- Legal and compliance obligations, including reviewing non-negotiable manufacturer terms of use, which would expose the health system to substantial risk.

Rather than enhancing program integrity, the rebate model would introduce a period of heightened compliance risk. Staff would be forced to balance existing regulatory requirements with the demands of building and operating an entirely new system, increasing the likelihood of errors, delays, and audit vulnerabilities.

Prescription Volume and Direct Patient Benefit

Across Vandalia Health's retail pharmacy network, 340B pricing directly supported at least 25,172 prescriptions during a recent reporting period (24,853 excluding one location). These prescriptions reflect instances where discounted 340B pricing was passed directly to patients, typically with only a nominal dispensing fee. Many patients travel over 80 miles one way each quarter to access these reduced costs. These figures represent only the majority of our retail pharmacy footprint and therefore understate the full scope of program utilization.

The program also supports patients who rely on life-sustaining medications through our hemophilia treatment center, oncology services, transplant programs, and HIV clinic, all located within our hospitals. In addition, 340B subsidizes operational support for West Virginia Health Right, a free and charitable clinic, by providing pharmacy, housekeeping, and other services for this vulnerable patient population.

A rebate model would disrupt these access points by introducing pricing uncertainty at the point of sale, delaying therapy, and threatening patient adherence.

Financial Operations, Medicaid, MDPNP, and Pharmacy Wholesalers

The most significant impact of a rebate model is the shift in financial burden from manufacturers to covered entities. For the 2026/2027 IRA and Medicare Drug Price Negotiation Program (MDPNP) drugs, Vandalia Health's 11 participating 340B hospitals would face $6.61 million in exposure over a 90-day period, or $33.4 million annualized. Under a rebate model, we would pay full acquisition costs upfront while awaiting reimbursement, effectively providing interest-free financing to drug companies.

West Virginia requires that Medicaid claims reflect actual acquisition costs to prevent duplicate discounts. Under a rebate model, Vandalia Health would not have actual

acquisition costs at the time of billing, creating compliance risk and potential regulatory exposure.

The model would also hinder our ability to maximize savings and discounts through pharmacy wholesalers. 340B pricing is currently incorporated into EMRs and hospital billing systems, enabling accurate cost-of-goods accounting and optimization of payment structures. A rebate model would require manual workarounds, additional staff effort, and introduce risk of mispricing, delayed revenue capture, and missed discounts.

Any issues with MDPNP should be addressed by CMS through targeted improvements rather than a disruptive overhaul of 340B. Vandalia Health is already building processes to review MDPNP delays and conduct good faith inquiries. A rebate model would require submission of rebate data for all 340B claims across all payers, vastly increasing administrative burden without improving deduplication compliance.

Impact on Critical Services and Vulnerable Populations

Vandalia Health's 340B hospitals support essential, high-cost service lines dependent on 340B savings. The rebate model would impair our ability to:

- Maintain adequate inventory of high-cost medications
- Offer financial assistance at the point of care
- Sustain service lines operating with minimal or negative margins

In rural communities we serve, there are often no alternative providers for these services. Reduced access would directly impact medically complex and financially vulnerable populations.

Systems and Data Infrastructure

Currently, our systems are not configured to extract and standardize required medical claims data across multiple EMRs or integrate with third-party administrators for real-time rebate processing. Required data elements are often not readily accessible and require manual validation. Manufacturer-specific data expectations further complicate operational feasibility. Existing vendor systems, such as 340B ESP, already create delays and require multiple follow-ups to resolve questions.

Reliance Interests and Program Integrity

Since its inception, the 340B Program has operated via an upfront discount model. Vandalia Health has reasonably relied on this structure in designing operations, staffing, and financial strategies. The system currently maintains rigorous compliance: in 2025 alone, we conducted more than 65 scheduled internal audits and examined over 400,000 data records, while engaging in state and national advocacy.

Implementing a rebate model would divert focus from these compliance efforts, requiring rework of retail pricing programs, increasing administrative risk, and potentially undermining patient access.

Conclusion

The data and experience above demonstrate that a rebate model is not a minor adjustment, it is a fundamental restructuring of the 340B Program. It would:

- Shift substantial financial burden onto covered entities
- Introduce significant administrative inefficiencies
- Increase compliance and operational risk
- Reduce patient access to affordable medications
- Undermine critical healthcare services in vulnerable communities

Vandalia Health, Inc. respectfully urges HRSA to abandon the rebate model concept and pursue less burdensome alternatives to address program integrity concerns. If HRSA chooses to proceed, covered entities must have the opportunity to comment on a fully developed proposal with all operational details and safeguards.

We appreciate the opportunity to provide these comments and welcome continued engagement.

Sincerely,

Brian E. Sayre, PharmD
Vice President Pharmacy Services
Vandalia Health, Inc.

LINCOLN COMMUNITY HEALTH CENTER, INC.

1301 Fayetteville Street • P.O. Box 52119
Durham, North Carolina 27717 – 2119

April 20, 2026

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

RE: Agency Information Collection Activities: Proposed Collection; Public Comment Request – *340B Rebate Model Pilot Program Application, Implementation, and Evaluation* (OMB No. 0906-NEW)

Dear Director Britton:

On behalf of **Lincoln Community Health Center, Inc. (LCHC)**, a Federally Qualified Health Center (FQHC) serving Durham, North Carolina, we appreciate the opportunity to respond to HRSA's Information Collection Request (ICR) for the proposed 340B Rebate Model Pilot Program.

Because the Paperwork Reduction Act assigns Office of Management and Budget (OMB) independent responsibility to reject collections that are unnecessary, duplicative, or unduly burdensome, these comments focus exclusively on the information-collection defects of the proposed rebate model as applied to Community Health Centers.

LCHC strongly urges HRSA to exempt all Community Health Centers (CHCs) from mandatory participation in the 340B Rebate Model Pilot Program.

Executive Summary

When applied to CHCs, the proposed rebate model is neither necessary nor minimally burdensome and fails to meet the standards of the **Paperwork Reduction Act (PRA)**. Specifically, the proposed ICR fails to satisfy the PRA's requirements that collections be **necessary for the proper performance of agency functions**, **non-duplicative**, and **the least burdensome means reasonably available**, particularly when applied to Community Health Centers.

As detailed below, it would impose extraordinary new administrative, financial, and operational requirements on already heavily regulated safety-net providers, while undermining patient access to affordable medications.

I. Organizational Overview

Organization: Lincoln Community Health Center, Inc.

LINCOLN COMMUNITY HEALTH CENTER, INC.
1301 Fayetteville Street • P.O. Box 52119
Durham, North Carolina 27717 – 2119

HRSA Designation: Section 330 Federally Qualified Health Center

Location: Durham, North Carolina

Patients Served Annually: 35,190

Uninsured Patients: 17,618

Annual Sliding-Fee Discounts: $16,018,239

340B Program Structure

- Entity-owned, in-house pharmacy dispensing only to LCHC patients, who are 100% 340B eligible.
- Clinic-administered drugs (CADs) embedded within PPS encounters
- No contract pharmacy arrangements
- 4.46 FTEs already devoted to 340B compliance and oversight
- Current annual 340B administrative cost: **$475,684.14**

This structure already satisfies HRSA program integrity requirements without reliance on a rebate mechanism. LCHC represents a low-risk 340B compliance profile with no diversion risk vectors such as contract pharmacies or mixed-use dispensing.

II. Requested HRSA Action

Lincoln Community Health Center requests that HRSA **exclude Community Health Centers from the scope of the proposed information collection**, as exemption is the **only practicable means of bringing the ICR into compliance with the Paperwork Reduction Act**.

This request aligns with NACHC's national position and is supported by LCHC-specific burden estimates that demonstrate the rebate model would create **disproportionate harm** to CHCs without producing additional program integrity benefits. Limiting the scope of the collection to entities for which HRSA lacks alternative enforcement visibility is the only PRA-compliant means of achieving the stated purpose without imposing unnecessary and duplicative burden.

LINCOLN COMMUNITY HEALTH CENTER, INC.
1301 Fayetteville Street • P.O. Box 52119
Durham, North Carolina 27717 – 2119

III. Administrative Burden

A. New Administrative Activities Introduced by the Rebate Model

The rebate model would require CHCs to implement entirely new activities that do not exist under the statutory 340B model, including:

- Submission of rebate claims to manufacturer-designated or third-party platforms
- Ongoing monitoring of claim status across multiple manufacturers
- Manual reconciliation of rebate payments
- Appeals and dispute resolution for denied or underpaid rebates
- Maintenance of duplicative rebate-specific audit records

Each listed activity is a direct artifact of the proposed information collection itself and does not exist under current statute or HRSA compliance mechanisms.

B. Workforce Impact

Consistent with NACHC burden modeling and LCHC's internal analysis:

- **Additional staffing required: At least 1.0 dedicated FTE, regardless of drug volume**
- **Incremental labor: ~1,300 additional labor hours per year** devoted solely to rebate reporting, monitoring, and reconciliation
    - **Rebate reporting (claims submission & validation):** ~7 hours/week
    - **Rebate monitoring & reconciliation:** ~15 hours/week
    - **Denials & disputes:** ~3 hours/week

These labor demands are **structural and irreducible**, arising from claim-level reconciliation and manufacturer-specific adjudication processes that cannot be automated or absorbed into existing 340B compliance workflows.

C. External Vendor and IT Costs

Rebate implementation would require CHCs to purchase and maintain new external services, including:

- Legal and compliance advisory support
- Pharmacy system configuration and reporting tools

These costs provide no clinical, safety, or compliance benefit beyond enabling submission and reconciliation of rebate data required by the collection.

Estimated annual cost to LCHC: $23,250, excluding one-time implementation costs or future escalation.

LINCOLN COMMUNITY HEALTH CENTER, INC.
1301 Fayetteville Street • P.O. Box 52119
Durham, North Carolina 27717 – 2119

IV. Clinic-Administered Drugs (CADs)

A. Current CHC CAD Model (Baseline)

At Lincoln Community Health Center:

- CADs represent a limited volume of overall 340B purchases
- Drugs are bundled into prospective payment system billing and not routinely claim-billed to payers
- Administrative and inventory records are maintained through a combination of electronic logs, paper logs and narrative EHR documentation

LCHC's current practice is compliant, auditable, and cost-efficient.

B. New CAD Burden Under a Rebate Model

The rebate model would force CHCs to convert non-claim-based CAD records into rebate-eligible electronic submissions, requiring:

- Manual data conversion
- New software or eMAR modules
- Staff training and ongoing maintenance

LCHC-specific burden estimate:

- **$103,033 in staff cost** for CAD data conversion alone

Notably, this burden is **fixed rather than volume-responsive**; even CHCs with minimal CAD utilization would be required to build and maintain rebate-eligible data infrastructure solely to satisfy manufacturer and HRSA reporting expectations.

Because CAD data are not natively generated in claim-based formats, the resulting rebate submissions would necessarily rely on manual conversion, increasing transcription error risk and undermining the accuracy and reliability of the collected data.

LINCOLN COMMUNITY HEALTH CENTER, INC.
1301 Fayetteville Street • P.O. Box 52119
Durham, North Carolina 27717 – 2119

V. Financial Burden and Cash-Flow Risk

A. Loss of Upfront 340B Pricing

Under the rebate model, CHCs would be required to purchase drugs at **Wholesale Acquisition Cost (WAC)** and wait for rebate payment after providing mediation to our patients. We are extremely concerned that this process will create cash flow issues.

For LCHC, this translates into:

- **$7.9–$8.7 million** in additional upfront annual drug spend
- **Typically 40 or more days** between purchase and rebate receipt during which covered entities must continue to finance drug acquisition while simultaneously performing ongoing rebate submission, tracking, and dispute resolution activities required by the information collection.
- Exposure to manufacturer delays, denials, and disputes

PRA requires consideration not only of reporting costs but of foreseeable financial consequences of delayed reimbursement directly caused by the information-collection structure.

Even a conservative **5% rebate denial rate** would generate **>$416,000 in unrecoverable losses annually**.

B. CHC Financial Reality

As noted by NACHC and reflected locally:

- Nearly half of CHCs operate with fewer than 90 days cash on hand
- One in four report negative operating margins

The rebate model transforms 340B from a resource-stretching tool into a **financing liability**, forcing reductions in services, staffing, or medication access.

VI. Patient Access and Legal Compliance Concerns

A. Sliding-Fee Scale Requirements

Because rebate adjudication occurs retrospectively and outside the point-of-care workflow, CHCs cannot operationalize statutory sliding-fee requirements without advancing subsidized pricing before reimbursement—creating both compliance exposure and unrecoverable financial risk.

CHCs are legally required to provide medications using a sliding-fee scale **at the point of care**. A rebate model:

- Displays full WAC pricing at dispensing

- Prevents real-time application of required discounts
- Creates a material and unavoidable risk of non-compliance with statutory sliding-fee requirements

---

B. High-Risk Medications and Insulin Access

LCHC has significant concerns about the impact 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the rebate model manage chronic conditions prevalent in primary care settings.

LCHC patients rely on affordable access to:

- Insulin
- Direct oral anticoagulants (e.g., Eliquis®, Xarelto®)
- SGLT2 inhibitors (e.g., Jardiance®)

In the proposed model, the wholesaler price file would reflect the WAC rather than the discounted 340B price. This makes the price unattainable for patients and precluding LCHC from meeting legal obligation in **Executive Order 14273**, which ties Section 330 funding expectations to point-of-care insulin affordability.

VII. PRA Analysis – Failure to Meet Statutory Standards

Under the Paperwork Reduction Act, including the approval standards set forth in 44 U.S.C. § 3507(c), HRSA must ensure collections are necessary, non-duplicative, and minimally burdensome. For CHCs, the proposed rebate model:

- Is unnecessary given existing compliance safeguards
- Duplicates HRSA audit and reporting requirements
- Imposes disproportionate administrative and financial burden

Accordingly, the proposed ICR **does not satisfy PRA standards** as applied to Community Health Centers. Because the collection would rely on converted, disputed, and manufacturer-adjudicated data, OMB cannot reasonably certify that the resulting information would be accurate, reliable, or fit for its stated purpose, as required under the PRA.

VIII. Conclusion

Lincoln Community Health Center respectfully submits that the **true burden of the proposed 340B Rebate Model Pilot Program far exceeds HRSA's estimates** and would cause disproportionate harm to Community

LINCOLN COMMUNITY HEALTH CENTER, INC.
1301 Fayetteville Street • P.O. Box 52119
Durham, North Carolina 27717 – 2119

Health Centers and the patients we serve. By including CHC in rebate model, HRSA will create a process that is foreseeably inaccurate, incomplete, and legally vulnerable under the PRA.

OMB approval of this data collection for Community Health Centers would misalign with PRA's mission to minimize processes that are unnecessary, duplicative, and unduly burdensome.

Requested Action:

Exempt Community Health Centers from participation in the 340B Rebate Model Pilot Program.

We appreciate the opportunity to comment and welcome continued engagement with HRSA on solutions that preserve patient access while maintaining program integrity.

Sincerely,

Claretta Foye

Claretta Foye
Chief Executive Officer
Lincoln Community Health Center, Inc.

MCHP
MOUNTAIN COMMUNITY
HEALTH PARTNERSHIP

April 27, 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 Mountain Community Health Partnership (MCHP), 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, MCHP again requests that CHCs be exempted from the pilot program.**

The 340b Rebate Pilot Program will have substantial operational and financial consequences for our organization. Specifically, they will impact our 35,000 340B contract pharmacy transactions and 11,497 patients annually.

At present, MCHP incurs approximately $3.9 million in annual contract pharmacy administrative costs. Under a rebate pilot model, these expenses are expected to increase markedly, placing additional strain on already limited resources.

340B program savings currently comprise approximately 40% of MCHP's annual operating budget. These funds are essential to maintaining critical services for our community, including our community health worker program, clinical pharmacy services, and other high-impact initiatives that directly support vulnerable populations. Any reduction in these savings would jeopardize the sustainability of our organization and, in turn, the health outcomes of the patients who rely on us.

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 **11,497** 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**: MCHP 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, MCHP will face an increased administrative burden to monitor rebate claims and payments. 20-30 hours per week will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: MCHP anticipates an additional $100,000 - $200,000 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. $24,000 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 11,497 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $231,285.13 annually.

The In-House Pharmacy: The Burden of IT Integration

Compounding these challenges, the implementation of the rebate pilot coincides with the planned opening of MCHP's first entity-owned pharmacy. While this investment reflects our commitment to expanding access to care in a medically underserved area, the additional administrative and financial burden introduced by the pilot may significantly hinder our ability to achieve this goal. Rather than strengthening access, these changes risk constraining our capacity to serve those most in need.

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 34 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 34 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 Mitchell/Yancey County, rural 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]

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 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

MCHP 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. At MCHP, we provide access to our sliding fee and discounted medications to all our patients at or below 200% federal poverty limit.

Conclusion

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

MCHP 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 me and/or our pharmacy director Emily Owens emily.owens@mchp.care.

Sincerely,

Tim Evans, CEO
Mountain Community Health Partnership
Tim.evans@mchp.care

April 27, 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 Coastal Health & Wellness, 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, Coastal Health & Wellness again requests that CHCs be exempted from the pilot program.**

Coastal Health & Wellness is a Federally Qualified Community Health Center serving Galveston County, providing comprehensive primary care, pediatric services, dental care, women's health, behavioral health, chiropractic care, substance use disorder treatment, and on-site lab and X-ray services. In 2025, we cared for more than 10,000 patients over 35,000 qualifying visits. Texas has some of the most restrictive Medicaid eligibility requirements in the U.S., leaving large numbers of low-income adults without coverage. As a result, more than 71% of our patients are uninsured and rely on us as their primary source of affordable medical care, medications, and preventive services. Last year alone, we provided over $2.5 million in sliding-fee medication discounts to ensure patients could access the treatments they 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 10,140 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**: Coastal Health & Wellness anticipates needing **1** 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, Coastal Health & Wellness will face an increased administrative burden to monitor rebate claims and payments. We estimate 30 hours per week will be required to report 340B rebate claims to a third-party platform. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, CHC administrative burden would increase substantially.

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 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 11 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. Under the proposed rebate model in 2025, chain pharmacies were already announcing that the 10 drugs selected for the rebate

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

model would be excluded from their 340B programs. One of the chain pharmacies we are contracted with has still chosen to exclude the 10 selected drugs if the payer is Medicare. This highlights their unwillingness to take on additional administrative and compliance burdens. This is particularly worrisome at the independent contract pharmacy we have partnered with who have chosen to not yet exclude the 10 selected drugs. They have already reported an increase in administrative burden since having to monitor MFP rebates and reconcile denials. They are experiencing approximately 21% of their MFP rebates being incorrectly denied due to being identified as 340B.

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), 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

Coastal Health & Wellness 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

[2] Internal NACHC survey data

[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)

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 individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Coastal Health & Wellness offers sliding-scale discounts to patients who are at or below the 200% Federal Poverty Level on most prescription drugs to make them more affordable for low-income individuals. Since we do not have an in-house pharmacy, we are only able to extend this benefit to our patients at our local, independent contract pharmacy.

Conclusion

Coastal Health & Wellness 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

[5] HRSA FAQ

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

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

Coastal Health & Wellness 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 Lane Baker at lbaker@gchd.org.

Sincerely,

Lane Baker, MHA, COO
Coastal Health & Wellness

WVUMedicine

WVUMedicine.org

West Virginia University Health System
PO Box 8059
1085 Van Voorhis Road, Suite 500
Morgantown, WV 26505
Phone / 304-598-4200
Fax / 304-598-4124

Monday, April 27, 2026

Submitted to: ***paperwork@hrsa.gov***

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX

Dear Administrator Engels:

Thank you for the opportunity to provide comments on Health Resources and Services Administration's ("HRSA") Information Collection Request ("ICR") regarding the burden assumptions under the Paperwork Reduction Act (codified at 44 U.S.C. §§3501-3521), for the proposed 340B Rebate Model Pilot Program. West Virginia United Health System, Inc. d/b/a West Virginia University Health System ("WVUHS") is an academic hospital system, primarily located in the underserved state of West Virginia. WVUHS consists of 9 Disproportionate Share Hospitals, 9 Critical Access Hospitals, 1 Rural Referral Center and 1 Sole Community Hospital. Each of these hospitals participate in the 340B Program. WVUHS is submitting comments on behalf of the 340B hospitals identified in the attached table.

The 340B Program plays a vital role in enabling safety-net providers like WVUHS to stretch scarce federal resources and expand services for vulnerable patients that we serve. West Virginia is one of the most economically disadvantaged states in the country, with a poverty rate of 16.7% in 2024. This statistic ranks West Virginia with the 4th highest poverty rate in the nation[1]. As a direct result, WVUHS provides vital care to a large population of rural, low-income patients. Compounding the poverty issue, the population WVUHS serves is one of the unhealthiest populations in the country and ranks highest in the nation in several health indicators. These indicators include diabetes, drug addiction, obesity, and cancer. Without the savings acquired from 340B, several of WVUHS's hospitals could be forced to reduce services. This creates logistical challenges for the most impoverished citizens of West Virginia, and the surrounding states we serve.

[1] wv poverty percentage 2024 - Census Bureau Search

WVUHS adamantly opposes any transition to a rebate-based model and strongly urges HRSA to maintain the upfront discount structure that has governed 340B for more than 30 years. WVUHS has relied on receiving 340B pricing through point-of-sale discounts. Changes to this structure will significantly impact our hospitals that already operate on thin margins and undermine the essence of the 340B Drug Pricing Program: to help safety-net healthcare providers stretch scarce federal resources as far as possible, reaching more patients, and offering more comprehensive services.

A rebate model poses significant threats to Covered Entities by increasing financial costs, adding complex administrative burdens, and requiring additional resources to manage. A rebate model would erode the benefit that should remain with the very providers that Congress intended to benefit from 340B. HRSA's assumption that a rebate model's burden on the covered entities "may not be significant," is fundamentally incorrect and not supported by operational realities.

Therefore, on behalf of its 19 hospitals participating in the 340B Program, WVUHS urges HRSA to abandon the Rebate Pilot Program for the following reasons:

I. Financial Burden

a. Cash Flow Concerns

Under HRSA's new Rebate Pilot Program policy, covered entities would purchase medications at significantly higher Wholesale Acquisition Cost ("WAC") rather than the up-front discount. Covered entities would be forced to wait an unknown period to receive the post-purchase rebate calculated by the difference between the WAC price and the 340B price. The proposed timeline of ten days to receive a rebate is not practical and will be much longer. Even if a rebate were paid, a rebate structure unfairly shifts operational and financial risk to the covered entity. In the meantime, a rebate model will float revenue in the form of interest-free loans to manufacturers while tying up critical resources that could otherwise be used by covered entities to support patient care. ***Over the course of a year, we estimate the total annual additional cost of purchasing the 25 Rebate Drugs at WAC for WVUHS covered entities would be approximately $62 million dollars.***

WVUHS is also very concerned that prompt pay discounts from manufacturers will be eroded. Manufacturers are stating that hospitals have 30 days to pay wholesaler invoices, when in fact WVUHS pays invoices twice monthly. Our hospitals receive a prompt pay discount from wholesalers based on the payment schedule. Even if we receive a rebate within ten days of submission to manufacturers, we would not be able to maintain the prompt pay discounts due to the rebate model, thereby even further reducing our cash flow. **Over the course of one year, we estimate our hospitals will be forced to forgo annual pre-pay discounts of $3.2 million dollars.**

b. Additional Expenses

We anticipate that the Rebate Pilot Program will result in **added annual costs to our organization of $3 million dollars,** including $2,312,000 for costs of complying with the model and $600,000 for dispute resolution processes. These additional costs are ongoing and substantial.

1. **Salary Expense:** WVUHS staffing, operations and program administration was designed with the current process of an upfront discount. A shift to a rebate model will require additional staff

to operate complexities of the Rebate Pilot Program. We estimate **that the salary expense needed to successfully manage the program will surpass $1,360,000.** This will create additional loss to the scarce funds covered entities could use to provide services and patient care.

- Due to the current manufacturer limitations of the 340B prices and requirement of 340B data submission as a condition of receiving 340B prices, WVUHS has been forced to add a team consisting of one 340B Manager and four full time pharmacy analysts to compile data, submit data, make designations, validate pricing, third party administrator ("TPA") review and engage with ESP, manufacturers and wholesalers when pricing is erroneously taken away. **The current team has added annual salary expense of over $740,546.**
- With implementation of the rebate model, another team of six full time pharmacy analysts will be required for the full process of data extraction, validation, formatting, transmission, and internal sign-off. This team will also be tasked with the back-end work that follows data submission. Tracking rebate payments by manufacturers, matching payments back to submitted claims, reconciling, resolving good faith inquiries, reconciliation of payments, and maintaining the audit trail can easily exceed the submission work itself. Hospital 340B programs have never been required to complete such tasks. **This will add an approximate additional salary expense of $621,549.**

2. **Advisory Fees**: Expenses for professional consultants and legal fees required to support review and navigation of rebate platforms and their terms of use as well as challenges with rebate denials will significantly increase. We estimate **that professional consultant fees will increase by 100% and attorney fees will increase by 50%.**
3. **Technology Fees:** Traditional TPAs were not built to support rebate models. Additional new expenditure on technology platforms and vendors will be necessary to support operations. A fully operational platform to assist with the current MTF process is still being developed. **Current vendors in the field are estimating costs of $300,000 per year.**

II. Data Submission Burden

The Rebate Pilot Program will require submission of claims detail to manufacturers including both retail-dispensed drugs and physician-administered drugs used in the hospital and outpatient clinic settings. HRSA's assertion that data submission will require minimal effort because we are already providing data to TPAs and will require only five hours per week of additional work is incorrect and grossly understates the new burdens.

a. **Administrative:** The process of claims processing from end-to-end is complex, and errors can occur at any step. To extract data for submission requires collaboration between TPAs, rebate-specific vendor platforms, purchasing platforms and pharmacy analysts to ensure accuracy, compliance, and completeness of 340B program data submissions. This collaboration also includes ongoing updates related to manufacturer-specific requirements tailored to each manufacturer. The rebate model will introduce the added responsibility of tracking rebate payments by manufacturers, matching payments back to submitted claims, reconciling, resolving good faith inquiries, reconciliation of payments, and maintaining the audit trail, which can easily exceed the submission work itself. Based on time that it takes for 340B ESP submissions and affiliated processes, we estimate that the entire end-to-end process could take

at least 15 hours per week per Covered Entity. **WVUHS would need to hire 7 additional FTEs.**

Additionally, submission of administration and claims detail could occur via multiple platforms as the manufacturers are each able to choose a method of data gathering. This will increase and complicate the operational burden of submissions as formatting and requirements may differ. Multiple platforms will create operational inefficiencies for the covered entities to comply with the already burdensome process.

b. **Accuracy and denials** Our experience with manufacturer data submission platforms (e.g., 340B ESP) has been marked by significant and costly challenges, including frequent errors, data inconsistencies, and unclear requirements, with access to 340B pricing often delayed or denied despite compliance with the manufacturers' policies. We often experience erroneous manufacturer denials. We must dedicate staff just to address these issues. Expanding a rebate model across all hospital settings, not just contract pharmacies, will substantially increase both administrative and financial risk.

c. **Physician-administered medications:** Significant challenges will be encountered for claims submission of physician-administered medications.

   i. Data that would be needed for physician-administered medications may not be readily accessible and retrievable. To gather the data required, one may need to access several different platforms. For example, for medical claim submissions manufacturers will have the option to require Plan ID, HCPCS Code and HCPCS modifiers submitted at the unit level, information not available in the TPAs. If WVUHS is not prepared to submit rebate requests for physician-administered medications all drugs included in the Rebate Pilot Program would be purchased at WAC. **The cost of buying these medications at WAC would amount to an additional annual expense of $5.6 million dollars.**

   ii. Significant delays in rebate processing are inevitable under this model. Typical hospital billing processes do not allow for immediate claims submission, as bills are submitted to payors only after patient discharge. As a result, covered entities would be required to purchase medications at WAC and then wait—potentially days, weeks, or even months—before submitting claims data to manufacturers to initiate rebate requests. Hospitals are not currently structured or required to submit data in this manner, making this a substantial operational shift.

   iii. HRSA asserts that comparable data is already submitted to the TPAs This assertion is incorrect. Many of the data fields required for submission are not submitted to the TPA. For example, medications that are administered in a "clean site" where all patients are outpatients and all are 340B eligible are not submitted to the TPAs. Reimbursement information is not submitted or managed by the TPA and will require separate platforms.

d. **Technology Burden:** As noted above, TPAs are not equipped or designed to fully automate a rebate model. Additional platforms will be needed to successfully manage not only submission but also denials, good faith inquiries, and reconciliation. These platforms are still in development and not fully operationalized. This will come at an additional expense further eroding the 340B benefit.

In closing, the 340B Program is a lifeline for the patients and communities we serve. The Rebate Pilot Program structure risks shifting financial and operational burdens onto covered entities, threatening our ability to provide affordable medications and essential services. We therefore urge HRSA to abandon the Rebate Pilot Program.

We appreciate HRSA's commitment to stakeholder engagement and respectfully request that these comments be taken into consideration.

Sincerely,

Albert L. Wright, Jr.
President and Chief Executive Officer
West Virginia United Health System, Inc.

WVUHS Covered Entities

WVUHS Covered Entity	Covered Entity Type	340B ID
City Hospital, Inc. dba Berkeley Medical Center	Disproportionate Share Hospital	DSH510008
Camden-Clark Memorial Hospital dba Camden Clark Medical Center	Disproportionate Share Hospital	DSH510058
Princeton Community Hospital	Disproportionate Share Hospital	DSH510046
Reynolds Memorial Hospital	Disproportionate Share Hospital	DSH510013
Thomas Memorial Hospital	Disproportionate Share Hospital	DSH510029
Uniontown Hospital	Disproportionate Share Hospital	DSH390041
United Hospital Center	Disproportionate Share Hospital	DSH510006
West Virginia University Hospitals	Disproportionate Share Hospital	DSH510001
Wheeling Hospital	Disproportionate Share Hospital	RRC510050
Barnesville Hospital	Critical Access Hospital	CAH361321
Braxton County Memorial Hospital	Critical Access Hospital	CAH511308
Community Health Associates dba Jackson General Hospital	Critical Access Hospital	CAH511320
Grant Memorial Hospital	Critical Access Hospital	CAH511316
Harrison Community Hospital	Critical Access Hospital	CAH361311
Jefferson Medical Center	Critical Access Hospital	CAH511319
Potomac Valley Hospital	Critical Access Hospital	CAH511315
St. Joseph's Hospital	Critical Access Hospital	CAH511321
West Virginia Health Care Cooperative, Inc. dba Summersville Regional Medical Center	Critical Access Hospital	CAH511322
GRMC, Inc. dba Garrett Regional Medical Center	Sole Community Hospital	SCH210017

CENTERVILLE CLINICS
Total Health Care for the Entire Community

1070 Old National Pike
Fredericktown PA 15333

April 27, 2026

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

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

Dear Director Britton:

On behalf of Centerville Clinics 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, Centerville Clinics Inc. again requests that CHCs be exempted from the pilot program.**

For patients of Centerville Clinics, transportation remains a critical barrier to healthcare accessibility across Greene, Fayette, and Washington counties. The regions rugged, rural geography lacks a cohesive public transit infrastructure, leaving a high volume of low-income residents-nearly 88% of whom live below 200% of the federal poverty level without reliable ways to reach appointments. Without consistent non-emergency medical transportation, these residents face a cycle of missed screenings and delayed treatments, directly fueling the region's high rate of chronic disease and lower life expectancy compared to the rest of Pennsylvania. The poverty rate for these rural counties averages 5% higher than the State and the Federal poverty rates. Fayette and Greene Counties are two of the least healthy, least wealthy counties in Pennsylvania. For these reasons, we have opened office sites in the small towns where the patients reside.

Since our FQHC Federal grant and our Medicare and Medicaid cost reimbursements have not increased at the same rate as our expenses, it is difficult to balance our operating budget. Additionally, to meet our patients' needs, we have opened office sites without receiving any additional Federal Funds. Since we have been operating for over 70 years, some of our offices need either renovation or replacement. For these reasons, we have used our 340B program income to balance our operating budget, establish new sites, and renovate or replace our existing offices. . We have been successful in receiving grants to subsidize some of the costs for purchasing facilities and or renovating our older facilities, however these grants did not cover all of our costs.

Our 340B program has given us the ability to provide a pharmacy sliding fee to those patients who are eligible. We recently opened our second in-house pharmacy, and we expect our sliding fee adjustment to reach over 1 million dollars.

The additional expense and the loss of receipts due to the rebate program implementation will force us to reduce the amount of sliding fee assistance that we now are able to offer our patients. Centerville is concerned that many of these patients with limited incomes will not be able to pay for their medication. This will mean that this will have a negative effect on their health. We will also be forced to eliminate or curtail our services such as food banks and diaper distribution to the poor, medical care for City Mission, and community health workers. We will also be forced to consider closing some of our sites that depend on the 340B program.

Centerville Clinics appreciates that the Federal grant and the 340B program has enabled us to provide services to the low income, who depend upon us for their medical, specialist, behavioral health, dental, and pharmacy services This is the reason for the last two months, the pharmacist manager, the manager of the 340B program, and our senior accountant have spent most of their time addressing this issue.

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 **31,584** 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

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

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**: Centerville Clinics Inc. anticipates needing 2.99 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, Centerville Clinics Inc. will face an increased administrative burden to monitor rebate claims and payments. Ten to Fifteen hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Centerville Clinics Inc. anticipates an additional $100,000 in additional costs related to the rebate model 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. A $50,000 one-time cost 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 approximately $40,000 annually to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 31,584 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $372,206 annually.

The In-House Pharmacy: The Burden of IT Integration

Centerville Clinics Inc. 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. Our current system does not have the ability to handle15003 the new rebate infrastructure; therefore, we have projected the cost for upgraded systems.

- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. Our estimate is that our costs will be between $60,000-$75,000 for integration costs.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend ten 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 thirty-nine 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 thirty-nine 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 Greene, Fayette, and Washington Counties, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3]

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

Centerville Clinics 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

[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

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.

Centerville has a board approved pharmacy assistance plan (Sliding Fee) that will assist patients in receiving their medications without creating a barrier to care.

---

[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

Pursuant to Centerville Clinic's sliding fee policy, Centerville assesses and at annual intervals, reassesses patient's income and family size for eligibility for the Sliding Fee program.

Whan a patient qualifies for the sliding fee discount program; Centerville Clinic pharmacies will charge the patient in accordant to the structure. The sliding Fee program is established annually based on the Federal Poverty Levels.

Conclusion

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

Centerville Clinics 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 Barry Niccolai, CEO at bniccolai@centervilleclinics.com.

Sincerely,

Barry Niccolai, CEO
Centerville Clinics Inc.

525 Clinton Street
Bow, NH 03304
Voice: 603-228-2830
Fax: 603-228-2464

BI-STATE PRIMARY CARE ASSOCIATION
1986 40th Anniversary 2026
Celebrating 40 Years
SERVING VERMONT & NEW HAMPSHIRE
Improving Access to Primary Health Care Since 1986
www.bistatepca.org

61 Elm Street
Montpelier, VT 05602
Voice: 802-229-0002
Fax: 802-223-2336

April 27, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 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 New Hampshire's and Vermont's Community Health Centers (also known as FQHCs) and the 300,000 medically-underserved patients they care for each year, we thank you for 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 FQHCs, Bi-State requests that FQHCs be exempted from the pilot program.

Established in 1986, Bi-State Primary Care Association (Bi-State) is a nonpartisan, nonprofit 501(c)(3) charitable organization promoting access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 21 Federally Qualified Health Centers, one Look-Alike, Planned Parenthood of Northern New England, Vermont's Free and Referral Clinics, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in New Hampshire.

The 340B program is foundational to FQHC's ability to serve the most vulnerable members of our community. The proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize FQHC 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 FQHCs from the 340B Rebate Model Pilot Program Due to Significant Financial and Administrative Burden

By requiring FQHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our FQHCs' ability to serve the over 300,000 patients who rely on us. Our health centers operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, FQHCs 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.

FQHCs 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: Our health centers have indicated that they need .5 to 2 FTE to account for the increase in operational, administrative, and compliance burden created by a rebate model. These would be ongoing costs.
- Number of Hours: Depending on the volume of prescriptions a pharmacy fills for just the 10 selected drugs, our health centers estimate that dozens of hours will be required each month to report 340B rebate claims to a third-party platform.
- External Vendor Costs: Our health centers also anticipate additional cost for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services. This would be a combination of initial, one-time and ongoing costs. Notably, if manufacturers are using multiple platforms, the cost will also multiply.

The In-House Pharmacy: The Burden of IT Integration

Several of our health centers have 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.
- Ongoing Resource Diversion: Staff who currently manage clinical pharmacy services will be forced to spend 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

All of our health centers utilize contract pharmacies to support access to needed medication for their patients. The rebate model introduces a new complexity that threatens the existence of contractual arrangements. Our health centers generally partner with dozens across their service area.

- TPA Reliance and Fees: Navigating manufacturers’ varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that TPAs will pass on the costs of developing rebate-tracking modules to our health centers through increased per-claim fees.
- Verification Latency: The rebate model creates a reconciliation gap. Our staff must monitor claims across dozens of 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. Our states have already experienced pharmacy closures with more anticipated[1].

II. Patient Impact

Bi-State 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. Our FQHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly

[1] https://www.unionleader.com/news/business/rite-aid-releases-latest-list-of-store-closings-including-6-more-in-nh/article_d43db9f9-8ccb-4d16-b29c-835b87b5d0c6.html

higher prevalence of illnesses like diabetes, hypertension, and obesity.[2] This patient population relies on affordable medications to manage these long-term conditions.

III. Financial Challenges

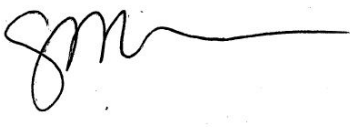
Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact FQHCs and trickle down to patients. Our FQHCs are financially fragile, and this rebate model exacerbates that. Under the proposed model, FQHCs would be required to purchase drugs at the WAC. FQHCs 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 FQHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.

Conclusion

Bi-State strongly urges HRSA to exempt FQHCs 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 our health centers to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, FQHCs 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. Bi-State believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Bi-State 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 me at gmaheras@bistatepca.org.

Sincerely,



Georgia J. Maheras, Esq.
SVP, Policy and Strategy
Bi-State Primary Care Association

[2] 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.

HARRISHEALTH

4800 Fournace Place, Suite 600E, Bellaire, Texas 77401-2324

Electronically submitted via paperwork@hrsa.gov

April 27, 2026

The Honorable Thomas J. Engels, Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Rockville, MD 20852

RE: Information Collection Request (ICR): **340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW (91 FR 9632)**

Dear Administrator Engels:

On behalf of Harris Health of Houston, we appreciate the opportunity to comment on the Health Resources and Services Administration (HRSA) and Department of Health and Human Services (HHS) "Information Collection Request (ICR): 340B Rebate Model Pilot Program".

Harris Health is a fully integrated healthcare system providing care to all residents of Harris County, Texas regardless of their ability to pay. Harris Health was the first accredited healthcare institution in Harris County designated as a Medical Home and today is still one of the largest in the country with this designation. Harris Health includes 18 community health centers, eight homeless shelter clinics, five same-day clinics, three multi-specialty clinic locations, a dental center, a dialysis center, mobile health units and two full-service hospitals – Ben Taub Hospital and Lyndon B. Johnson Hospital. ***In Fiscal 2025, Harris Health provided $805M in uncompensated care costs. The 340B Program supported us by providing upfront discounts for pharmaceuticals valued at approximately $275M, and we filled 1.95M outpatient prescriptions through our inhouse outpatient pharmacies.*** These numbers illustrate the outsized role that Harris Health has in our Houston community, and how important the 340B Program is in allowing us to fill that role. The 340B Program is essential to Harris Health's financial stability and our ability to deliver charity care, affordable drug access and comprehensive safety-net services. Because of our payer mix and role as a super safety-net provider, Harris Health is uniquely exposed to financial, operational, and patient-access harms associated with a rebate-based model.

As explained in our RFI response letter dated April 20, 2026, any rebate mechanism will impose enormous costs and burdens on Harris Health that far outweigh any benefits that might come from it, thus, we continue to oppose the imposition of any rebate model in the 340B Drug Pricing Program. In our opinion, HRSA's objective to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In fact, HRSA must give primacy to the needs of Covered Entities so that they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services". Preserving the upfront discount mechanism, which Harris Health has relied on since the inception of the 340B Program, is the best way to fulfill that purpose. We continue to believe that manufacturers are using the implementation of the Inflation Reduction Act (IRA) negotiated drug pricing framework as an improper justification for seeking a rebate model in the 340B Program. Structuring both the 340B Program and the IRA negotiated pricing programs as upfront discounts would make them more efficient, more consistent with congressional intent and most certainly less prone to manufacturers abuse.

For this ICR, HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Our responses follow.

1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions:

Data Collection by Covered Entities. During the prior iteration of the Rebate Program, both HRSA and the drug companies stated that a rebate mechanism would not impose new data-related burdens on 340B hospitals like ours. For example, both insisted that hospitals already provide the required information through 340B ESP. ***That is incorrect for those Covered Entities who only use inhouse pharmacies, such as Harris Health.***

- Currently, Harris Health collects, maintains, retains, and validates/audits data related to 340B Program participation. This continuous and ongoing work is done internally, is periodically reviewed by our Compliance team, and includes a robust cross-functional Governance Team for oversight. Prior to the notice of a Rebate Model Pilot in late 2025, Harris Health was not running claims reports in the Rebate Pilot format, nor were we submitting all of this data to our wholesaler and all that that entails. It is only recently that Harris Health began submitting claims data in the Rebate Pilot format to ESP for both Eli Lilly and Novo Nordisk, and most recently, AstraZeneca has been added to the list. Prior to February 1, 2026, the individual manufacturer claims filing requirements were for those Covered Entities that were using Contract Pharmacies. Again, Harris Health does not use Contract Pharmacies.
- A potential 340B Rebate Model Pilot Program would absolutely change current data collection activities, adding a whole new subset of work required to accomplish the pilot claims data filing requirements, including ongoing reconciliations and manual review of individual denials.
- HRSA has said in its Information Collection Request: "OPA expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. **Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant**." Unfortunately, this is not accurate, and our preliminary estimates of additional time and money are significant.

Our recent experience with individual manufacturer data platforms (e.g., ESP) has been rife with costly and time-consuming challenges, such as addressing errors with no ability to download a list of claims considered to be non-conforming, inconsistencies and vague or unclear error messages, and insufficient information at the claim level for denials, all of which adds a great deal of manual back tracking to find the claims in question. Access to 340B pricing is at risk, without a clear explanation of when and how this might occur, and what might the path be to rectify the situation, if this were to occur. We must dedicate staff to address these issues and respond to each non-conforming claim, or risk the loss of the 340B discount. This means our already tight resources are being realigned to deal with all of these new requirements. In our opinion, the manufacturers are being allowed to run their own version of the Rebate Pilot Program, though there is no rebate involved, only the possibility of losing access to the 340B upfront discount. **If this is any indication of how a Rebate Pilot would unfold, it is concerning as to the breadth of resources we will need to expend to manage the new processes, workflows, reconciliations and denial management.**

2) The accuracy of the estimated burden:

Administrative Costs under a Potential 340B Rebate Program. Any rebate program would require Harris Health to spend significant sums on new administrative costs. When we chose to participate in the 340B Program, Harris Health understood that we would incur some reasonable administrative costs. We designed our hiring, operations and program administration around an upfront discount model. A shift to a new kind of discount mechanism demands new resources, imposing considerable additional costs and burdens on our institution that go far above and beyond what we had expected and planned for as a 340B hospital—and far above and beyond

what we are experiencing now. In effect, adding a Rebate model pilot basically adds a completely new set of work that must now be done, at the same time as maintaining the current workload required to manage the existing 340B Program. This is not an insignificant addition of work to an already overly taxed staff, especially given the fact that the additional work will not result in any tangible improvement to the Program as a whole.

Staffing Impacts Under a Potential 340B Rebate Program. Harris Health does not currently have the staff needed to comply with a Rebate Program. We estimate a need to hire at minimum, two additional staff in order to manage the submission of claims data, reconciliations of denials and rebates, and working through the individual denials to determine what is necessary to turn the denied claim into an allowed claim. Our current staff would also be required to reallocate some of their work hours to assist in the rebate pilot work. This estimate is based upon the 25 drugs chosen for the Rebate Pilot Program, but due to the manual nature of reviewing denials and gathering the necessary information to submit and hopefully overturn said denials, and all of the manual reconciliations that will need to occur to ensure we are submitting 100% of the claims data and receiving 100% of the expected rebate monies, we fully expect that number to increase, and for current staff, continued and further realignment of their job duties will occur.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Program. Harris Health has designed its technological systems and operational infrastructure in reliance on an upfront discount model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems. We have already been spending significant IT and other resources in an effort to write reports and work flows to comply with not only the Rebate Pilot requirements, **but also the individual manufacturer newly required claims data submissions, in order to maintain access to the 340B discounts (Elli Lilly, Novo Nordisk, Exelixis, AstraZeneca).** At this time, we continue to analyze whether we should bring in an outside firm to assist with the new requirements. It may be necessary at some point, if we determine the burden to be too much to manage with internal resources, and we worry about the high costs associated with bringing in consultants to help.

Payment Timing and Potential Cash Flow Impacts. Unlike the existing upfront discount mechanism, any rebate mechanism will force Harris Health to effectively provide drug companies interest-free loans as we await the discounts that we are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our institution and the patients we serve. Harris Health is a public hospital funded in part by the County with ad valorem taxes. The taxes are remitted to our bank account at the beginning of the calendar year, and we use those funds throughout the year to pay our bills. As the year goes on, there is no replenishment of these ad valorem monies, and so there could be instances where our cash flow is impacted in such a way as to put us at risk of lower liquidity and possible violation of our bond covenants.

In the past, HRSA has noted the position of drug companies is that "the rebate in most instances will be paid before the purchase invoice from a wholesaler for the WAC amount is due." This may or may not be true, and assumes no delay due to denial of claims, which is a highly unlikely scenario. Harris Health currently operates under net fifteen (15) day payment terms with its wholesale drug supplier. This is longer than the HRSA 10-day requirement, however we fully expect rebate delays of at minimum 30 to 60 days—and this would create immediate financial strain. Such delays could force Harris Health to:

- Draw down limited operating reserves,
- Access external credit, or
- Delay or restrict inventory purchases.

Given the volume and acuity of medications required to serve our patient population, extended rebate float is not operationally sustainable. ***A potential 340B Rebate Model Pilot Program could require that all rebates be paid to the Covered Entity immediately upon submission of claims. That is the only way to avoid allowing the manufacturers free use of our upfront paid monies.***

Adverse Impacts of these Additional Costs and Burdens. All of these many different costs and burdens add up to significant dollars. Unfortunately, this means that Harris Health will no longer be able to use our 340B savings as effectively and comprehensively as we did under an upfront discount model. As a result, our patients and community will suffer in concrete ways. This uncertainty will impact our budget and planning processes, and could result in a direct impact to our patients if we had to delay or stop providing certain services. Currently, Harris Health provides low or no cost pharmaceuticals to our Financial Assistance qualified uninsured patients based upon our cost using 340B discounted prices; and this might need to be re-evaluated if a Rebate Pilot results in significant denials or slow paying of rebates. This would be monumentally harmful to our patient population, which is more than 43% uninsured.

3) Ways to enhance the quality, utility, and clarity of the information to be collected and 4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden:

Reform: We encourage HRSA to consider reforming the 340B Program, instead of instituting a Rebate Pilot Program. We believe time would be well spent to carefully study exactly what kinds of information would be useful and who would have access to what data. This could be done within the scope of reform, and done really well using our clearinghouse approach. Some suggested reforms are:

1. A National Clearinghouse,
2. a complete redesign of the Child Site requirements using the CMS 855 records,
3. an improved, clearer patient definition,
4. and transparent annual reporting by both Covered Entities and manufacturers.

We believe with these and possibly other robust reforms, the 340B Program would be more transparent and both Covered Entities and manufacturers would be assured of accurate discounts being provided, with even more protections in place to eliminate the possibility duplicate discounts. The National Clearinghouse option would also remove the need for manufacturer-imposed claims data requirements (e.g., the recent Eli Lilly, Novo Nordisk and AstraZeneca policies that attempt to unilaterally impose extra-statutory program requirements). As you may be aware, the Front Line Hospital Alliance (of which we are a member), has proposed a super safety net designation, and this could help protect hospitals like ours from the devastating impacts discussed in this letter.

Closing Comments: Although we appreciate HRSA's efforts to collect detailed feedback on a rebate model, **HRSA must consider alternatives**. From its inception, the 340B Program has operated using an upfront discount approach. Covered Entities have relied on that program design for almost 40 years, setting up care models around it that have greatly expanded patient access to care services. Although the Rebate Pilot model was not premised on addressing duplicate discounts, this is a chief manufacturer complaint and almost certainly underpins the manufacturer push for a rebate model. However, Covered Entities do not have a program integrity problem — ample safeguards already exist to address duplicate discounts, including OPAIS option to "opt in" for Medicaid, billing modifiers, HRSA and manufacturer audits, including the good faith effort work being done today through cooperation with both manufacturers and Covered Entities.

For all of the above stated reasons, Harris Health again respectfully submits that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse, and other suggested reforms.

4800 Fournace Place, Suite 600E, Bellaire, Texas 77401-2324

We appreciate your consideration of these comments and look forward to working with HRSA on this important issue, which has profound implications for the millions of patients who rely on the 340B Program. ***In addition, we are in full support of the comments submitted by the Front Line Hospital Alliance (of which we are a member), including their proposal for a super safety net designation, which could help protect hospitals like ours from the devastating impacts discussed above. We are particularly interested in being a reliable partner in the Reform of the 340B Program, helping to make it stronger and effective for many years to come.*** Please contact me if you have questions.

Sincerely,

Esmaeil Porsa, M.D.
President and C.E.O.
Harris Health, Houston, Texas

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

April 27, 2026

Thomas J. Engels
Administrator
Health Resources and Services Administration 5600 Fishers Lane
Rockville, MD 20857

RE: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX
Published Document: 2026-03833 (91 FR 9632)

Submitted to *paperwork@hrsa.gov*

Dear Administrator Engels:

The Allegheny Health Network (AHN), which has three covered entities within our health system (West Penn Hospital, Saint Vincent Hospital and Positive Health Clinic), appreciates this additional opportunity to provide comments to the Health Resources and Services Administration (HRSA) regarding the proposed information collection for the 340B Rebate Model Pilot Program.

As a nonprofit health network, we aim to extend our reach to as many people as possible to offer them a broad spectrum of care and services. We have 14 hospitals and more than 200 primary-and specialty-care practices in more than 300 clinical locations and offices. In addition, AHN has approximately 2,600 physicians in every clinical specialty, 23,000 employees, and thousands of volunteers. AHN's service area spans western Pennsylvania and portions of New York, Ohio and West Virginia where we provide world-class medicine to patients in our communities.

These comments supplement the detailed Request for Information (RFI) submission we provided on April 20, 2026 (HHS Docket No. HRSA-2026-03042), and further underscore our grave concerns regarding the necessity, practicality, and the significant underestimation of burden inherent in the proposed rebate model.

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

AHN is a nonprofit health network dedicated to extending our reach to as many people as possible, providing comprehensive care across western Pennsylvania and parts of New York, Ohio, and West Virginia. The 340B Program is critical to our ability to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Our comments are structured to address the specific areas outlined by HRSA in its information collection request, drawing upon the detailed analysis presented in our RFI:

1. The Necessity of this Proposed Information Collection for 340B Rebate Submissions

Comment: AHN firmly asserts that **the proposed 340B Rebate Model is not necessary** to achieve the stated goal of preventing duplicate discounts. As detailed in our RFI submission, AHN, like many Covered Entities (CEs), already employs robust and effective mechanisms to prevent duplicate discounts.

- **Existing Safeguards:** Our internal processes, comprehensive TPA systems, and adherence to industry best practices, coupled with the use of the Medicaid Exclusion File, are designed to identify and prevent 340B/Medicaid duplicate discounts. We have a proven track record of effectively managing compliance without issues being raised by manufacturers.
- **Proven Effectiveness:** Our experience, as highlighted in our RFI, demonstrates that effective deduplication can be achieved without a burdensome rebate model. Since January 1, 2026, we have not encountered significant challenges in identifying potential duplicate discounts through our robust internal processes and TPA systems.
- **Statutory Intent:** The current upfront discount model aligns with the statutory intent of the 340B Program, providing immediate financial relief that directly supports patient care. A rebate model fundamentally shifts this benefit, making it a post-purchase payment that is both uncertain and delayed. The extensive information collection proposed is thus an overreach, attempting to solve a problem that is not widespread and can be managed through less disruptive means.

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

2. The Accuracy of the Estimated "Burden" (Time and Resources) Involved for Respondents, as Detailed in the Burden Table (e.g., Plan Submission, Monthly Purchase Reports, Claims Data Reporting)

- **Comment:** HRSA's estimated "burden" for this information collection is grossly underestimated and does not accurately reflect the tremendous financial and administrative burdens this rebate model would impose on covered entities and manufacturers. This severe underestimation was a central theme of our RFI response and we urge HRSA to reconsider its calculations based on real-world operational realities.
- **Gross Underestimation:** HRSA's estimate of 5 hours per response for Covered Entities reporting claims data is woefully inadequate. As articulated in our RFI (pages 2-7), a rebate model would introduce prohibitive new administrative, staffing, and IT costs that would significantly erode 340B savings and jeopardize patient care. Our detailed analysis projects:
    - **One-Time Startup Costs:** A total of **620 - 1,240 hours** (15.5 to 31 full-time weeks) for initial setup, including legal review, IT build-out, operational workflow changes, training, and analytics.
    - **Specialized Software Implementation:** Estimated **one-time costs of $1.2M - $1.5M+** for specialized 340B software implementation and IT system development.
    - **Ongoing Staffing Costs:** An estimated **120 - 160 hours per week** (representing 3 to 4 full-time equivalent employees) would be required for ongoing program management, totaling **$390,000 - $625,000 annually** in new staff salaries. These positions would be permanent due to the continuous and complex nature of the work.
    - **Additional Costs:** An estimated **$500K – $900K** for other significant one-time and recurring costs for legal review, staff training, and consulting services.
- **Fundamental Misunderstanding of Scope:** As detailed on page 4 of our RFI, HRSA's estimate of 5 hours per week is a gross underestimate because it fundamentally misunderstands the comprehensive scope of new activities

Allegheny Health Network

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

required. It narrowly focuses on data submission, neglecting critical upstream and downstream activities such as:

  - Extensive legal review and data governance.
  - Complex IT build-out and integration with disparate internal systems (claims, pharmacy, EHR, purchasing).
  - Entirely new operational workflows for claims processing, data submission, reconciliation, audit support, denial tracking, appeals management, and manufacturer portal logins.
  - Complex accrual calculations and labor-intensive reconciliation and denial management.
  - Program tracking and analytics.

- **Financial Liquidity Threat:** The shift to a rebate model would critically disrupt AHN's cash flow (pages 6-7 of our RFI), forcing us to provide significant "interest-free loans" to drug manufacturers. Our estimated cash flow float of approximately $10M+ would reduce liquidity, increase borrowing costs, and risk violating bond covenants, undermining financial stability and strategic investments crucial for patient care.
- **Impact on Patient Services:** These incremental costs are not merely administrative nuisances but represent a significant drain on resources, directly compromising AHN's capacity to serve patients and the community. This will inevitably lead to cuts in vital patient services, community health programs, infrastructure improvements, and direct financial assistance to patients, as elaborated on pages 3 and 6 of our RFI.

3. Ways to Enhance the Quality, Utility, and Clarity of the Information to Be Collected

- **Comment:** Given our strong position that the rebate model is not necessary, our primary recommendation is to abandon this concept entirely. If, however, HRSA insists on pursuing an information collection to address duplicate discounts, then the focus must be on maximizing clarity, standardization, and minimizing burden.

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

- **Unified and Neutral Platform:** As highlighted in our RFI (page 8), to truly enhance quality, utility, and clarity, HRSA must mandate one central, neutral platform, one consistent data format, one universal set of terms of use, and one clear privacy statement that can be agreed upon by all covered entities. This is essential to avoid the chaos and burden of engaging with multiple manufacturer portals, each with varying requirements. Data must reside on a neutral platform, independent of any manufacturer, to protect sensitive CE data from unauthorized reuse or resale.
- **Data Minimization and Standardization:** HRSA should adopt a minimalist approach, collecting only the minimum necessary data, de-identified to the greatest extent possible, as advocated in our RFI (page 9). Specific data elements, such as detailed invoice numbers for every claim, are not readily available in a single, integrated source and impose undue burden, effectively negating the function of existing split-billing software. Clear, explicit definitions for all required data elements are crucial to prevent misinterpretation.
- **Guardrails for Privacy and Security:** Our RFI emphasizes the critical need for robust guardrails for privacy and security. This includes standardized, negotiable, and balanced terms and conditions for data use, explicit data use agreements prohibiting commercial use, and independent third-party auditing of platform technology.

4. The Use of Automated Collection Techniques or Other Information Technology to Minimize the Burden

- **Comment:** While AHN advocates for the elimination of this rebate model, we recognize the potential for technology to mitigate some burdens if information collection is absolutely unavoidable. However, this must be approached carefully to avoid merely shifting, rather than truly minimizing, the burden.
- **Leverage Existing Standards and Interoperability:** Any automated solution must leverage existing, proven technologies and data exchange standards (e.g., HL7, FHIR, existing EDI infrastructure) and prioritize interoperability with existing pharmacy dispensing systems, EHRs, and claims processing platforms. The

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

creation of entirely new, bespoke systems for each covered entity or manufacturer is inefficient and costly.

- **Alternative, Less Burdensome Methods:** We strongly reiterate that there are alternative, less burdensome methods for preventing duplicate discounts that could be significantly enhanced through technology, without creating an entirely new, heavy infrastructure. As recommended in our RFI (page 8), AHN's primary recommendation is to abandon the rebate model concept entirely and, if HRSA insists on addressing duplicate discounts, to embrace a neutral, third-party clearinghouse as a less burdensome and effective alternative.
    - **Manufacturer Accountability:** Manufacturers, as beneficiaries of a delayed payment model, should bear the primary reporting burden to demonstrate compliance and program integrity. This includes real-time updates on claim status, detailed rationales for denials, and itemized payment details, as outlined on page 11 of our RFI.
    - **Focus on Root Causes:** Manufacturers could significantly reduce the potential for duplicate discounts by re-evaluating and adjusting other rebates and discounts currently paid to payers that might overlap with 340B discounts.
    - **Enhanced Real-Time Solutions:** Strengthening existing real-time claims adjudication flags within PBM systems to identify potential duplicate discounts *before* they occur would be a much more efficient and less burdensome approach than a post-purchase rebate system.
    - **Avoid Increased Risk from Complexity:** As detailed in our RFI (page 12), the increased complexity, administrative burden, and cash flow challenges of a rebate model would severely undermine 340B program integrity, creating an environment ripe for errors and compliance risks, potentially leading to *more* duplicate discounts rather than fewer.

Conclusion:

Allegheny Health Network
Fifth Avenue Place
120 Fifth Avenue
Pittsburgh, PA 15222

ahn.org

The Allegheny Health Network urges HRSA to carefully reconsider the implementation of the proposed 340B Rebate Model Pilot Program. Our detailed RFI submission and these supplemental comments demonstrate unequivocally that the estimated burden on covered entities is profoundly understated. The model itself introduces unnecessary complexity, administrative overhead, and significant financial strain that will divert critical resources from patient care, fundamentally undermining the mission of the 340B Program and directly harming the vulnerable patient populations we serve.

We believe that more effective, less burdensome, and technologically appropriate solutions exist to address concerns about duplicate discounts within the 340B Program. AHN stands ready to support HRSA in its efforts to find viable solutions such as a neutral clearinghouse that protects the vital role of 340B in ensuring access to care for millions of patients.

Thank you for your consideration of these critical comments.

Sincerely,

Laura Mark Vice President, Pharmacy Allegheny Health Network

cc: Mark Sevco, President, AHN
Jacqueline M. Bauer, General Counsel and Chief Administrative Officer, AHN
Daniel A. Onorato, Executive Vice President, Corporate Affairs, Highmark Health

COASTAL COMMUNITY HEALTH

100 Professional Center Dr.
Brunswick, GA 31525
912-275-8028

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 No. 0906-NEW)
Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Coastal Community Health Services, Inc.**, a federally qualified health center serving **Brunswick, Georgia. A coastal community with extremely high poverty and uninsured rates making this area a deeply underserved area.** We appreciate the opportunity to provide comments regarding the proposed information collection requirements associated with the 340B Rebate Model Pilot Program. Given the significant administrative, financial, and operational burden this model would impose, we respectfully request that Community Health Centers (CHCs) be exempted from participation in the pilot program.

The 340B Program is foundational to our ability to serve vulnerable populations and stretch scarce federal resources. At **Coastal Community Health**, we dispense approximately **36,000 prescriptions annually** across **97 pharmacy locations**. The program generates approximately **$3 million annually**, which is reinvested into essential patient services including **free medication delivery, dental services, behavioral health programs, care coordination, medication access programs, and many other critical clinical services**. A shift to a rebate model fundamentally disrupts this structure by transferring financial and operational responsibility from manufacturers to safety-net providers.

Under the proposed model, we would be required to purchase medications at full Wholesale Acquisition Cost (WAC) and wait for rebates, creating immediate and material cash flow strain. We estimate an increase in monthly inventory spend of approximately **$425k**, requiring additional working capital of **$1.7 million** to sustain operations. For organizations like ours operating on thin margins and serving **22,000 patients**, this creates significant financial

instability and may force reductions in services, staffing, or medication access. The risk of delayed or denied rebates further compounds this issue and introduces uncertainty into an already complex system.

Operationally, the rebate model introduces a parallel claims lifecycle that does not exist today. We would be required to identify eligible claims post-dispense, submit claims-level data across multiple manufacturer platforms, track rebate payments, reconcile discrepancies, and manage disputes. Based on our current operations, we estimate the need for **3 additional FTEs**, approximately **55 hours per week** dedicated to rebate tracking and reconciliation, and an increase of **$360k annually** in administrative costs. We also anticipate **$225k in vendor-related expenses**, including third-party administrators, consultants, legal support, EMR and pharmacy system upgrades, and reconciliation tools.

The burden extends across all aspects of our pharmacy and clinical operations. In-house pharmacy systems will require significant customization to integrate with rebate platforms, including API development, pricing validation tools, and ongoing manual verification processes. Across our contract pharmacy network of **3 partners**, we will need to monitor claims and rebate activity across multiple external systems, significantly increasing coordination complexity and administrative overhead. There is also a real risk that contract pharmacies may opt out of participation due to increased financial and operational burden, further limiting patient access.

Clinic-administered drugs present an additional layer of complexity, as many are not captured in traditional claims data due to bundled payment structures. This would require new systems, workflows, and manual processes to convert existing documentation into rebate-eligible formats. We estimate this will require **900 hours and approximately $140k annually** to support, driven by system integration, training, and manual data conversion.

These challenges are compounded by existing manufacturer restrictions, which have already significantly increased administrative costs and operational strain. National assessments, including those conducted by the National Association of Community Health Centers (NACHC), demonstrate that the financial and administrative burden associated with rebate-style models is substantial and unsustainable. Tools such as NACHC's Operational & Administrative Cost Calculator further confirm that CHCs would face significant increases in staffing, IT infrastructure, and ongoing operational costs under a rebate model.

Most importantly, the proposed model will directly impact patient access. CHCs serve populations with disproportionately high rates of chronic conditions such as diabetes, hypertension, and obesity. Many of the drugs included in the proposed model treat these conditions, making affordability critical. The inability to access upfront 340B pricing creates a scenario where medications must be purchased at full WAC, making it operationally impossible to provide discounted pricing at the point of care. This directly conflicts with federal requirements, including obligations tied to Section 330 funding and sliding fee scale programs, which require CHCs to provide affordable access to medications based on patient income. **Coastal Community Health currently provides medication discounts through our in-house pharmacy and 340B contract pharmacy, and this model would severely disrupt our ability to continue doing so.**

A rebate model represents a fundamental departure from the intent of the 340B Program. It introduces unnecessary administrative burden, creates financial instability, and places patient access at risk. Covered entities like ours depend on the immediacy and predictability of upfront discounts to operate effectively and provide essential services.

Conclusion

For these reasons, **Coastal Community Health** strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. The proposed model will create significant operational and financial challenges while undermining the very purpose of the 340B Program. We believe this approach will disproportionately harm safety-net providers and the patients they serve.

We appreciate the opportunity to provide comments and welcome continued engagement on this critical issue. If you have any questions, please contact **Cheryl Woods, Chief Deputy Director at cheryl.woods@coastalchs.org**.

Sincerely,

Cheryl Woods
Chief Deputy Director
Coastal Community Health Services, Inc.
cheryl.woods@coastalchs.org
(912) 275-8028

April 25, 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 **VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, 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, VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC., again requests that CHCs be exempted from the pilot program.**

VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC., focuses primarily on populations in its service areas who are most impacted by the substance use epidemic (SUD diagnosed, collaterals of persons diagnosed, people at risk), using appropriate evidence-based practices (EBP) including Motivational Interviewing (MI), Trauma Informed Care (TIC), Relapse Prevention (RP), Recovery Coaching (RC) and Patient-Centered Care.

Most of the Bronx and the areas served by **VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC**., have been classified as medically underserved. Our core values drive every aspect of the work that we do.

We are:
Mission Driven: Improving our patients' and clients' health and well-being (meaning non-medical factors that affect health) is why VIP was created and why we are here. Everything we do should be toward achieving our mission.
Person-Centered: The person (patient, client, family, VIP team) is at the center of our decisions and will drive how we do things in as holistic a way as possible.
Compassionate: When we are compassionate, we listen, we ask questions, we try to understand where the person is at, we are culturally sensitive, we are understanding. It will help us achieve our mission.

Respectful: We don't have to agree with or even like the other person, whether they are a client, a patient or another staff member, but we will always act professionally. It is a way of showing care, concern or consideration.
Data & Quality Informed: Having data about what we do and how well we are doing it is the only way for us to know if we are in fact achieving our mission. And there is always room for us to do it better, so we will always strive to achieve better quality in everything we do.

Our person-centered philosophy tailors' services to the individual needs of each client through a wholistic approach to care, meeting clients where they are at. We work with individuals, families and the larger community, and often provide services in partnership with other organizations to ensure clients are provided with the best support for their needs.

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 5000 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.

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

Workforce Impact:

- **Staffing Impact**: **VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES**, INC anticipates needing at least 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, **VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC.,** will face an increased administrative burden to monitor rebate claims and payments. At least 10 hours extra will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs: VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC.,** anticipates an additional **$**500K for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services. These costs are driven by fixed /semi fixed costs such as claims tracking system/vendor platform, data submission in addition to reconciliation workflows, compliance and audit processes, and staffing, in addition to variable costs such as volume of claims, denials, cash flow burden caused by fronting WAC drug costs.

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. estimated one-time costs of $50,000 to $75,000 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 approximately $100,000 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves approximately 5000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at approximately $200,000 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 2 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 2 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 Bronx area of New York 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] **VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC.,** estimates it will take **10 hours and roughly $1000 to $2500** to upload records related to CADs. These costs reflect the need to implement new EHR functionality, engage external vendors for rebate-tracking support, and dedicate staff time across pharmacy, IT, and compliance functions to ensure accurate and timely data submission. While modest in isolation, these recurring administrative burdens compound across reporting cycles and contribute to the overall financial strain associated with the rebate model.

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

VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, 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

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

[3] Internal NACHC survey data

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

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

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. Our organization makes prescription drugs affordable through a combination of strategies designed to reduce or eliminate cost barriers at the point of care. We implement a sliding fee discount program that lowers medication prices based on patient's income relative to the federal poverty level, with nominal or no cost prescriptions available for the lowest income patients. We use savings generated through the 340B program to subsidize the cost of medications, allowing them to offer prices below acquisition cost when necessary and maintain consistent, predictable pricing for underinsured patients. We often provide access to low-cost generic formularies, contract pharmacy services, and care coordination support to help patients obtain and adhere to needed medications. Together, these approaches ensure that patients can access essential therapies without delay, regardless of their ability to pay.

Conclusion

VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, 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

[6] HRSA FAQ

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

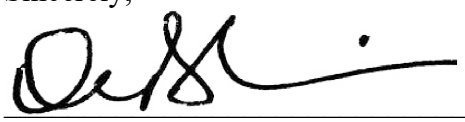
about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, 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. **VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, INC.,** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

VOCATIONAL INSTRUCTION PROJECT COMMUNITY SERVICES, 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:

DEBBIAN FLETCHER-BLAKE
PRESIDENT AND CEO
dblake@vipservices.org

DARCIA BRYDEN-CURRIE
SENIOR VICE PRESIDENT AND CHIEF CLINICAL OFFICER
dcurrie@vipservices.org

Sincerely,



Debbian Fletcher-Blake, APRN, FNP
President and CEO
Vocational Instruction Project Community Services, Inc.

HIGH COUNTRY community health

April 27, 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 **High Country Community 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, High Country Community Health again requests that CHCs be exempted from the pilot program.**

High Country Community Health places a strong emphasis on serving underserved and vulnerable populations, including individuals and families living at or below 200% of the federal poverty level, the uninsured, and those facing barriers to care. **With a sliding fee scale and various assistance programs, HCCH works to eliminate financial obstacles and ensure that cost is not a barrier to receiving essential healthcare services. In 2025, HCCH provided services to 17,319 unique patients with 72,440 visits, demonstrating both reach and trusted community presence.**

Beyond clinical services, HCCH partners with local organizations, schools, and community groups to expand preventive care and health education, address social determinants of health, and build trust and long-term engagement with vulnerable populations.

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 17,319 patients in Western, North Carolina 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**: **High Country Community Health** anticipates needing **more than 2 FTEs to account for this** 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, **High Country Community Health** will face an increased administrative burden to monitor rebate claims and payments. **An estimate of at least 10 hours each week** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **High Country Community Health** anticipates an additional cost **estimated at $145,000 annually** 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

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

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. High Country Community Health has already spent $20,000 for a pharmacy software upgrade just 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. This additional amount charged for such services is unknown to us at this time as those fees will be chosen by each respective TPA upon implementation.
- **Total Cost:** For our CHC, which serves **17,319** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$145,000** annually.

The In-House Pharmacy: The Burden of IT Integration

High Country Community Health currently operates two entity-owned 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. This requires manually pulling files on purchases and pricing for each of our entity-owned pharmacies, as well as manually reconciling each of those anticipated rebate payments, on a weekly basis just to ensure we are receiving the statutory 340B price. **Please consider the time it will take to file a good faith inquiry (GFI) on each individual claim where a rebate was either denied or just not received. High Country Community Health estimates an additional 1-2 hours per week or more just to track down 1-2 missing or incomplete rebate claims.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **Our software vendor has quoted costs at $200 per hour for report development. The number of hours required are not known at this time as we are unsure of what those reporting elements are.**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **at minimum 20 hours per week** manually pulling “Purchase Files” and “Price Files” to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. Our CHC currently partners with 62 individual contract 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 two entity-owned and 62 individual contract pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In four Western North Carolina counties (Watauga, Avery, Burke, and Surry), 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 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

High Country Community 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

[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

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. **This does not alleviate the burden of carrying the cost of these medications plus interest while awaiting rebate payments.** In our current state, we purchase our medications via invoicing every 7 days, no interest is incurred. If forced to go to a rebate-based model, we will incur additional interest from our wholesaler because we would be financially unable to pay for these medications up front. **High Country Community Health estimates that purchasing the 10 selected MFP drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by $72,000, not including additional interest incurred.**
- **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-

[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

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. **This is a life-saving service High County Community Health provides for our rural communities, and this service currently costs Americans nothing extra for us to continue operating as we have been since the inception of our CHC in 2012. A rebate model would be financially devastating for our health center causing a ripple effect across the rural Western North Carolina community that we serve.**

Conclusion

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

High Country Community Health appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **If you have any additional questions, please contact Stephanie Hazle, Director of Pharmacy, at pharmacy@hcchmail.org.**

Sincerely,

Stephanie Hazle

Stephanie Hazle, PharmD
On behalf of Alice Salthouse CEO
High Country Community Health

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

Outreach
Community Health Centers

Milwaukee, Racine, WI
April 15, 2026

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

RE: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (HHS-2026-03042)

Dear Director Britton:

On behalf of Outreach Community Health Centers (OCHC), I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to 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 NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses:** Nationwide, CHCs report an average loss of **$500,000 to $3 million** from entity-owned pharmacy operations and OCHC estimates a loss of $100,000 to $200,000 from a **reduction in savings. OCHC estimates a reduction of $100,000-$200,000** for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.
- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs annually to manage the pilot. OCHC estimates: $60,000 to $70,000 in one time technology improvements for IT integration. At present it has cost over 100 Pharmacist hours to prepare and implement required reports at $8,500. We would need a Third Party Administrator (TPA). TPAs charge an average of $15 per dispensed 340-B claims in 2025 OCHC had 30,000 claims which would mean costs/lost revenue of at least $450,000. We would need to hire a Pharmacy Coordinator with experience in 340-B at an expense of $111,250 (salary and benefits). Total ongoing program expenses are estimated at $569,750.

I. We Strongly Urge HRSA To Exempt CHCs from the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program is a direct threat to CHCs' core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over three decades, the 340B program has enabled CHCs to purchase outpatient medications at significantly

reduced prices, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHCs.

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us. For Outreach Community Health Centers in particular, this means it will impact:

- 8,562 estimated patients accessing 340-B.
- Estimated $119,750 in staffing costs already, dealing with manufacturer requirements. 100 Pharmacist Director hours to prepare and implement required reports at $8,500.
- OCHC uses 340-B revenue to help pay for services for uninsured patients. 340-B revenue funds are also reinvested into services to increase pharmacy services and clinical services ,and to improve workflow and workspace.

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

II. Patient Impact

Most importantly, a 340B rebate model poses a direct and serious threat to medication access for the vulnerable patients that CHCs serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model could render critical medications financially out of reach. Patients may be forced to make tough decisions in transitioning to other medications, due to cost or lack of availability, as a direct result of a 340B rebate pilot program. These forced therapeutic interchanges introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by.

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

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

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

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

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

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

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

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally

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

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

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

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

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

impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

III. Administrative Complexities and Financial Challenges for CHCs

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

340B Rebate Model Operational & Administrative Cost Calculator Description

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

- **Sliding Fee Discount**: In 2025, Outreach Community Health Centers provided $212,638.31 in **2025 Sliding Fee Discounts for an estimated 7,233 patients. These discounts were for medical, dental, behavioral health and for discounted medications.** We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: Outreach Community Health Centers anticipates needing a 1 FTE as a result of the Rebate Model. Additional FTEs are needed to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, Outreach Community Health Centers anticipates an increase of $120,000 to $750,000 in additional costs related to the rebate model for Third Party Administrators. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Workforce Impact

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

- According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.[7] OCHC anticipates the need to hire a 1 FTE.
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $100,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities.
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. OCHC estimates a minimum of 20 hours per week will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the drug manufacturers' plans. The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens.
- Outreach Community Health Centers urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. IT costs are estimated at $100,000 to $150,000 and a minimum of 100 hours from our Pharmacy Director at an estimated cost of $8,500.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings. We utilize the most popular pharmacy operating system in the US and yet there were no reports developed by the software system nor standardization for gathering the claims submission data required for uploading to MTF, 340B Beacon, and 340B ESP platforms – this means that these reports were developed and designed independently by Pharmacy Director for Outreach. Additionally, there is limited automation processes available – currently all uploads to the required 3rd party platforms is manually achieved by Pharmacists at Outreach.
-

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

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

For CHCs that operate their own 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 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. Outreach Community Health Systems uses OCHIN EPIC EHR Significant work is needed to build reports.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend a minimum of 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

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. OCHC currently partners with 9 pharmacies to increase access to affordable medications, and to provide mail order and delivery options.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across at least nine different contract pharmacies that may require high-level TPA intervention. We anticipate that TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across at least ten different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in Milwaukee and particularly on the vulnerable north side with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

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

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory

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

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

[11] Internal NACHC survey data

logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added 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 electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.

- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.
- **HRSA should explicitly exclude CADs from any 340B rebate model pilot.** At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

A. Financial Challenges

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

The proposed 340B Rebate Model Pilot would directly impact CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to purchase at full WAC pricing upfront. CHCs' pharmacies, as well as entity-owned and contract pharmacies, will not have access to the 340B price when the patient needs medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC. The rebate model creates confusion about its impact on a CHC's ability to offer sliding-fee discounts at the point of purchase. As an example, the cost of Xarelto is going from $0.30 per month to $611 per month, yet Outreach will still be expected to offer Xarelto to 340B patients for our discounted cash price of ~$5/month.

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the

project.[12] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[13] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. As an example, the cost of Xarelto is going from $0.30 per month to $611 per month, yet Outreach will offer Xarelto to 340B patients for our discounted cash price of ~$5/month. Xarelto is a commonly used blood thinner used for patients with heart disease.

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. The financial impact is further compounded when CHCs have entity-owned pharmacies with physical inventories and must stock their shelves with purchases at WAC. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[14] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

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

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. It is important to note that many CHCs are currently under financial strain. Nearly half of CHCs operate with fewer than 90 days of cash on hand, and one in four reports approximately negative five percent (-5%) operating

[12] HRSA FAQ

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

[14] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review

margins. Below, you will find specific data demonstrating the significant increase in financial costs CHCs will incur under a 340B Rebate Model.

340B Rebate Drug Cost Impact Calculator Description

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

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.
- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).
- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHCs must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate acquisition costs for the ten drugs would increase by at least would increase in upfront capital required for $500k annually.

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, Outreach Community Health Centers anticipates needing to reduce: It is estimated the monthly drug spend for OCHC would increase $45,000 -$500,000.

- **Essential Clinical Services:** To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services, such as services to the chronically homeless and respite services for patients in the most vulnerable homeless situations. We have

[15] https://340bpricing.hrsa.gov/

[16] https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip

plans to expand our pharmacy to meet current patient demand and these plans will need to be shelved in the Rebate program goes through.

- **Workforce & Staffing:** The administrative burden of this pilot requires us to divert funds away from clinical staff. For every "Rebate Coordinator" we are forced to hire, we lose the ability to fund a Case Manager or Outreach Worker. This directly impacts access to services for vulnerable patients. We will need at least one 340-B Rebate Coordinator/Specialist at a cost of $80,000 for salary and an additional + $20,000 in benefits.
- **Patient Financial Assistance:** Our ability to provide medications at "zero-pay" or deeply discounted rates under our sliding fee scale will be compromised. If the cash is not in our accounts because it is being held by a manufacturer, we cannot provide the "bridge" support that prevents our 11,690 uninsured patients from rationing their insulin or heart medication.

B. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHCs have suggested that paying for medications upfront at WAC prices would require dipping into limited financial reserves or taking out loans, thereby defeating the purpose of the 340B program.

Outreach Community Health Centers asserts that taking out a loan or an extended line of credit to fund drug procurement is a high-risk strategy that places our organization in a state of "financial limbo." This approach fundamentally defeats the purpose of the 340B program—to "stretch" scarce federal resources—by diverting patient-care funds toward interest payments, origination fees, and debt service. Relying on credit to "float" manufacturer rebates is particularly dangerous at a time when all other major revenue sources are unstable.

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHCs are unable to disclose their exact prompt-pay discount. However, Outreach Community Health Centers, estimates its 2027 Annual Rebate Opportunity Cost to be approximately $125,000 per year.
- **Outreach Community Health Centers** estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by $45,000-$50,000 per year.

  Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our

organization may be forced to t**ake out a line of credit or utilize limited financial reserves to cover costs.** This is not a sustainable solution and would force us to shift costs currently dedicated to key homeless and other healthcare programs. Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on Outreach Community Health Centers, the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 34 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

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

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative **5%** denial rate would result in a net annual loss of **$50,000-$75,000.** This is a sum our CHC cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

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

IV. Reconciliation and Rebate Denials Operational Challenges

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

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

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

V. Existing CHC Compliance Actions

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

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

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten

the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

VI. Establishing a National, Neutral Claims Clearinghouse

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

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

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

Conclusion

Outreach Commui8ty 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. Outreach Community Health Centers believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Outreach Community 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 Julia Harris-Robinson, CEO at 414-964-9012, Ext 2302 or juliahr@orchc-milw.org

MEDICAL ASSOCIATES Plus
THE ROAD TO HEALTHY
@Belle Terrace

2467 Golden Camp Road
Augusta, GA 30906
Phone: 706.790.4440

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 No. 0906-NEW)
Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Neighborhood Improvement Project, Inc.**, a federally qualified health center serving **Augusta, Georgia. A large, diverse, and economically challenged community with high poverty rates that create persistent barriers to healthcare access.** We appreciate the opportunity to provide comments regarding the proposed information collection requirements associated with the 340B Rebate Model Pilot Program. Given the significant administrative, financial, and operational burden this model would impose, we respectfully request that Community Health Centers (CHCs) be exempted from participation in the pilot program.

The 340B Program is foundational to our ability to serve vulnerable populations and stretch scarce federal resources. At **Neighborhood Improvement**, we dispense approximately **27,000 prescriptions annually** across **118 pharmacy locations**. The program generates approximately **$6.6 million annually**, which is reinvested into essential patient services including **free medication delivery, dental services, behavioral health programs, care coordination, medication access programs, and many other critical clinical services**. A shift to a rebate model fundamentally disrupts this structure by transferring financial and operational responsibility from manufacturers to safety-net providers.

Under the proposed model, we would be required to purchase medications at full Wholesale Acquisition Cost (WAC) and wait for rebates, creating immediate and material cash flow strain. We estimate an increase in monthly inventory spend of approximately **$325k**, requiring additional working capital of **$1.3 million** to sustain operations. For organizations like ours operating on thin margins and serving **60,000 patients**, this creates significant financial instability and may force reductions in services, staffing, or medication access. The risk of delayed or denied rebates further compounds this issue and introduces uncertainty into an already complex system.

Operationally, the rebate model introduces a parallel claims lifecycle that does not exist today. We would be required to identify eligible claims post-dispense, submit claims-level data across multiple

2467 Golden Camp Road
Augusta, GA 30906
Phone: 706.790.4440

manufacturer platforms, track rebate payments, reconcile discrepancies, and manage disputes. Based on our current operations, we estimate the need for **3 additional FTEs**, approximately **60 hours per week** dedicated to rebate tracking and reconciliation, and an increase of **$390k annually** in administrative costs. We also anticipate **$275k in vendor-related expenses**, including third-party administrators, consultants, legal support, EMR and pharmacy system upgrades, and reconciliation tools.

The burden extends across all aspects of our pharmacy and clinical operations. In-house pharmacy systems will require significant customization to integrate with rebate platforms, including API development, pricing validation tools, and ongoing manual verification processes. Across our contract pharmacy network of **5 partners**, we will need to monitor claims and rebate activity across multiple external systems, significantly increasing coordination complexity and administrative overhead. There is also a real risk that contract pharmacies may opt out of participation due to increased financial and operational burden, further limiting patient access.

Clinic-administered drugs present an additional layer of complexity, as many are not captured in traditional claims data due to bundled payment structures. This would require new systems, workflows, and manual processes to convert existing documentation into rebate-eligible formats. We estimate this will require **800 hours and approximately $120k annually** to support, driven by system integration, training, and manual data conversion.

These challenges are compounded by existing manufacturer restrictions, which have already significantly increased administrative costs and operational strain. National assessments, including those conducted by the National Association of Community Health Centers (NACHC), demonstrate that the financial and administrative burden associated with rebate-style models is substantial and unsustainable. Tools such as NACHC's Operational & Administrative Cost Calculator further confirm that CHCs would face significant increases in staffing, IT infrastructure, and ongoing operational costs under a rebate model.

Most importantly, the proposed model will directly impact patient access. CHCs serve populations with disproportionately high rates of chronic conditions such as diabetes, hypertension, and obesity. Many of the drugs included in the proposed model treat these conditions, making affordability critical. The inability to access upfront 340B pricing creates a scenario where medications must be purchased at full WAC, making it operationally impossible to provide discounted pricing at the point of care. This directly conflicts with federal requirements, including obligations tied to Section 330 funding and sliding fee scale programs, which require CHCs to provide affordable access to medications based on patient income. **Neighborhood Improvement currently provides medication discounts through our in-house pharmacy and 340B contract pharmacy, and this model would severely disrupt our ability to continue doing so.**

A rebate model represents a fundamental departure from the intent of the 340B Program. It introduces unnecessary administrative burden, creates financial instability, and places patient access at risk. Covered entities like ours depend on the immediacy and predictability of upfront discounts to operate effectively and provide essential services.

MEDICAL ASSOCIATES Plus
THE ROAD TO HEALTHY
@Belle Terrace

2467 Golden Camp Road
Augusta, GA 30906
Phone: 706.790.4440

Conclusion

For these reasons, **Neighborhood Improvement** strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. The proposed model will create significant operational and financial challenges while undermining the very purpose of the 340B Program. We believe this approach will disproportionately harm safety-net providers and the patients they serve.

We appreciate the opportunity to provide comments and welcome continued engagement on this critical issue. If you have any questions, please contact **Wesley Wood, Chief Financial Officer at wesley.wood@mapbt.com**.

Sincerely,

Wesley Wood
Chief Financial Officer
Neighborhood Improvement Project, Inc.
wesley.wood@mapbt.com
(706) 790-4440 x100

Carolina Family
Health Centers, Inc.

April 27, 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 Carolina Family Health Centers, 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,** Carolina Family Health Centers (CFHC) **again requests that CHCs be exempted from the pilot program.**

Carolina Family Health Centers is a federally qualified community health center (CHC) with locations in rural Edgecombe, Nash and Wilson counties of Eastern North Carolina. CFHC provides comprehensive, high quality, and cost-effective health care which includes primary care, dental, behavioral health, and pharmacy services. Enabling services include transportation, medication delivery, and case management. As part of primary care services, CFHC offers gynecology, rheumatology, general surgery, radiology, mammography, substance use disorder treatment, and care for individuals living with HIV and AIDS. A broad range of services is combined to increase access to healthcare and is available regardless of ability to pay. In 2025, approximately 78% of our 23,935 patients had a household income at or below 100% of the federal poverty level, and 44% did not have insurance.

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 23,935 patients who rely on us. Many CHCs operate on razor-thin margins, and these additional costs are not an option for maintaining full operations. 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 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**: CFHC anticipates needing 1 to 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, CFHC will face an increased administrative burden to monitor rebate claims and payments. CFHC estimates that 6 to 8 hours weekly will be required to report 340B rebate claims to a third-party platform; additional time needed for monitoring, reconciling, and troubleshooting is estimated at another 6 to 8 hours each week.
- **External Vendor Costs**: CFHC anticipates an additional **$**30,000 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. $8,500 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 to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 23,935 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $40,000 to $50,000 annually.

The In-House Pharmacy: The Burden of IT Integration

Carolina Family Health Centers operates 3 in-house, entity-owned pharmacies with more than 212,000 prescriptions dispensed in 2025. 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. Our pharmacy software can only handle one acquisition cost per drug file which is currently set based on last cost paid to our pharmaceutical wholesaler for the product. **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 8 to 16 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] CFHC anticipates adding an additional EHR module and a separate vendor to assist with the rebate reporting for CAD with an associated cost of more than $40,000 annually.

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.

[2] Internal NACHC survey data

II. Patient Impact

Carolina Family 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.[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 individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. All patients of Carolina Family Health Centers are encouraged to apply for our Sliding Fee Discount Program, and qualifying patients are

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

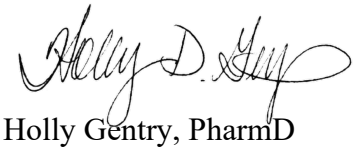
provided discounts based on their household income. Uninsured, low-income patients on the lowest tier of the program are currently able to access life-saving medications for a nominal fee which has not been increased in the past 10 years.

Conclusion

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

Carolina Family 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 do not hesitate to contact me at hgentry@cfhcnc.org.

Sincerely,



Holly Gentry, PharmD
Chief Pharmacy Officer
Carolina Family Health Centers