Kalihi-Palama Health Center
Hale Ho'ola Hou~House of New Life

915 North King Street
Honolulu, Hawaii 96817

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 Kalihi-Palama Heatlh Center**,** I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on Kalihi-Palama Heatlh Center again requests that CHCs be exempted from the pilot program.**

Kalihi-Palama Health Center (KPHC) is an independent, 501(c)(3) non-profit, organization that plays a crucial role in the Kalihi-Palama community as a provider of health and social services to patients who typically face significant barriers when accessing health care. KPHC is in the heart of Kalihi-Palama; an urban, inner-city community that is home to 63,820 residents, many of them who are vulnerable, underserved Asian, Native Hawaiian and Pacific Island minorities. KPHC serves more than 20,000 patients annually.

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 **63,820** 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**: KPHC anticipates needing six additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** KPHC will face an increased administrative burden to monitor rebate claims and payments. 10 to 14 hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: KPHC anticipates an additional $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. $50,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees of $60,000 annually to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.

The In-House Pharmacy: The Burden of IT Integration

KPHC operates 3 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 10-15 hours per week manually pulling “Purchase Files” and “Price Files” to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with Walgreens 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 5 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 Honolulu**,** 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] KPHC estimates it will take 20 hours and cost $100,000 annually to upload records related to CADs.

Most CADs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

KPHC 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.

Conclusion

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

KPHC 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.

Jan Hasegawa, Pharm D
Director of Pharmacy
Kalihi Palama Health Center.

Peak Vista
Community Health Centers

April 27, 2025

Chantelle Britton
Director
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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 Peak Vista Community Health Centers (Peak Vista), thank you for the opportunity to provide input on the proposed Information Collection Request (ICR) related to the 340B Rebate Model Pilot Program.

Peak Vista is the medical home for 70,195 patients in the Pikes Peak and East Central regions of Colorado. The 49,000 households we serve each year have limited access to resources, with 63% living at or below the Federal Poverty Level (FPL) and 89% at or below 200% of FPL. Providers at our 20 sites deliver integrated medical, dental, and behavioral health services. Approximately 10% of our patients reside in rural service areas, 10% are elderly, 1% identify as homeless, and 2% are veterans.

The 340B program is foundational to our ability to serve vulnerable populations. However, our ability to respond to this ICR is significantly limited by the lack of detail regarding the proposed rebate model pilot program. The ICR requests feedback on burden, data collection processes, and use of technology; however, key elements—including data submission requirements, system architecture, manufacturer-specific expectations, and dispute resolution processes—have not been defined.

As a result, the responses below are based on reasonable assumptions informed by existing manufacturer requirements, current contract pharmacy restrictions, and limited available information regarding the proposed model. Where appropriate, we note areas where additional specificity from HRSA is required to provide accurate and meaningful feedback.

(1) Necessity and Utility of the Proposed Information Collection

HRSA has requested input on the necessity and utility of the proposed information collection for agency functions. Based on currently available information, it is not yet possible to fully assess necessity or utility, as the scope and purpose of the required data collection have not been clearly defined.

The proposed information collection appears to assume standardized data elements, submission processes, and supporting technology. However, current manufacturer practices demonstrate significant variability in data requirements and operational expectations. If a similar approach is permitted under a rebate model, the resulting data collection may lack consistency and comparability across entities.

Without clearly defined, standardized requirements, the utility of the collected information for oversight, compliance monitoring, or program evaluation is uncertain. Additional details regarding required data elements, reporting formats, and intended use of collected information is necessary to evaluate whether the proposed collection will effectively support HRSA's functions.

To the extent the intent of the proposed information collection is to support prevention of duplicate discounts, HRSA should require a **single, standardized data submission framework** utilizing **minimally necessary data elements** applied consistently across all manufacturers.

While prior models have incorporated centralized data submission mechanisms, any approach adopted by HRSA must be **independent, neutral, and not controlled by any single stakeholder group**, with clear governance and transparency. Without these safeguards, reliance on external platforms may introduce concerns related to data access, control, and equity across covered entities.

Absent a uniform, standardized approach, requiring covered entities to submit similar data in multiple formats across different manufacturers will increase burden without improving the accuracy or utility of the information collected.

(2) Accuracy of the Estimated Burden

HRSA defines burden as the total time required to generate, maintain, validate, reconcile, and report required information, including system development, staff training, and ongoing operational activities. Based on this definition, Peak Vista believes the estimated burden of 260 annual hours is significantly understated.

Peak Vista operates a complex system that includes 20 clinical sites in a geographic area that is larger than nine of the American states, two in-house pharmacies, and participation from 71 contract pharmacies. Based on our current prescription volume and reasonable assumptions regarding rebate processing, we estimate an annual administrative burden of approximately **4,160 hours**, equivalent to **two full-time employees** dedicated to:

- Data collection and validation
- Reconciliation of rebate claims and payments
- Monitoring and reporting activities
- Managing discrepancies and potential disputes

This estimate is conservative and dependent on limited available information. It does not fully account for variability in manufacturer requirements, system limitations, or potential dispute resolution processes. The burden would increase substantially with expansion of medications included in the pilot program.

In addition to staffing, Peak Vista anticipates the need for external vendor support, including third-party administrators (TPAs), consultants, legal counsel, and system vendors. Without a defined operational framework, it is unclear how many system changes will be required; however, all anticipated changes are expected to **generate additional costs without offsetting revenue.**

(3) Enhancing the Quality, Utility, and Clarity of Information

To enhance the quality, utility, and clarity of the proposed information collection, HRSA should establish clear and standardized requirements across all participating entities.

Specifically, HRSA should:

- Define **standardized data elements and submission formats**
- Establish **uniform reporting timelines and requirements**
- Require **consistent validation and reconciliation processes**
- Provide clear guidance on **audit expectations and documentation standards**
- Define a **standardized dispute resolution process**

Without standardization, covered entities will be required to navigate multiple, potentially conflicting manufacturer requirements, resulting in fragmented data collection and increased administrative burden. This fragmentation reduces the overall usefulness of the data for program oversight and evaluation.

(4) Use of Automated Collection Techniques to Minimize Burden

HRSA has requested input on the use of automated collection techniques or information technology to minimize burden. At present, meaningful automation is not feasible due to lack of system interoperability and undefined technical requirements.

Peak Vista utilizes separate Electronic Health Record (EHR) and pharmacy management systems that are not interoperable. Both vendors have confirmed that **the interfaces required to support a rebate model are not feasible**, including both bidirectional and unidirectional integration, requiring reliance on manual processes for data extraction, validation, and reconciliation.

Implementation of a rebate model would require significant modifications to pharmacy systems, third-party administrator platforms, and internal workflows, including:

- **One-time implementation costs** for system customization, dashboard development, and workflow redesign

- **Ongoing operational costs** associated with maintaining rebate-tracking functionality Increased reliance on TPAs, with anticipated increases in per-claim and service fees

To meaningfully reduce burden through automation, HRSA would need to:

- Require development of **standardized, interoperable systems**
- Support **centralized data exchange mechanisms**
- Provide sufficient time for system development, testing, and implementation

Without these elements, automation will be limited and the burden will remain largely manual.

Operational and Financial Impact Considerations

Implementation of a rebate model represents a significant operational and technological shift rather than a simple accounting change.

In-House Pharmacy Operations:
Peak Vista operates two in-house pharmacies. To remain compliant, these systems would require costly customization to provide accurate, real-time information. Due to lack of interoperability between EHR and pharmacy systems, staff would be required to manually extract and reconcile data. Based on current volume of the originally identified medications, this could require approximately 40 hours per week of staff time, diverting resources from clinical care activities.

Contract Pharmacy Network:
Peak Vista partners with 71 contract pharmacies to expand access to medications. The rebate model introduces significant operational complexity across this network. Variability in manufacturer requirements, combined with reliance on TPAs, will increase administrative burden and operational risk.

We anticipate:

- Increased TPA fees to support rebate tracking and reporting
- Delays in verification and reconciliation across multiple pharmacy locations

- Potential withdrawal of contract pharmacy partners due to administrative complexity

In rural areas such as Limon, Strasburg, Divide, and Fountain, loss of contract pharmacy participation would significantly reduce patient access to medications.

Clinic-Administered Drugs:
Implementation of a rebate model for clinic-administered drugs would require new systems, integration, and staff training. External estimates suggest costs ranging from $30,000 to $50,000 annually, with potential for higher costs depending on system requirements.

Patient and Financial Impact

The operational and administrative burden associated with the proposed information collection has direct downstream impacts on patient access to care.

Peak Vista has significant concerns regarding the ability to maintain affordable access to medications under a rebate model. The requirement to purchase medications at Wholesale Acquisition Cost (WAC) and wait for rebates introduces material cash flow constraints. Many CHCs operate with limited financial reserves, and this model would require allocation of resources toward administrative infrastructure rather than patient care.

Additionally, no current operational mechanism exists to ensure that discounted pricing can be consistently provided to patients at the point of sale under a rebate model. This creates uncertainty in meeting statutory requirements related to affordability programs, including access to discounted insulin and other essential medications.

Conclusion

In summary, Peak Vista is unable to fully evaluate the proposed information collection due to limited program detail. Based on reasonable assumptions, the estimated burden appears significantly understated, and the lack of standardization and technological infrastructure will limit both feasibility and utility of the data collection.

We recommend that HRSA provide additional specificity regarding data requirements, system expectations, and operational processes prior to finalizing burden estimates or advancing implementation. Without these details, the proposed information collection risks creating substantial administrative burden without corresponding benefit to program oversight or patient care.

Based on the significant administrative, financial, and operational burden outlined above—and the lack of sufficient detail to accurately assess or operationalize the proposed requirements—Peak Vista strongly urges HRSA to **exclude Community Health Centers (CHCs) from participation in the 340B Rebate Model Pilot Program**.

As currently contemplated, the model introduces substantial burden without defined processes, standardized data requirements, or feasible technological pathways to support implementation. Proceeding under these conditions would place disproportionate strain on CHCs while creating risk to patient access and program integrity. Absent significant modifications and clear operational guidance, exemption of CHCs from the pilot program is necessary to avoid unintended harm to the safety-net providers and patients the 340B program is intended to support.

Peak Vista appreciates the opportunity to respond to this ICR and looks forward to continued engagement with HRSA on this important issue. If you have any questions, please contact Katie Boudreaux, PharmD, 340B ACE, Vice President of Pharmacy Services, at 719.344.6269 or Katie.Boudreaux@PeakVista.org.

Sincerely,

Jaeson Fournier, D.C., MPH
President & Chief Executive Officer
Peak Vista Community Health Centers

From: Hill, Jeffrey
To: HRSA Paperwork
Subject: [EXTERNAL] Comment Letter ICR Rebate Pilot UMC Health System
Date: Monday, April 27, 2026 6:43:55 PM

HRSA ICR Rebate Pilot Letter 20260427.pdf

UMC HEALTH SYSTEM

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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 UMC Health System, Lubbock, TX, 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".

UMC Health System ("UMC") is the super safety net county hospital system for Lubbock County, Texas serving more than 265,000 square miles across West Texas, Eastern New Mexico, Southern Colorado and the Oklahoma Panhandle. UMC servs a population of over 3 million and receives over 9,000 transfer requests annually from 50 regional facilities. More than 60 percent of our patients are covered by government sponsored insurance, primarily Medicare and Medicaid, or are uninsured. UMC's mission is to care for everyone regardless of ability to pay while reducing barriers to care and improving community health outcomes.

In Fiscal 2025, UMC Health provided over $101M in uncompensated care costs. The 340B Program providing upfront discounts for pharmaceuticals valued at approximately $101.6M.

These numbers illustrate the significant role UMC has in the community and region, and how important the 340B Program is in allowing UMC to fulfill its mission. The 340B Program is essential to UMC's financial stability and ability to deliver charity care, affordable drug access and comprehensive safety-net services. Because of UMC's payer mix and role as a super safety-net provider, UMC is significantly exposed to financial, operational, and patient-access harms associated with a rebate-based model.

The proposed rebate mechanism will impose new costs and potentially detrimental burdens on UMC that erode precious resources needed to fulfill the mission of caring for the poorest and sickest in the community; thus, we oppose the rebate model in the 340B Drug Pricing Program. We believe priority should be given to covered entities, like UMC, allowing federal resources to be leveraged as far as possible thus maximizing the care eligible patients receive. Preserving the upfront discount mechanism, which UMC relies upon, is the best way to fulfill that purpose.

UMC HEALTH SYSTEM

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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. It is widely believed that a rebate mechanism would not impose new data-related burdens on 340B hospitals like UMC, with many insisting that hospitals already provide the required information through 340B ESP. ***This belief is incorrect for covered entities like UMC.***

Currently, UMC Health System collects, maintains, retains, and validates/audits data related to 340B Program participation. This continuous and ongoing work is done internally and is periodically reviewed by our Compliance department. Prior to the notice of a Rebate Model Pilot in late 2025, UMC was not running claims reports in the Rebate Pilot format, nor were we submitting the required volume of data to our wholesaler.

A 340B Rebate Model Pilot Program changes required data collection activities, adding a new subset of work necessary 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 material and adverse to the program's intended benefits.

2) The accuracy of the estimated burden:

Administrative Costs under a Potential 340B Rebate Program.
Under the current 340B upfront discount model, UMC purchases drugs at Wholesale Acquisition Cost (WAC), validates 340B eligibility at the point of dispensing or administration, and replenishes inventory at the 340B ceiling price for eligible uses. Savings are realized promptly and consistently, allowing those resources to be reinvested into patient care, charity care, and medication access programs.

UMC HEALTH SYSTEM

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Under a rebate-based model, UMC would be required to:

- Purchase drugs at WAC;
- Dispense medications to 340B-eligible patients;
- Replenish inventory again at WAC; and
- Wait for manufacturers to retroactively determine eligibility and issue rebates.

This structure requires repeated upfront exposure to full WAC costs while delaying access to 340B savings that are critical to ongoing patient care and operational sustainability.

Impact on Uninsured Patients
For uninsured patients, UMC continues to offer affordable cash pricing regardless of whether a prescription ultimately qualifies for 340B pricing. Because manufacturer determinations may occur after dispensing, there is inherent financial risk, and in some cases pricing may be based on WAC rather than confirmed 340B savings.

Despite this uncertainty, UMC assumes this risk today in order to avoid increasing barriers to medication access for uninsured patients. A rebate-based model significantly expands this exposure and limit UMC's ability to sustain these practices.

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: UMC encourages reform of the 340B Program rather than a rebate pilot program. We believe reforming the existing program would ultimately serve covered entities, patients, pharmaceutical manufactures and the federal government better than a rebate program.

We suggest the following reforms of the existing program:

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 reforms provide more transparent data and information of and for all parties and that all parties would have greater assurance and transparency of discounts offered. We also believe that transparency offered through a neutral, third-party clearinghouse eliminates concerns of duplicate discounts and standardizes data set requirements creating efficiencies.

UMC HEALTH SYSTEM

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Closing Comments:
We appreciate efforts to improve the existing 340b program. We believe alternatives to a rebate model are possible, models that preserve upfront discounted pricing while also providing transparency, accountability and fairness to all parties involved in the program.

We encourage review of comments provided by the Front-Line Hospital Alliance (of which we are a member), including their proposal for a "super safety net designation."

We are particularly invested in being a reliable partner in reforming the 340B Program to make it stronger and more effective for years to come.

Please contact me if you have questions.

Sincerely,

Electronically signed by:
Jeffrey J. Hill
Senior Vice President, Support Services and Government Relations
Date: 04/27/2026
Location: Lubbock, TX

April 20, 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
Submitted electronically at http://www.regulations.gov

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

Dear Administrator Engels:

On behalf of Allina Health, this letter is in response to the request for comments on the Department of Health and Human Services' (HHS) *Request for Information (RFI): 340B Rebate Model Pilot Program.* Among other things, this RFI asks "whether HRSA should implement a rebate model under the 340B program" instead of the upfront discount model that has worked successfully for decades. Allina Health does not support a rebate model.

As explained below, *any* rebate mechanism will impose enormous costs and burdens on Allina Health that far outweigh any perceived benefits that might come from it. HRSA must follow the intent of the program, which prioritizes 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 Allina Health has relied on for years, is the best way to fulfill that purpose of the 340B program.

Allina Health, an integrated health system, is dedicated to the prevention and treatment of illness and enhancing the greater health of individuals, families, and communities throughout Minnesota and western Wisconsin. We serve our communities by providing exceptional care as we prevent illness, restore health, and provide comfort to all who entrust us with their care - regardless of race, color, national origin, sex, age, or disability. As a nonprofit health care system with 28,000 employees, Allina Health cares for patients from beginning to end-of-life through our 90+ clinics, 12 hospital campuses, 16 retail pharmacies, specialty care centers and specialty medical services providing home care, senior transitions, hospice care, and emergency medical transportation services.

Request For Information: 340B Rebate Model Pilot Program

The RFI presents multiple questions and invites respondents to provide substantiated facts, research, and evidence in their submissions. For the purpose of estimating operational and financial impacts, Allina Health has assumed that any prospective Rebate Program would be limited to the 10 drugs previously authorized by HRSA for the original 340B Rebate Pilot Program. Should HRSA opt to expand the program to include additional medications—such as those approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027—the administrative complexity, financial risk, and operational demands outlined below would increase significantly. Every added drug results in a greater volume of claims to submit, increased rebates to monitor and reconcile, more funds required to advance to pharmaceutical companies pending statutory discounts, heightened potential for disputes over delays and denials, and consequently, reduced resources available for Allina Health to allocate toward patient care and comprehensive health services.

Administrative and Staffing Costs Under A Potential 340B Rebate Program

Any rebate program would require Allina Health to spend significant sums on new administrative costs. When we chose to participate in the 340B program, Allina Health understood that we would incur some reasonable administrative costs. Our internal staffing, program administration, compliance infrastructure, and vendor relations were designed to support an upfront discount model. Our current 340B operations are supported by a team consisting of one Program Manager, three compliance analysts, and one informatics specialist, supplemented by third-party vendor support for split-billing and contract pharmacy administration. These resources are calibrated to an upfront pricing model and are not sufficient to support a rebate-based framework.

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 health system with several 340B hospitals—and far above and beyond what we are experiencing now. **We strongly disagree with prior estimates suggesting minimal additional workload** (e.g., two hours per week). The operational requirements of a claims-based rebate system are substantial and continuous, requiring dedicated staff with specialized expertise in pharmacy operations, finance, and compliance.

Allina Health does not currently have sufficient staff to administer a rebate-based 340B program. Based on the functions described below, we anticipate the need to hire additional personnel or reallocate existing staff away from patient care and clinical support activities.

Under a rebate model, we estimate:

- One-time startup costs of approximately 1,500–2,300 labor hours, driven by workflow redesign, system configuration, staff training, and vendor integration.
- Ongoing administrative costs equivalent to 1.5–2.0 full-time employees annually, reflecting the need for continuous claims submission, reconciliation, denial management, and financial oversight.

These estimates are informed by our experience with other rebate-based programs, including the facilitation of the Medicare Drug Price Negotiation Program's Maximum Fair Price structure.

Key ongoing operational functions would include:

- **Claims-level rebate submission and monitoring -** Preparation, validation, and submission of rebate requests for each eligible dispense, likely on a frequent cadence to mitigate cash-flow exposure. This function alone is estimated at 0.5–1.0 FTE annually (1,000–2,000 hours).
- **Rebate reconciliation, denial management, and appeals -** Identification and resolution of unpaid or denied claims, coordination with manufacturers and vendors, and alignment with internal financial records. Estimated at 0.5 FTE annually (~1,000 hours).
- **Finance and accounting workload -** Tracking receivables, monitoring aged balances, and managing cash-flow exposure. Estimated at 300–500 hours annually.
- **Audit and compliance oversight -** Maintaining claim-level documentation and responding to audits. Estimated at 200–300 hours annually.

Systems and Infrastructure

In addition to labor costs, we anticipate increased expenditures related to IT systems, third-party vendors, legal review, training, and consulting services. Importantly, these costs would erode the financial benefits of the 340B program. Allina Health's current systems and protocols are designed to support upfront discount purchasing and do not currently capture or transmit all data elements required under a rebate model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems and would require:

- New or significantly modified IT infrastructure to support data extraction, claims submission, tracking, and reconciliation;
- Development of new interfaces with third-party administrators and manufacturers;
- Ongoing system maintenance and updates.

We estimate approximately $200,000 in system development and implementation costs, in addition to ongoing maintenance expenses.

A key challenge is that required data elements are often dispersed across multiple systems and are not currently integrated into vendor platforms. As a result, compliance would likely require significant manual intervention, increasing both cost and risk of error. This existing format is a

product of how the existing 340B program is structured, and further underscores how disruptive a rebate model would be to existing workflows.

Data Collection and Reporting

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. Contrary to those assertions, the data required under a rebate model are not currently submitted in a standardized or comprehensive manner through existing systems. Allina Health maintains 340B participation data internally and relies on third-party vendors for split-billing and contract pharmacy administration. A rebate model would require:

- New processes to aggregate and validate data across multiple systems;
- Additional data elements not currently captured or transmitted in existing workflows;
- Ongoing manual processes to reconcile discrepancies.

The breadth and sensitivity of the data required under a rebate model introduces significant new risks that are not present under the current 340B framework. To address privacy and security risks, any rebate model must include:

- Strong data-use limitations for clearinghouses and manufacturers specifying that data is only to be used for purposes of rebate qualifications;
- Business associate agreements (BAAs) governing data handling;
- Clear accountability for data, providing protections for covered entities in the event of a security breach.

Payment Timing and Cash Flow Impacts

A rebate model fundamentally transforms pharmaceutical participation obligations into unprecedented financial risk imposed on covered entities by requiring providers to purchase drugs at Wholesale Acquisition Cost (WAC) and await reimbursement through rebates. This effectively means that covered entities are providing drug companies with interest-free loans as we await the discounts that we are owed under the 340B statute. Under our current model:

- Drugs are purchased at or below the 340B ceiling price;
- Payment terms are predictable; and
- Cash outflows and inflows are closely aligned.

Importantly, prior assertions that “the rebate in most instances will be paid before the purchase invoice from a wholesaler for the WAC amount is due” are not consistent with our operational reality. Under our current wholesaler contracting structure, the vast majority of our pharmaceutical purchases—including both 340B and non-340B drugs—are subject to Net 7 payment terms. These terms apply uniformly across our accounts and are triggered by invoice date, not by

dispense activity, reimbursement, or manufacturer adjudication. As a result, payment obligations are fixed and must be met regardless of whether any rebate has been processed or received.

In limited cases involving specialty distributors or restricted distribution drugs - which represents a small portion of total purchasing volume - payment terms may extend to Net 30. However, these exceptions do not meaningfully offset the broader liquidity challenges introduced by a rebate model.

Under a rebate framework, eligibility for the 340B discount would only be determined after the drug is dispensed, data are compiled and submitted, and the manufacturer completes its validation and adjudication process. Any delays in data acceptance, claim rejection, or dispute resolution would extend the period between initial cash outlay and rebate receipt. Even if rebates are nominally paid within a defined window (e.g., 10 days after claim submission), the total time from drug purchase to rebate receipt would routinely exceed our invoice payment obligations.

Additionally, Allina Health participates in prompt-pay programs under which adherence to Net 7 payment terms generates meaningful cost-of-goods discounts from our primary wholesaler. These discounts are supported by the current chargeback system, which enables manufacturers to provide 340B pricing upfront. Transitioning to a rebate-based model would disrupt this structure. In the absence of chargebacks, wholesalers would effectively be financing inventory at WAC without manufacturer offset, and we anticipate this would result in less favorable pricing and reduced cost-of-goods discounts. Any such changes would represent a separate and material financial impact, compounding the liquidity challenges associated with delayed rebates.

Therefore, a rebate model would require Allina Health to consistently front the difference between WAC and the 340B ceiling price, creating a persistent and scalable liquidity gap. This gap would be particularly acute for high-cost and specialty drugs and would introduce significant volatility into cash-flow forecasting, as rebate timing would depend on multiple external entities and processes rather than a single, predictable wholesaler invoice.

Moreover, inventory management practices further exacerbate this issue. Pharmacies often purchase and hold drugs in advance of patient need, meaning that the time between acquisition and dispense may extend for days or weeks. In these scenarios, the timeline for rebate eligibility—and therefore reimbursement—would be further delayed, increasing the duration of financial exposure well beyond any stated rebate payment window.

For health systems operating with thin or negative margins, these changes would materially increase financial risk and could place pressure on key metrics such as days cash on hand. The cumulative effect of these factors demonstrates that **a rebate model would not merely adjust**

payment timing—it would fundamentally shift financing responsibility onto covered entities in a manner that is operationally unworkable and financially unsustainable.

Denials and Dispute Resolution

A rebate-based approach introduces a fundamental imbalance by allowing manufacturers to control payment determinations after the point of sale, exposing covered entities to heightened financial uncertainty and dispute risk. While we fundamentally disagree with this model, any rebate model must include strict guardrails governing manufacturer denials. At a minimum:

- Denials should be limited to clearly defined and narrow circumstances (e.g., verified duplicate discounts).
- Manufacturers should be required to provide standardized, claim-level documentation supporting any denial, including key identifiers such as NPI and prescription number.
- A standardized dispute resolution process with defined timelines should be established.
- HRSA must also require public reporting of manufacturer rebate denial rates to ensure transparency and accountability by all parties.

Critically, covered entities should not bear the financial burden of disputed or improperly denied claims during the adjudication process. A neutral data clearinghouse model would better allocate and distribute this risk.

Duplicate Discount Prevention and Alternatives

HRSA has already made clear that drug companies have other available options to address the need to deduplicate 340B and MDPNP pricing. Given the tremendous costs that a rebate mechanism will impose on Allina Health**,** HRSA should rely on those other options. Any other decision would impermissibly privilege the interests of drug companies over those of covered entities, their patients, and the communities they serve.

Likewise, we support the American Hospital Association's position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. In particular, we urge HRSA to adopt a third-party clearinghouse, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any other potential benefits. At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

Allina Health has implemented established, good-faith processes to prevent duplicate discounts across 340B, Medicaid, and MDPNP. These processes are embedded in our operational workflows and reflect ongoing coordination across multiple departments within our organization. Specifically, our organization:

- Implemented universal UD modifiers on all hospital claims where Medicaid is a payer, including when Medicaid is in the second or third position of responsibility;

- Conducts routine audits of our OPAIS records to ensure alignment between listed NPIs and active billing entities, with updates made as needed;
- Maintains regular coordination between our 340B team, reimbursement team, and credentialing staff to identify and reconcile any changes affecting program eligibility or claim designation.
- Applies the 20 DK modifier on outpatient prescription claims for our owned retail pharmacies, consistent with state Medicaid carve-in requirements.

Through these measures, Allina Health has developed a consistent and reliable framework to identify and prevent duplicate discounts. Importantly, these processes operate within existing claims and compliance workflows and do not require the extensive additional infrastructure contemplated under a rebate model.

A rebate model is not necessary to address duplicate discount concerns and would introduce significant additional complexity. Instead, we support the use of a neutral third-party clearinghouse as a more efficient and less burdensome alternative.

Adverse Impacts on Patients and Communities

The cumulative effect of increased administrative costs, staffing burdens, and financial risk would directly reduce the resources available for patient care. As a result, covered entities may be forced to scale back or eliminate certain patient support programs and reassess service line offerings, particularly those with high drug costs.

These impacts would disproportionately affect providers like Allina Health that serve a higher proportion of patients on Medicare and Medicaid and could reduce access to essential medications and services in the communities we serve. Our communities depend on us to be reliable partners beyond the walls of our facilities - our ability to be a trusted ally and resource, may be directly impacted if we lose the ability to capture upfront drug savings under the 340B Program.

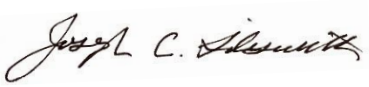
Conclusion

For all of these reasons, Allina Health respectfully submits that the costs of *any* Rebate Program will outweigh any expected benefits. Therefore, HRSA should abandon the concept altogether.

If, however, HRSA chooses to move forward with this effort, it must allow Allina Health and other covered entities to comment on the specifics of its new program. While we have endeavored to provide the most detailed information possible, we are doing so without precise knowledge of which drugs will be included in a Rebate Program and many other critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails).

On behalf of Allina Health, we appreciate your consideration of these comments and look forward to working with HRSA on this important issue. Please feel free to contact us with any questions.

Sincerely,



Joe Silversmith
Manager, Federal Government Relations and Regulatory Affairs
Allina Health

Contentnea Health
7 Professional Drive
Snow Hill, NC 28580

April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Contentnea Health is a Federally Qualified Health Center serving eastern North Carolina through eight sites across Greene, Pitt, and Pamlico counties. The organization provides compassionate, quality care through integrated medical, dental, behavioral health, student health, diabetology, pharmacy, and mobile health services, with a mission of delivering care every day for all. Contentnea Health also offers sliding fee scale assistance for qualifying patients, helping improve access to care for individuals and families across the communities it serves.

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 **37,000** 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**: **Contentnea Health** anticipates needing **1.25** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Contentnea Health** will face an increased administrative burden to monitor rebate claims and payments. **12 to 15 hours per week** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Contentnea Health** anticipates an additional **$103,000**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.

- **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 **37,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$624,474.00** annually.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.

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

- **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 **12 to 15** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 25 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 **25** 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, Pitt, and Pamlico 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]

II. Patient Impact

Contentnea Health has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[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.

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

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

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

- **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. **Contentnea Health provides access to affordable medications at our entity-owned pharmacy as well as contract pharmacies. As our pricing hinges on the cost of medications, a rebate program will make it difficult to establish pricing before the rebate is processed. If a rebate is denied, this could mean that the pharmacy would have dispensed at a significant loss.**

Conclusion

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

Contentnea Health appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Melissa Torres at mtorres@contentnea.org .**

Sincerely,

Melissa Torres
Chief Executive Officer
Contentnea Health

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

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 Community Health Net (CHN), we appreciate the opportunity to comment on the proposed information collection associated with the 340B Rebate Model Pilot Program issued by the Health Resources and Services Administration (HRSA).

CHN offers the following comments aligned with the Paperwork Reduction Act (PRA) evaluation criteria.

Necessity and Practical Utility

CHN supports appropriate oversight of the 340B Program; however, the proposed collection appears to require highly granular, claim-level data that may not be necessary to achieve program integrity, compliance monitoring, or evaluation objectives.

Much of the requested information is already maintained by covered entities in the normal course of pharmacy operations, claims adjudication, and 340B compliance activities. As such, HRSA could achieve its oversight objectives more efficiently by leveraging existing data streams and applying targeted or aggregated reporting approaches rather than requiring comprehensive prescription-level submissions across all dispensing channels.

CHN encourages HRSA to clearly define the purpose of each data element and ensure that the scope of collection is directly tied to a demonstrated program need.

Accuracy of Burden Estimate and Operational Impact

CHN believes the proposed burden is significantly underestimated. While CHN currently maintains systems and workflows to support 340B compliance, the proposed collection would require substantial new processes to extract claim-level data across disparate clinical, pharmacy, and third-party systems; re-format and standardize that data to meet submission requirements; and continuously reconcile submitted information against external feedback, including manufacturer responses.

These steps introduce ongoing administrative functions that are not fully automated within current infrastructure and would require additional staff time, system configuration, and sustained operational oversight. They also increase the risk of data inconsistency, reporting delays, and integrity issues due to manual intervention and cross-platform reconciliation.

Minimizing Burden

CHN encourages HRSA to adopt burden-reducing approaches that improve feasibility and consistency across participating entities. These include standardized submission formats, alignment with existing pharmacy transaction and claims processing systems, and reduced frequency or tiered reporting where appropriate.

Requiring covered entities to recompile and reformat information already generated through routine operations introduces unnecessary duplication and inefficiency. HRSA should prioritize interoperability with existing systems rather than creating parallel reporting structures.

CHN also notes that the cumulative administrative, staffing, and technology requirements associated with this collection may create a practical threshold at which participation becomes operationally and financially unsustainable for smaller safety-net providers. At that point, administrative costs risk outweighing program benefits, undermining the intended purpose of the 340B Program to support provider participation in serving vulnerable populations.

Confidentiality and Data Sensitivity

CHN requests clarification regarding how submitted data will be stored, secured, and accessed, including safeguards for prescription-level and operationally sensitive information. Given that the proposed collection may include HIPAA-sensitive data, CHN also requests information regarding limitations on third-party access, data sharing practices, and any secondary uses of submitted information, including manufacturer access or external redistribution.

Conclusion

Community Health Net appreciates the opportunity to comment on this proposed information collection. While CHN supports efforts to ensure program integrity, the current proposal introduces operational and administrative requirements that appear disproportionate to its intended purpose.

CHN is particularly concerned that, for smaller safety-net providers, the cumulative burden of this collection may reach a point where the cost of participation exceeds the benefit. This outcome would be inconsistent with the statutory purpose of the 340B Program, which is to enable covered entities to stretch scarce federal resources to serve more eligible patients and provide more comprehensive care.

In practice, the administrative and financial demands associated with this model could create significant cash flow challenges, forcing providers like CHN to make difficult decisions regarding staffing, service levels, and formulary availability. Compliance would also require substantial investment in information technology infrastructure and personnel to support expanded data extraction, validation, and reporting across multiple systems. These pressures risk introducing barriers for patients, particularly those who are uninsured or underinsured and rely on sliding fee scales and 340B-supported discounts, by limiting CHN's ability to provide timely and affordable access to medications.

We encourage HRSA to refine the scope of the collection, clearly define data requirements, and adopt burden-reducing mechanisms that ensure feasibility for safety-net providers while preserving program integrity.

If you have any questions, please contact the undersigned. Alternatively, inquiries may be directed to Craig Ulmer, Chief Executive Officer, at culmer@community-healthnet.com.

Sincerely,

On behalf of Community Health Net

Linda Pinnell
Email: lpinnell@community-healthnet.com

April 21st, 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 **Thrive Alabama,** 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, Thrive Alabama again requests that CHCs be exempted from the pilot program.**

Thrive Alabama is a nonprofit healthcare organization that provides compassionate, accessible, and comprehensive medical services to communities across North Alabama. It operates clinics in Huntsville, Florence, and Albertville, offering primary care, pediatrics, behavioral health, HIV prevention and treatment, STI care, case management, and supportive services.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **5,841** 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**: **Thrive Alabama** anticipates needing **2** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Thrive Alabama** will face an increased administrative burden to monitor rebate claims and payments. **15 hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Thrive Alabama** anticipates an additional **$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. **$50,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees**$100,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **6000 plus** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$150,000** annually.

The In-House Pharmacy: The Burden of IT Integration

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

Thrive Alabama operates 1 in house pharmacy. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **15 to 20** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 129 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 **129** 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 North Alabama, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

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

Most CADs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers. CHCs maintain limited inventories of CADs and typically do not separately bill on claims. Administration and inventory logs are commonly maintained on paper, with text documentation in patient visit notes describing what was administered. While CHCs maintain perpetual inventories and complete administrative records, paper records impose an additional burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs),

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

[3] Internal NACHC survey data

which are common in hospital EMRs. Where eMARs are available, they incur an additional cost and often require CHCs to pay for a standalone software system.

II. Patient Impact

Thrive Alabama 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,

[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

based on a patient's income and family size. **We do this by providing copay or premium assistance to our patients. We also are proactive at ensuring patients have discount of copay cards to assist with payments.**

Conclusion

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

Thrive Alabama 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 **Stephanie Harville at sharville@thrivealabama.org.**

Sincerely,

Mary Elizabeth Marr
CEO
Thrive Alabama

Community Health Centers

April 26, 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 **Community Health Centers of the Central Coast,** I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Community Health Centers of the Central Coast again requests that CHCs be exempted from the pilot program.**

- The 340B Program enables covered entities, such as Federally Qualified Health Centers, to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The 340B Program is beneficial for CHC. Our patients benefit from reduced drug pricing, and cost savings allow CHC to invest in expanded patient services. The 340B Program, after all program expenses (drug costs,related 340B staff salaries and all other related expenses) were deducted, providing additional savings which have allowed CHC to realize its mission of providing quality health care services to the medically underserved community. CHC serves more than 120,000 patients in San Luis Obispo and northern Santa Barbara Counties. The 340B Program has been able to benefit the majority of these patients. Examples of programs that will be made possible through the use of 340B funds are described below:
- CHC provides free nutrition and disease prevention and management education through regularly scheduled classes. The curriculum covers chronic condition education, proper nutrition, exercise, and healthy lifestyle choices.
- In addition to group education, CHC's registered dietitians and health educators provide individualized nutrition and lifestyle counseling to support disease prevention and management. These services help patients achieve healthy weight goals, manage chronic conditions, and make sustainable behavior changes that promote overall well-being.
- CHC also offers educational sessions for staff on integrating these benefits into the Patient-Centered Medical Home model of care, reinforcing coordinated, preventative, and whole-person health services.

- With an aging population, there are plans to place more emphasis on services for seniors. These serviceswill be developed and using funds from the 340B program, will be offered at low or no cost to insure affordability. These services will include audiology, optometry, selected diagnostic testing, behavioral health, and transportation services.
- CHC will enhance their current telemedicine capabilities by investing in equipment and expanding their telemedicine provider network. This will help CHC deliver a more robust selection of specialty services,which will be capable of reaching more rural areas. CHC will also pilot Remote Patient Monitoring (RPM) systems and invest in RPM equipment for populations experiencing chronic disease.

Transportation Services

CHC provides/pays for transportation for underserved populations who lack transportation to obtain health care at CHC facilities. Transportation is necessary for all patient populations especially as many of our patients live in rural areas with decreased access to public transportations.

Population Health

CHC uses population health software to improve patient outcomes by aggregating data from electronic health records (EHRs), claims, and social determinants of health (SDOH) to identify high-risk groups, close care gaps, and enable proactive and personalized interventions. CHC uses this approach to reach out to CHC's sickest patients and improve health outcomes.

Outreach Program

Community Health Centers of the Central Coast (CHC) operates a robust community health outreach program aimed at closing the gap in healthcare access for disadvantaged communities on the Central Coast. The CHC Outreach Team provides mobile healthcare outreach services and health service linkage for agricultural workers, the homeless, public housing residents, students, veterans, immigrants, refugees, and other medically underserved and uninsured community members:

- Collaborating with local Community Based Organizations (CBOs) to provide healthcare resources and care linkage to food distribution centers, low-income and public housing sites, community parks, places of worship, public schools, and agricultural worker housing sites;
- Providing mobile medical healthcare services for agricultural workers throughout Northern Santa Barbara and San Luis Obispo Counties, in collaboration with local employers, public health departments, Spanish language radio stations, and other CBOs;
- Providing mobile medical healthcare services (immunizations, hearing, and vision testing) at local schools in Northern Santa Barbara and San Luis Obispo Counties;

- Conducting Medi-Cal/Health Insurance enrollment and outreach to connect uninsured community members with assistance in attaining, maintaining, or renewing their health coverage; and
- Providing mobile dental clinics in rural communities, local schools, and homeless shelters to provide preventive dental care services to children and their families.

CHC continues to strengthen its Outreach Program to facilitate access to quality healthcare and address the health equity needs of patients outside of traditional clinic settings. Through its efforts, the CHC Outreach Team brings critical services and information directly to community members to ensure that healthcare services are available to all. The CHC Outreach Team will continue to respond to community needs based on a community needs assessment and other tools tailored to the needs of the diverse populations being served with in Northern Santa Barbara and San Luis Obispo Counties.

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from the National Association of Community Health Centers (NACHC) and our own internal assessments, the hours and dollars spent complying with a rebate program are staggering.

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **124,834** 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**: **Community Health Centers of the Central Coast** anticipates needing **an** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Community Health Centers of the Central Coast** will face an increased administrative burden to monitor rebate claims and payments. **40hrs/week** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Community Health Centers of the Central Coast** anticipates an additional **$100,000** 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. **$25,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **124,834** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$170,000** annually.

The In-House Pharmacy: The Burden of IT Integration

Community Health Centers of the Central Coast operates a single in-house pharmacy. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **One-Time Integration Costs:** We anticipate high upfront costs ($10,000) 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 **6** 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 86 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 **87** 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 San Luis Obispo and Northern Santa Barbara 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

Community Health Centers of the Central Coast 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

[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)

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.

Conclusion

Community Health Centers of the Central Coast strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **Community Health Centers of the Central Coast** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

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[6] HRSA FAQ

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

Community Health Centers of the Central Coast 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 **Derek Yip (derek.yip@chccc.org)**

Sincerely,

Ron E. Castle
Community Health Centers of the Central Coast

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April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Erie Family Health Centers, 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, Erie Family Health Centers again requests that CHCs be exempted from the pilot program.

Erie Family Health Centers (Erie) is a Federally Qualified Health Center (FQHC) with fourteen locations in Chicago and the surrounding suburbs. Erie provides high-quality medical, dental, and behavioral healthcare to all who need it, regardless of their ability to pay. Erie serves approximately 96,000 patients annually. In fiscal year 2025, Erie served patient pharmaceutical needs through 123,531 individual 340B transactions. Community Health Centers, including Erie, participate in the 340B Drug Pricing Program (340B Program) as a vital means of making prescriptions affordable for our low-income patients, while also providing financial support for the care provided by the health center. At Erie, we reinvest every penny of 340B savings into expanding care for our medically underserved patients. Law, regulation, and mission require us to utilize 340B savings to provide more comprehensive care to a greater number of eligible patients. Erie patients have chronic conditions, exacerbated by economic challenges. We know that improving health outcomes depends on Erie providing comprehensive care and case management, integrated psychiatry services, behavioral health services, dental care, health coaches, and a range of other essential services. Without 340B savings, Erie would not have the funds to support these programs – many of which are not reimbursed. Community Health Centers are proud of our reputation as good stewards of the 340B

program, and we appreciate this opportunity to provide feedback on the 340B Rebate Model Pilot Program.

The proposed 340B Rebate Model Pilot Program poses a fundamental challenge to the mission of Community Health Centers (CHCs) and departs significantly from the program's original purpose. For over three decades, the 340B Drug Pricing Program has helped CHCs secure outpatient medications at steep discounts, allowing them to expand access to affordable, and in some cases no-cost, treatment for millions of underserved and uninsured individuals. Congress established the program with the clear goal of enabling safety-net providers to "stretch scarce Federal resources as far as possible." The rebate model threatens to erode this foundation by imposing substantial financial strain on CHCs such as Erie.

I will address each of the four areas in which HRSA has requested comments in the Information Collection Request (ICR).

NECESSITY AND UTILITY OF THE PROPOSED INFORMATION COLLECTION FOR THE PROPER PERFORMANCE OF THE AGENCY'S FUNCTIONS

Issues with the Pricing Structure in the Pilot

Unfortunately, a rebate model will likely make it extremely challenging for CHCs to adhere to their long-standing policy—and President Trump's expectations—that they pass on 340B savings to low-income patients. This is because standard pharmacy software displays only one price per NDC code, the price charged by the wholesaler. To date, this has always been the 340B price, but under a rebate model, our wholesaler catalog price will switch to the WAC price. As a result, if we are subject to the rebate pilot, pharmacy staff and software systems will no longer have access to the 340B price, and without this information, cannot pass 340B savings onto low-income patients at the point of sale, because they do not know what the savings are. There is no easy or quick technical fix to this issue as it is an inherent flaw in the rebate model structure. Due to Erie's extensive urban service area of over 200 zip codes and lack of an entity-owned pharmacy, Erie is entirely reliant on contract pharmacies for 340B access. With current systems and software, it is not operationally feasible to offer 340B cash discounts at the point-of-sale under a rebate model because the software will not know the 340B ceiling price, particularly at contract pharmacies. Additionally, offering upfront 340B discounts to uninsured patients will now expose Erie to significant risk if subsequent rebates are denied. Any form of a rebate model pilot program does a grave disservice to the millions of low-income patients served by our nation's community health centers. This is because a rebate model prevents health centers like Erie from operationalizing point-of-sale cash discounts due to the inherent risk of not receiving a rebate payment. As noted, since its inception, Congress did not intend for the 340B Program to be subject to manufacturer-driven rebates nor was it intended for covered entities to face such financial and operational burdens.

Rebate Model Structure Creating Unstainable Cash Flow Implications for Covered Entities

Erie is especially concerned that having to purchase medications at full wholesale acquisition cost (WAC) could strain cash flow, exceed our credit limits with wholesalers, and stress our payment processing and financial processes organization wide. Although rebate payments are projected in the RFI document to be issued within 10 days of complete data submission, covered entities cannot be expected to submit detailed claims data every day; thus, the previous version of the pilot allowed up to 45 days for submission. As a result, the total time between dispensing a medication and receiving the rebate could stretch to as long as 55 days. To align with the current manufacturer contract pharmacy restriction administrative burden, Erie would likely submit rebate data every two weeks. Submitting data every other week would mean Erie waits between 11 and 25 days for a rebate payment, assuming everything goes smoothly.

Our national organization, NACHC, created a calculator to help us assess the anticipated financial impact of a rebate model, specifically for Erie. Financial data and projections utilize CHC-specific purchasing data, 340B and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of Medicare Drug Price Negotiation Program (MDPNP) selected drugs by NDC. Based on our organization's data, we estimate it would cost Erie $520,000 monthly to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends $20,000 per month to purchase these same drugs at the 340B ceiling price. This represents a 2,500% increase in upfront capital required to purchase 340B drugs under a rebate model.

Erie cannot easily absorb a $500,000 increase in drug costs each month. We would be forced to make hard decisions, such as scaling back crucial services noted above, such as comprehensive care and case management, integrated psychiatry services, behavioral health services, dental care, health coaches, and a range of other essential services.

Erie currently receives 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 cannot disclose their exact prompt-pay discount. However, Erie estimates its 2027 annual rebate opportunity cost to nearly $1.3 million. This cost aggregates the estimated financial impact of rebate denials and loss of wholesaler purchase discounts.

Each dollar spent upfront at WAC becomes tied up in the manufacturer's reconciliation process, effectively limiting access to those funds. While awaiting rebate payments, we lose the financial flexibility needed to respond quickly to urgent public health needs or unexpected operational issues. To manage under a rebate structure, our organization would have to draw from already limited reserves. This kind of financial strain would quickly ripple through our operations, resulting in fewer available services, and a diminished capacity to offer the deeply discounted medications our patients rely on.

THE ACCURACY OF THE ESTIMATED BURDEN

The shift to a rebate-based model would significantly increase Erie's operational demands, particularly in tracking rebate activity and ensuring accurate payment reconciliation. Erie has robust internal 340B personnel resources, but a change of this magnitude has required additional consulting support and many hours of educational webinars. Since August 2025, Erie has spent over $7,000 on consulting services specifically related to the proposed rebate model. Erie projects that submitting 340B rebate data through an external platform and monitoring payments will take roughly **20 hours per week**, assuming the manufacturers have relatively similar processes and platforms. This is four times the "average burden per response" estimated in the ICR. To absorb this additional workload, Erie anticipates the need to expand its 340B team. Erie plans to add an additional staff resource (**0.5 FTE**) to our 340B team, focused entirely on managing rebate-related responsibilities. The estimated annual expense for this additional staffing resource is $**50,000**. This increased administrative overhead and additional staff resources would pull capacity away from essential management of the program.

In anticipation of the previous 340B Rebate Pilot Program, Erie's clinical and pharmacy support staff had to spend dozens of hours to educate more than 700 patients and hundreds of our providers about the pending loss in 340B pricing at our largest 340B contract pharmacy partner, Walgreens. Specifically, Erie's staff was required to execute this patient and prescriber training and communication plan within just a few weeks since Walgreens announced that they were removing 340B pricing on the drugs in-scope for this rebate program by December 23, 2025. Then compounding this complication for our patients and providers was that after the Federal Court in Maine issued an injunction to pause this previous rebate program, Erie's staff during the New Year's holiday week had to inform these 700+ patients and all of our providers that for the time being, patients would have to access to 340B pricing for these drugs at Walgreens. The rapid back-and-forth among patients, providers, and pharmacies created a chaotic environment for our patients, providers, and administrative staff. We believe this rebate-related disruption may have caused gaps in patients' access to their medications. This effort will again be required to move forward with a new pilot as well as ongoing patient education if a rebate model is adopted.

WAYS TO ENHANCE THE QUALITY, UTILITY, AND CLARITY OF THE INFORMATION TO BE COLLECTED

<u>Rebate Model Requiring Unnecessary BIN and PCN Data</u>

If HRSA moves forward with a rebate model, it should be limited to retail pharmacy claims to avoid unnecessary disruption where no risk of overlapping with Medicare Drug Price Negotiation Program (MDPNP) exists. For example, expanding the model to clinic-administered drugs (CADs) would add a significant administrative burden without advancing the pilot's goals. Health centers such as Erie typically do not bill CADs as individual drug claims and often lack the electronic data needed

for rebate processing. We have auditable records demonstrating that all CADs were administered or dispensed to eligible patients, but the data is not in a format ready for electronic submission to a rebate platform. Applying a rebate model to medical claims would require entirely new systems, workflows, and ongoing costs, greatly complicating our compliance efforts.

Data elements required for a rebate model should be strictly limited to the absolute bare minimum to accomplish the goal of deduplication with the MDPNP. CMS, in its 2026 physician fee schedule rule (FRN 2025-13271, page 32643), proposes establishing a CMS 340B repository to receive 340B claims data from covered entities, for the purpose of excluding 340B claims from the rebate calculations that are called for under the 2022 Inflation Reduction Act. CMS has identified the data elements needed for that purpose. The CMS-identified data elements are as follows: (1) Date of Service, (2) Prescription Number, (3) Fill Number, (4) Dispensing Pharmacy NPI, and (5) NDC-11. As you can see, BIN and PCN are not required data elements for the CMS repository, and CMS can match claims without them. If the premise of the rebate model is to deduplicate between MFP and 340B, the platforms and the manufacturers should be able to accomplish that aim without BIN or PCN. If allowed to proceed as proposed, a rebate model pilot program that required BIN/PCN would have the same disastrous impact as contract pharmacy restrictions, because it would mean that covered entities using Walgreens contract pharmacies would not be able to participate in the rebate mode because covered entities like Erie would not have the information needed to be able to comply with the BIN/PCN requirement.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Model Pilot Program

Participating in this pilot would demand more than additional personnel—it would necessitate substantial modifications to pharmacy systems and Third-Party Administrator (TPA) processes. Erie urges HRSA to account for the heightened compliance challenges that arise when manufacturers are permitted to set differing data submission requirements and formats. Furthermore, if manufacturers continue to use separate software platforms, as is common under current contract pharmacy arrangements, CHCs will face a significantly heavier administrative load managing multiple systems and workflows.

We do not yet know what additional service costs our contract pharmacy partners and TPAs will charge under a future rebate model, but we do know the real financial harm that Erie faced immediately prior to the Rebate Model Pilot Program's pause on December 31, 2025. Our largest contract pharmacy partner is Walgreens. Our service area includes Chicago and the surrounding suburbs, and most of our patients choose to fill their prescriptions at Walgreens. Erie has built our longstanding 340B contract pharmacy relationships with Walgreens to provide access and break down barriers that might otherwise prevent patients from accessing affordable drugs. Prior to the pause, Walgreens (and its TPA 340B Complete) were not ready to operationalize a rebate model and we were forced to exclude the ten rebate model drugs across all payers, not just Medicare Part D, but also commercial and uninsured patients. During the lead-up to the original rebate model pilot, tens of thousands of Erie patients were no longer able to access an upfront discount on one of the ten rebate

model drugs, should they need that treatment. Beyond the harmful impact on uninsured patient access, **Erie stood to lose $86,000 per month ($1,032,000 annually)** in 340B savings, all because the TPA systems were unable to respond, react, and reconfigure to meet the extraordinarily different technology needs of a rebate model.

Inconsistent requirements and the absence of a standardized approach across manufacturers will likely require Erie to rely on multiple internal systems to track, manage, and report identical data, driving up costs and complicating operations. To reduce these challenges, Erie strongly encourages HRSA to establish uniform requirements for participating manufacturers to mitigate both the administrative workload and financial strain associated with securing timely and accurate 340B rebate payments.

Risks of Rebate Denials and Ways to Partially Reduce Their Impact

Although the request for information (RFI) text implies that rebate denials *could* be limited and that the manufacturer *could* be required to provide rationale and documentation for such denials, we have no assurance that this would be the case. Erie implores HRSA that if any rebate model is allowed to move forward, manufacturers and their rebate platforms must have very specific guardrails around when it is appropriate to deny a rebate request.

Any rebate denials must follow existing statutory and regulatory guidance. Rebate requests should be assumed valid unless a manufacturer can clearly prove, with claim-level evidence, a specific legal reason to deny them.

Right now, manufacturers and their vendors, Beacon Channel Management and 340B ESP, provide very little transparency into internal workings and decisions occurring on the product's backend. We understand that under the current MFP Refund process, denials are often based on vague, unpublished standards. It is unfair and inappropriate to allow manufacturers to determine the reasons for denying rebates; they must be constrained to clearly articulated, tightly limited specific scenarios consistent with 340B rules and regulations. We can think of only two appropriate scenarios in which a manufacturer would deny a rebate. One would be if another covered entity had already received a rebate on that exact claim; that would be an appropriate reason to deny a rebate. The only other appropriate scenario we foresee is if a State Medicaid agency has already received a MDRP rebate on a Medicaid Fee-for-Service claim; however, a rebate model should not become the primary method for avoiding duplicate discounts, as there are already processes in place for that.

For any questions related to possible Medicaid Managed Care (MCO) duplicate discounts, those items should be worked out between the manufacturer and the State, as part of their current processes, and should not be grounds for rebate denial. In HRSA's 1996 Manufacturer Audit Guidelines, manufacturers already have established processes for requesting and conducting good-

faith inquiries and audits of covered entities, and they should not be given the power to deny rebates to circumvent the established program integrity guidelines.

Manufacturers are already requiring many claims data elements to be submitted through vendor platforms (e.g., 340B ESP™ and Truzo™) as a condition for health centers to continue serving patients through contract pharmacies, which has been extremely difficult for Erie and other health centers. Our team spends hours each week uploading data, fixing ongoing issues, and working with consultants just to manage reporting requirements. The administrative burden is significant, and even centers that try to comply often lose access to 340B pricing, not because they failed to comply, but because the process itself is overly complex and hard to manage. We fear that a future rebate model platform will have some of those same challenges, if not more.

There should be a clear process for resolving situations where a health center's submitted data doesn't match the manufacturer's calculations. From our experience with 340B ESP, some manufacturers seem to misunderstand the range of compliant inventory models, such as virtual replenishment of dispensed drugs. Manufacturers often expect to see purchase first, then claims. Under a virtual replenishment model, the order of those dates is reversed. Another very significant challenge is that the vendor systems compare claims and purchase data at the pharmacy store level rather than the chain level. For example, if a health center has 10 Walgreens contract pharmacies, the health center aggregates prescription dispenses across those 10 stores and then replenishes the full package to a single store, but they will be penalized by 340B ESP™ for this very normal inventory method. Because manufacturers and health centers use different methods, their view of the numbers can differ even when the health center is fully compliant. When this happens, manufacturers have been known to block us from buying at 340B prices until we meet their unclear data submission standards – which sometimes is impossible to do, or the expectations keep changing.

Manufacturers should be required to report to HRSA the percentage of rebates paid within ten days of data submission, as well as a detailed breakdown of each rebate denial rationale, available in aggregate and by covered entity type.

THE USE OF AUTOMATED COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY TO MINIMIZE THE INFORMATION COLLECTION BURDEN

Manufacturers often state that a rebate model is necessary to avoid duplicate discounts. Erie is committed to avoiding duplicate discounts. We do not have any in-house pharmacies, but across all our contract pharmacies, we exclude Medicaid FFS from our 340B program, and we carefully audit 100% of our claims each month to ensure no Fee for Service (FFS) Medicaid claims slip through our guardrails. In the clinic-administered setting, we apply the UD modifier when billing Medicaid for a 340B drug and regularly self-audit to ensure its proper application.

It is a false premise to say that a rebate model is necessary to address the issue of MDPNP nonduplication. That is simply not true; a rebate model is not the only option. There are other options that would be far less burdensome and financially taxing for health centers. A clearly superior alternative to a rebate model is a neutral claims clearinghouse.

An alternate technological approach to a rebate model – a neutral claims clearinghouse – can achieve accurate deduplication at far lower cost and with far less administrative strain. In this model, covered entities would submit standardized claims data for each 340B drug dispensed to Medicare Part D patients. The neutral clearinghouse would compile this information and provide it to the Medicare Transaction Facilitator (MTF) and manufacturers to identify potential duplicate discounts. A neutral claims clearinghouse would maintain upfront 340B discounts, avoiding cash-flow challenges for CEs and enabling Erie to continue offering discounted drugs to eligible patients at the point of sale. It would significantly reduce administrative burden by removing the need for complex tracking, reconciliation, and compliance systems. A neutral clearinghouse would supply manufacturers with accurate deduplication data on a regular, timely schedule.

We believe that the minimum data elements necessary for a manufacturer to identify potential duplication are Date of Service, Prescription Number, Fill Number, Dispensing Pharmacy NPI, and NDC-11-- the same data elements that CMS identified under the 2022 Inflation Reduction Act, as described above.

CONCLUSION

As noted throughout this letter, there are issues with both the necessity and the utility of the proposed information collection that would impede the proper performance of HRSA's functions rather than assist. If this rebate model pilot moves forward, Erie would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates at least four times the estimated burden of five hours per week. I have noted several areas where the process could be improved, but we firmly believe that implementation of the rebate model will leave the 340B program in a worse place than it is today, and that an alternative technological approach to address issues within it should be pursued instead. 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. Erie Family Health Centers believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, and services. If HRSA still intends to move forward despite the numerous issues, Erie Family Health Centers strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program.

Thank you for soliciting feedback on the pilot program through this Information Collection Request. If you have any questions, please contact me at dbruce@eriefamilyhealth.org.

Sincerely,

David C. Bruce
Authorizing Official In-Charge of 340B Program
Erie Family Health Centers

CCALAC
Community Clinic Association of Los Angeles County

MEMBER DRIVEN. PATIENT FOCUSED.

April 27, 2026

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

Submitted via paperwork@hrsa.gov

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 the Community Clinic Association of Los Angeles County (CCALAC) and our 68 nonprofit community health center (CHC) member organizations, we appreciate the opportunity to comment on HRSA's Information Collection Request (ICR) regarding a potential 340B rebate model pilot program. CHCs provide high-quality, mission-driven health care services to over 2 million patients at nearly 600 sites throughout Los Angeles County.

The 340B program is foundational to CHC's ability to serve their patients and communities. 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, the hours and financial resources that would be spent complying with a rebate program are staggering. CCALAC echoes the comments submitted by the National Association of Community Health Centers (NACHC) and urges the administration to exempt health centers from the pilot program. This letter is intended to supplement comments and information submitted by CCALAC member health centers, which provide specific data in response to the ICR.

I. CCALAC requests that HRSA exempt CHCs from the 340B rebate model pilot program due to significant financial and administrative burden.

This model would require CHCs to purchase medications at full price and wait for rebates, which would cause significant financial turmoil and directly affect Los Angeles County health centers' ability to serve over 2 million patients that rely on them. CHCs operate on razor-thin margins; 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. CHCs will face an increased administrative burden in monitoring rebate claims and payments. 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

CHCs will need additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative and additional staffing burden to monitor rebate claims and payments. Extra time will be required to report 340B rebate claims to a third-party platform. Not only will CHCs have to absorb extra internal staffing costs, they will also have to pay for external support and 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 will require significant changes to workflows and software. HRSA should consider the increased compliance burdens of allowing manufacturers to have flexibility to require varying data submission standards and elements. If manufacturers can select different software platforms, like current contract pharmacy policies, the CHC administrative burden increases substantially. CHCs will see high upfront costs to adapt their pharmacy software, pay for custom dashboard modifications, and design new internal workflows. After implementation, CHCs' TPA and software vendors will likely charge ongoing service fees to maintain rebate-tracking features. These permanent, recurring costs diminish 340B savings.

In-House Pharmacies: The Burden of IT Integration

The rebate model is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter. Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. CHCs will see high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. Staff who currently manage clinical pharmacy services will be forced to spend time manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

Contract Pharmacies: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. CHCs' TPAs will pass on the costs of developing rebate-tracking modules to CHCs through increased per-claim fees. The rebate model creates a reconciliation gap. CHC staff will need to monitor claims across different pharmacy locations to ensure rebates are paid correctly. 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.

Clinic Administered Drugs: The Burden of New Systems

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.[1]

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

[1] Internal NACHC survey data

administrative records, there will be an additional burden of converting paper records 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

CCALAC has significant concerns about the impact a 340B rebate model pilot would have on 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.[2] 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,[3] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing patients with low incomes 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, as outlined below.

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. CHCs are particularly concerned that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them 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.[4] In line with their mission, CHCs offer flat or sliding-

[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.
[3] 2025 UDA Data, HRSA (hrsa.gov)
[4] HRSA FAQ

scale discounts on prescription drugs to make them more affordable for low-income individuals.[5] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

Conclusion

CCALAC 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 those who are uninsured, 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. CCALAC believes that a 340B rebate pilot would cause disproportionate harm to CHC patients.

Thank you for your consideration and we look forward to continuing to engage with HRSA on this issue.

Sincerely,

Joanne Preece, MPH
Director of Government and External Affairs

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

April 14, 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: LGBT Life Center Comments in Response to: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Information Collection Request Federal Register Notice

Dear Director Miller:

LGBT Life Center appreciates the opportunity to submit comments 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 so highly burdensome. In the FRN and in its previous Rebate Model Pilot Program ICR, HRSA drastically underestimates the burden of such a collection, and fails to consider less burdensome alternatives that would enhance the collected information.

As demonstrated by the data and information we provide below, we are deeply concerned about the tremendous administrative and financial burdens a rebate model would place on our patients, our organization, and other covered entities. We respectfully urge HRSA to refrain from implementing a Rebate Model Pilot 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.

The proposed 340B Rebate Model presents significant financial and operational risks for safety-net providers. Requiring covered entities to purchase medications upfront at Wholesale Acquisition Cost (WAC) and await reimbursement would create immediate cash flow challenges, potentially limiting the ability to consistently procure essential medications. For organizations already operating with constrained resources, this shift could destabilize day-to-day operations. Loss or delay of 340B savings would directly impact the ability to sustain critical wraparound services that support patient care, including copay assistance, transportation, food access, and other enabling services. These programs are essential to ensuring patients can access and adhere to treatment, and reductions in these services would likely lead to decreased medication adherence, poorer health outcomes, and increased disparities. The model also introduces broader public health concerns. Interruptions in access to affordable medications for individuals living with HIV and those at risk of sexually transmitted infections could increase transmission rates and reverse progress made in prevention and treatment efforts. Additionally, these impacts would place further strain on local healthcare systems. Overall, while the intent of the rebate model may be to improve oversight or access, it does not align with the operational realities of safety-net providers and risks undermining the very populations the 340B program is designed to support.

LGBT Life Center is a Ryan White and STD-funded safety-net provider serving individuals living with HIV and those at risk of or affected by sexually transmitted infections. As a qualifying covered entity under the 340B Drug Pricing Program, the organization leverages 340B savings to expand access to **care**

beyond clinical services, including medication affordability programs, prevention services, and essential support such as transportation and food assistance. These savings are reinvested directly into patient care and public health initiatives, making the 340B program a critical component of sustaining comprehensive, equitable healthcare services for a vulnerable population.

HRSA's Rebate Model Pilot Program Proposal is Unnecessary and Untenable

Financial Impact of Increased Drug Acquisition Costs

A Rebate Model Pilot will increase covered entities' drug acquisition costs because we will lose the upfront 340B price reductions and subceiling discounts that we receive at the time of purchase. We will be forced to pay wholesale acquisition cost for drugs at the point of sale and face the uncertainty of obtaining a rebate in the future. This process places a cash flow strain on our already under-resourced organization and threatens our ability to provide patients with upfront discounts on their medications at the point of sale.

Implementation and Administrative Burden

For the last 30 years, covered entities and their vendors partners have developed sophisticated technologies and workflows to manage the complexities of 340B compliance and operations. These carefully crafted systems are built on the premise that entities receive 340B ceiling prices as upfront discounts. Converting 340B into a rebate program completely upends these systems, poses substantial implementation and managements costs, and does nothing to improve 340B compliance or operations. Covered entities will have to make significant upfront and ongoing financial investments in technology, staff, and redesigning workflows to accommodate a rebate program. Worst of all, these investments will diminish covered entities' ability to care for their patients.

Some RWCs are also federally qualified health centers (FQHCs) and participate in 340B as FQHCs. The administrative burden of a rebate model would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when uploading data to manufacturer platforms. If HRSA were to advance its rebate model, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

HRSA's Burden Estimation Drastically Underestimates the Effort to Implement the Rebate Model

A Rebate Model Pilot Program, by its very nature, will significantly increase our organization's drug acquisition costs because we will lose the upfront 340B price reductions and subceiling discounts that we currently receive at the time of purchase. We 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 our already under-resourced organization. HRSA has not accounted for this additional cost. Nor has the agency accounted for additional upfront costs to implement a Rebate Model Pilot Program like additional staffing or purchasing of additional equipment to implement the model.

HRSA failed 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 Rebate Model Pilot Program requirements. In the FRN, HRSA justifies its low burden estimate for the Rebate Model Pilot Program 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. To help HRSA adequately evaluate the Rebate Model Pilot Program costs, we have presented our estimate of the impact that the Rebate Model Pilot Program would have on our organization below.

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	**Time Estimate per Claim**
Time Spent Reporting Rebate Claims	7200	12-17 minutes

HRSA Failed to Consider More Efficient Rebate Model Alternatives

Listing all Viable Alternatives

HRSA has proposed various Rebate Model Pilot Program iterations since July 2025 to prevent 340B-Medicare Part D inflation rebate duplicate discounts. Despite public comments describing the burdensome nature of the rebate model, HRSA has failed to consider any more efficient rebate model alternatives such as: implementing a neutral clearinghouse, prospective maximum fair pricing, or use of a modifier to delineate 340B claims.

* * *

We appreciate HRSA’s consideration of our comments. For further information, please contact For further information, please feel free to contact me, at creybrouck@lgbtlifecenter.org or at 757-640-0929.

Sincerely,

Christopher Reybrouck
Senior Director, Strategy & Operations
LGBT Life Center

open door
Community Health Centers

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☐ **Burre Dental Center | Mobile Dental Services**
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☐ **Ferndale Community Health Center**
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Ferndale, CA 95536
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☐ **Fortuna Community Health Center**
3304 Renner Drive
Fortuna, CA 95540
707-725-4477

☐ **McKinleyville Community Health Center**
1644 Central Avenue
McKinleyville, CA 95519
707-839-3068

☐ **Mobile Health Services | Telehealth & Visiting Specialists Center**
2426 Buhne Street
Eureka, CA 95501
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☐ **Plaza Community Health Center**
770 10th Street
Arcata, CA 95521
707-630-5177

☐ **Redwood Community Health Center**
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Medical 530-629-3111

April 15, 2025

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

RE: Request for Information: 340B Rebate Model Pilot Program (HRSA-2026-03042)

Dear Director Britton:

On behalf of Open Door Community Health Centers, thank you for extending the comment deadline to April 20, 2026. This additional time has allowed our organization to more fully assess the operational and financial risks posed by the proposed 340B Rebate Model Pilot Program to Community Health Centers (CHCs).

The 340B program is foundational to CHCs' ability to serve low income, uninsured, and medically underserved patients. Shifting responsibility for 340B pricing from manufacturers to safety-net providers through a rebate model -represents- a fundamental change to a program that has functioned effectively for more than 30 years. Based on national assessments from NACHC, CHCs are already experiencing significant impacts from manufacturer restrictions, which the proposed pilot would compound:

- **Financial Losses:** CHCs are projected to incur average annual losses of at least **$500,000, with potential losses reaching up to $1.6 million** in entity-owned- pharmacy operations and **$400,000–$1.5 million** in contract pharmacy savings due to manual reconciliation requirements.
- **Projected Cost Increases:** A single mid-sized CHC is projected to incur more than $3 million in annual operating costs under a rebate model.
    - **Rural Impact:** Rural Health Centers invest approximately **25% of their 340B savings** in rural-specific infrastructure, such as mobile clinics and telehealth, making the rebate model particularly harmful to rural communities.

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

The proposed 340B Rebate Model Pilot is a direct threat to CHCs' mission and a significant departure from the original intent of the 340B Drug Pricing Program. Congress designed

Patients relying on:

- **Direct oral anticoagulants (DOACs)** (e.g., Xarelto® and Eliquis®),
- **SGLT2 inhibitors** (e.g., Farxiga® and Jardiance®),
- **Behavioral health medications** included in the 2027 MDPNP list, and
- **Insulin**, required by federal mandate to be available at discounted rates,

would face significant access barriers under a rebate model. In the case of insulin, the rebate structure directly conflicts with **Executive Order #14273**, as there is no operational method to provide discounted insulin at the point of care when drugs are purchased at WAC.

Without upfront 340B pricing, CHCs cannot reliably offer sliding fee discounts as required by law. This model would create new barriers for uninsured patients and weaken the safety--net- that millions depend on for affordable medications.

III. Administrative Complexities and Financial Challenges for CHCs

The proposed pilot would impose significant new administrative and IT burdens on CHCs, duplicating existing compliance systems without corresponding benefits. CHCs would need to manage:

- Multiple manufacturer data submission standards,
- Non-standardized- timelines for rebate reconciliation,
- Dispute resolution processes for denied rebates, and
- Increased staffing and vendor support to maintain compliance.

Operational & Administrative Cost Impacts

Open Door Community Health Centers estimates:

- **$177,000** in sliding fee discounts provided in 2025 may be reduced in 2026
- **Two additional FTEs** required, increasing costs by **$264,000 annually**
- **$25,000 annually** in additional vendor costs
- **92 hours per month** required solely for rebate reporting activities

These costs divert resources away from patient care and strain already limited operational capacity.

A. Financial Challenges

Purchasing drugs at full WAC fundamentally disrupts CHC cash flow and creates extended reimbursement delays—often **40–85 days** from purchase to rebate receipt. During this

period, CHCs must carry the full cost of inventory, risking credit limit exhaustion and loss of supplier access.

For **Open Door Community Health Centers, this would mean**:

- Drug purchases for the selected MDPNP drugs would increase from 340B Pricing of **$50,000** to WAC pricing of **$5.7 million in 2026 with an annual interest rate fee of $362,000**
- The proposed drug list for 2027 will increase upfront WAC costs to $**11.6 million**
- The proposed drug list for 2028 will increase upfront WAC costs to **$14.3 million**

These costs are unsustainable and would necessitate reductions in clinical services, clinic hours, clinical staffing, and patient financial assistance programs. As one of the largest employers and health care providers in our community, any reduction in workforce or services would be highly detrimental to patient access to care and the stability of our local rural economy.

IV. Reconciliation and Rebate Denials Operational Challenges

If HRSA proceeds with a rebate-based- model, strict safeguards are essential. These must include:

- Uniform national standards,
- Transparent and limited denial criteria,
- Enforceable payment timelines for both initial and corrected rebates,
- Manufacturer accountability, and
- A neutral dispute resolution framework.

Without these protections, the rebate model effectively becomes an interest free loan from safety--net- providers to manufacturers.

V. Existing CHC Compliance Actions

CHCs are already highly regulated and subject to extensive oversight, including:

- Section 330 sliding fee- requirements,
- 340B eligibility and audit standards,
- Operational Site Visits, and
- Annual UDS reporting.

CHCs are not the source of misuse in the 340B program. They are established models of compliance, and a rebate model would impose disproportionate harm on providers that already meet rigorous regulatory requirements.

VI. Establishing a National, Neutral Claims Clearinghouse

We strongly recommend HRSA pursue a **Neutral Claims Clearinghouse (NCC)** as a more effective alternative. An NCC would:

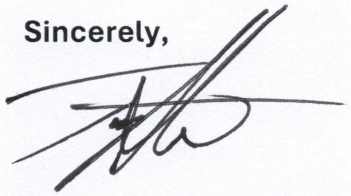
- Preserve upfront 340B discounts,
- Reduce administrative burden,
- Improve rebate accuracy,
- Prevent duplicate discounts, and
- Protect patient access to care.

Conclusion

Open Door Community Health Centers strongly urges HRSA to exempt Community Health Centers (CHCs) from the 340B Rebate Model Pilot Program. A rebate-based approach reverses the intent of the 340B statute, destabilizes safety-net providers, and creates significant barriers to medication access for vulnerable patients. For Open Door alone, the pilot would result in a minimum loss of **$7.2 million** in annual 340B savings, resources that are essential to sustaining patient services and affordability. We respectfully request that HRSA reconsider this approach and adopt solutions that preserve the integrity, intent, and effectiveness of the 340B program.

Thank you for the opportunity to submit comments. For questions, don't hesitate to get in touch with me at tstarr@opendoorhealth.com or Adriana Campbell, 340B Program Manager at adcampbell@opendoorhealth.com

Sincerely,



Tory Starr, MSN, PHN, RN
President & Executive Officer
Open Door Community Health Centers

MetroHealth
Devoted to Hope, Health, and Humanity

Electronically submitted via email to: 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 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

Introduction and Organizational Background

The MetroHealth System ("MetroHealth") is the super safety-net county hospital system for Cuyahoga County, Ohio. More than 75 percent of our patients are covered by government-sponsored insurance, primarily Medicaid, or are uninsured. MetroHealth's mission is to care for anyone and everyone, regardless of ability to pay, while reducing barriers to care and improving community health outcomes.

The 340B Drug Pricing Program is essential to MetroHealth's financial stability and to our ability to provide charity care, sliding-scale medication access, and comprehensive safety-net services. As a large public hospital system with a high-acuity, high-need patient population, MetroHealth is uniquely exposed to the financial, operational, and data-security risks associated with a rebate-based approach to 340B pricing.

MetroHealth appreciates the opportunity to submit comments on HRSA's proposed Information Collection Request (ICR) for the 340B Rebate Model Pilot Program Application, Implementation, and Evaluation. Our comments below are organized in direct response to the four Paperwork Reduction Act (PRA) criteria on which HRSA specifically solicited public input.

ICR Question 1: Necessity and Utility of the Proposed Information Collection

The proposed information collection is not necessary for HRSA to perform any statutorily assigned function under the 340B Program. The ICR does not identify a clear agency purpose for

the collection of covered-entity claims-level data, nor does it explain how HRSA would use such data to advance program oversight, compliance, or integrity.

Covered entities are already legally responsible for preventing diversion and Medicaid duplicate discounts and do so effectively through existing, HRSA-approved mechanisms, including registration in HRSA's Medicaid Exclusion File and the use of claim-level modifiers. These controls are sufficient, auditable, and widely implemented and do not require manufacturers to receive covered-entity claims data.

The information collection described in the ICR instead appears designed to support manufacturers' and pharmacy benefit managers' private rebate and reimbursement arrangements—relationships to which covered entities are not parties and for which covered entities have no statutory compliance responsibility. The inclusion of claims-level data across all payers, rather than limiting collection to Medicaid or Medicare Drug Price Negotiation Program claims, further demonstrates that the proposed collection exceeds any plausible 340B program-integrity purpose.

Because HRSA has not articulated a specific agency function served by this information collection, MetroHealth cannot conclude that the proposed collection satisfies the PRA's necessity or utility standards.

ICR Question 2: Accuracy of the Estimated Burden

The burden estimates included in the ICR are significantly understated and do not reflect the operational reality of administering a rebate-based model.

The estimates appear to account only for the act of transmitting data to manufacturers and fail to account for the substantial downstream burden imposed on covered entities, including but not limited to tracking submissions, approvals, denials, and payment status; investigating and disputing erroneous rebate denials; responding to repeated and unauthorized secondary data requests; reconciling expected rebates against actual payments received; maintaining internal databases to track claim-level status over time; supporting audit, accounting, compliance, and reporting functions; and supervisory, management, training, and information-technology support.

MetroHealth's experience with the Medicare Drug Price Negotiation Program demonstrates that even a limited number of drugs can require the equivalent of at least one full-time employee devoted solely to rebate reconciliation and dispute resolution. Expansion of this model under the proposed pilot would increase burden exponentially.

By way of illustration, MetroHealth's experience with this comparable rebate-based program demonstrates the scale of burden not captured in the ICR's estimates. Even with a limited number of drugs, rebate reconciliation, denial review, dispute management, and payment tracking require sustained staff effort equivalent to at least one full-time position. This experience reflects only a narrow subset of drugs and does not include additional information technology, compliance, supervisory, or data-security support. Expanding these requirements under a broader rebate-based pilot would materially increase burden for large safety-net hospitals such as MetroHealth, underscoring that the ICR's aggregate burden estimates significantly understate real-world impact

The ICR also fails to account for non-time-based burden, including data-security, privacy, and financial risk. Covered entities would be required to submit sensitive patient and utilization data through manufacturer-controlled platforms under non-negotiable terms, placing legal, compliance, and cybersecurity risk entirely on covered entities without compensation or meaningful safeguards.

Finally, the ICR provides a single aggregate burden estimate without accounting for variation in covered-entity size, patient acuity, outpatient drug volume, or specialty mix, rendering the estimate unreliable and inconsistent with PRA requirements.

ICR Question 3: Ways to Enhance the Quality, Utility, and Clarity of the Information

The quality, utility, and clarity of any information collection cannot be enhanced absent a clearly articulated purpose and defined use of the data by HRSA.

The ICR does not specify the precise data elements to be collected; how those data elements would be evaluated; the criteria HRSA would use to assess manufacturer participation; how success or failure of the pilot would be determined; or the duration of the pilot program.

Without defined objectives, metrics, and evaluation standards, covered entities cannot meaningfully assess whether the proposed data collection is appropriate, proportionate, or effective.

If HRSA's objective is prevention of Medicaid or Medicare Drug Price Negotiation Program duplicate discounts, that objective can be achieved through far less burdensome alternatives, such as standardized claim modifiers coupled with protections against discriminatory PBM reimbursement practices. The failure to pursue these alternatives suggests that the proposed data collection serves purposes beyond those stated in the ICR.

ICR Question 4: Use of Automated Collection Techniques to Minimize Burden

Automated data-collection techniques do not minimize burden when the underlying eligibility-determination process is inaccurate, opaque, and controlled by manufacturers.

MetroHealth's experience with automated processes under the Medicare Drug Price Negotiation Program demonstrates that manufacturers frequently misidentify claims, improperly deny rebates, and rely on automated systems to avoid accountability. Covered entities bear the burden of disproving incorrect determinations, often through manual, time-intensive reconstruction of inventory and utilization histories that are not designed to be claim-specific.

In this context, automation shifts—rather than reduces—burden by increasing dispute volume, obscuring decision-making logic, requiring extensive manual intervention to correct automated errors, and expanding unsanctioned data demands unrelated to the disputed claim.

Absent a neutral, HRSA-governed platform and clearly defined eligibility standards, increased automation will amplify administrative burden rather than mitigate it.

Conclusion

MetroHealth urges HRSA to reconsider the proposed information collection associated with the 340B Rebate Model Pilot Program. As structured, the ICR does not meet the Paperwork Reduction Act's standards for necessity, utility, or accurate burden estimation and would impose significant administrative, financial, and data-security burdens on safety-net providers without advancing 340B program integrity.

MetroHealth appreciates the opportunity to provide these comments and stands ready to assist HRSA in further evaluation of approaches that preserve statutory 340B pricing while minimizing unnecessary burden on covered entities.

Sincerely,

Kinsey Jolliff
Vice President, Reimbursement
The MetroHealth System

FQHC 340B Compliance
THE PREFERRED RESOURCE FOR COMMUNITY HEALTH CENTERS

April 27, 2026

Via Email to paperwork@hrsa.gov

HRSA Information Collection Clearance Officer
Health Resources and Services Administration
5600 Fishers Lane, Room 13N82
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 (HRSA-2026-03833)

To Whom It May Concern,

On behalf of FQHC 340B Compliance**,** we would like to thank the Health Resources and Services Administration (HRSA) for the opportunity to provide comment on any future iterations of a **340B Rebate Model Pilot Program**. As HRSA stated in the initial 340B Rebate Pilot Proposal, the change from upfront discounts represents a fundamental shift in how the program has operated for over 30 years[1], with the potential to have major implications for both 340B stakeholders and the communities they serve.

FQHC 340B Compliance (FQHC 340B) works in 43 states with over 150 of the 1512 Community Health Centers in the country, as well as with other covered entity types, to support ongoing 340B Program compliance and oversight. Our organization serves as 340B Technical Advisor for the National Association of Community Health Centers and a number of state Primary Care Associations. We provide monthly educational webinars and podcasts to the 340B community to help strengthen 340B stakeholders' understanding of the 340B statute, regulations, guidance, and compliance principles. FQHC 340B actively engages with the broad 340B community from the perspective that the covered entities participation in the program must first be rooted in compliance to achieve the 340B Programs intent stated in the House Report, Legislative History, "to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] It is also our firm belief that calls for transparency must be equally applied to all participants of the 340B Program, covered entities and manufacturers alike.

Based on extensive operational experience supporting Federally Qualified Health Centers (FQHCs), look-alikes, and other grantee covered entities across diverse pharmacy models, including entity-owned pharmacies, contract pharmacy arrangements, and clinic-administered drug programs, we respectfully submit that the 340B Rebate Pilot Model burden estimates reflected in this information collection request (ICR)[3] materially understate the true operational effort required of covered entities. In particular, the estimate that covered entities will expend

[1] 90 FR 36163, 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program
[2] H.R. Rep. No. 384(II), 102ND Cong., 2ND Sess. 1992, 1992 WL 239341 (Leg.Hist.)
[3] 91 FR 9632 Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation

approximately **five (5) hours per week** on claims-level data reporting does not align with the actual workflow, staffing mix, reconciliation requirements, and compliance safeguards necessary to support retrospective rebate determination models. This assessment is the result of years' of experience helping covered entities submit and reconcile claims data as a part of manufacturers' contract pharmacy policies, in addition to experience navigating the first months' of reconciling MFP effectuation for covered entities and pharmacies alike.

Consistent with HRSA's request, our comments address the necessity and practical utility of the proposed information collection; the accuracy of HRSA's burden estimates; the quality, utility, and clarity of the information to be collected; and opportunities to reduce burden through alternative approaches.

1. Necessity and Practical Utility of the Information Collection

The proposed 340B Rebate Pilot Model[4] contemplates routine submission of claims-level data by covered entities to participating manufacturers in order to effectuate access to 340B pricing through retrospective rebates. This represents a fundamental shift from prospective ceiling price access—the mechanism under which the 340B Program has operated for more than three decades—to a model that conditions access to a statutory price on additional administrative processes performed by covered entities.

Covered entities already maintain auditable records sufficient to demonstrate compliance with statutory prohibitions on diversion and duplicate discounts. These records are reviewed through HRSA audits and, when necessary, through manufacturer audits conducted under HRSA-approved standards. The 340B Rebate Pilot Model ICR does not clearly articulate how requiring covered entities to transmit undisclosed claims-level data elements to manufacturers, potentially through manufacturer-controlled platforms with unpublished validation logic, would provide improved program integrity benefits beyond those achieved through existing compliance frameworks.

Instead, the 340B Rebate Pilot Model ICR and the RFI previously presented appear primarily designed to support manufacturer eligibility determinations for rebate payment, thereby shifting both operational responsibility and financial risk to covered entities. From a Paper Work Reduction Act (PRA) perspective, this raises significant concerns as to whether the scope of the collection proposed for the 340B Rebate Pilot Model is necessary for HRSA's functions, or whether it instead facilitates manufacturer administration of the MFP deduplication, a HRSA function not sanctioned by IRA[5] or 340B[6] statute.

2. Accuracy of Burden Estimates

The 340B Rebate Pilot Model ICR estimates that approximately **14,600 covered entities** will each expend **five (5) hours per week** submitting claims data, resulting in nearly **3.8 million annual burden hours**. While this figure appears substantial in aggregate, the per-entity estimate materially understates the actual workload associated with claims-level data submissions in a rebate environment.

[4] 91 FR 9632 Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation
[5] Inflation Reduction Act, 42 USC 1320f–2(d)
[6] Section 340B of the Public Health Service Act, 42 U.S.C.

The estimate assumes that covered entities are merely transmitting data files already available in existing systems. In practice, claims-level reporting for rebate purposes requires a multi-step, labor-intensive process that extends well beyond file generation.

Based on observed operational practices across health centers of varying size and complexity, a more realistic weekly time burden includes, **at minimum,** the following activities:

Data Extraction and Normalization (3–5 hours/week)
Covered entities routinely operate across:

- Multiple pharmacy management systems
- One or more third-party administrators
- Multiple contract pharmacies with differing submission cadences
- Clinic-administered drug workflows not integrated into pharmacy dispensing systems or discrete, reportable fields within electronic health records

Extracting claims data in the format required by manufacturer or pilot-specific templates requires:

- Filtering out non-340B eligible claims
- Ensuring correct 340B ID attribution at the site level
- Normalizing data across systems with inconsistent field definitions
- Addressing required data elements that do not exist in current electronic systems (i.e., claim number and claim line number for clinic administered drugs that are not included directly on billing claims)
- Formatting files to meet platform-specific technical requirements

This work is typically performed by pharmacy managers, compliance pharmacists, or senior analysts—not clerical staff—and routinely requires **3 to 5 hours per week**, even before submission.

Pre-Submission Validation and Error Prevention (2–4 hours/week)
To avoid loss of access to pricing or retroactive denials, covered entities must perform internal validation to confirm that claims submitted align with:

- HRSA patient definition requirements
- Medicaid carve-in/carve-out status
- Contract pharmacy eligibility rules
- Manufacturer-specific participation conditions

Unlike current 340B replenishment models, where eligibility logic is applied prospectively within covered entity systems, rebate-based models require covered entities to anticipate downstream manufacturer determinations without access to the manufacturers' eligibility algorithms. As a result, additional review steps are required prior to every submission.

Submission Management and Error Resolution (2–3 hours/week)
Manufacturer-run data platforms frequently:

- Reject submissions for formatting or validation reasons
- Flag claims as incomplete without providing actionable detail
- Identify missing data elements without reference to source system constraints

Because many platforms do not provide real-time submission balances or transparent error diagnostics, staff must manually investigate discrepancies—often by tracing individual claims

back through historical upload files and source systems. This alone consumes **2 to 3 hours per week** under current manufacturer data submission regimes and would increase materially at scale.

Ongoing Reconciliation and Record Maintenance (4–6 hours/week)
Perhaps the most significant unaccounted burden in the ICR is the requirement to reconcile manufacturer determinations back to covered entity records, in order to maintain auditable documentation.
In a rebate model:

- A drug's "340B pedigree" is not established at purchase, but only after rebate payment
- Covered entities must crosswalk purchases, claims, and rebate files to demonstrate compliance
- Denied or adjusted claims must be tracked and revisited over time

Health centers report that reconciling a **single denied or questioned claim** in the existing manufacturer contract pharmacy policies or MFP effectuation processes can take **90 or more minutes**, depending on data availability. Even modest denial rates therefore create recurring weekly workloads of **4 to 6 hours or more**, particularly where appeals or corrections are required.

Estimated Health Center Reconciliation Time By Year

		2027			2028		
	CHC Type	MFP NDC Rx /Month	AVG Hrs/ Month	FTEs	MFP NDC Rx /Month	AVG Hrs/Month	FTEs
1	Small CHC	85	37	0.2	89	39	0.2
2	Med CHC	321	140	0.8	351	154	0.9
3	Med CHC	374	164	0.9	380	166	0.9
4	Med CHC	389	170	1.0	420	184	1.0
5	Med CHC	393	172	1.0	425	186	1.0
6	Med CHC	430	188	1.1	472	207	1.2
7	Med CHC	503	220	1.2	550	241	1.4
8	Large CHC	619	271	1.5	770	337	1.9
9	Large CHC	807	353	2.0	907	397	2.2
	TOTALS	**3921**	**1715**	**9.7**	**4364**	**1909**	**10.8**

* Claim Reconciliation Assumptions: 85% Regular Claims (5 min MIN, 15 min AVG, 25 min MAX), 15% Complex Claims (90 min each). Overall average = 1.2 FTE Numbers created matching MFP NDCs by price applicability year to blinded health center claim data.

Total Realistic Weekly Time Burden
When aggregated, a conservative estimate of weekly time burden for covered entities participating in a rebate pilot is:

- **Low-complexity entities:** 10–20 hours per week
- **Moderate-complexity entities (typical FQHC):** 40–60 hours per week
- **High-complexity or multi-site entities:** 80+ hours per week

These estimates are **significantly higher** than the 340B Rebate Pilot Model ICR's stated assumption and do not include the indirect costs associated with additional staffing, system modifications, or external vendor support many entities would be required to procure.

3. Quality, Utility, and Clarity of the Information Collected

The 340B Rebate Pilot Model ICR anticipates that future guidance will define required data elements and submission standards. However, collecting extensive claim-level data without corresponding requirements for manufacturers to disclose eligibility determination methodologies,

aggregation logic, and denial rationales undermines the 340B Rebate Pilot Model's goal for improving transparency.[7]

Covered entities cannot validate or efficiently correct errors when decision-making standards are unpublished. This asymmetry diminishes the usefulness of the information collected and increases compliance risk for entities acting in good faith.

From a PRA standpoint, information collections must be designed so that respondents can reasonably understand how their submissions will be used and evaluated. Absent such transparency, the proposed collection does not meet this standard.

4. Auditable Records Concerns

A critical consideration in implementing a nationwide 340B Rebate Pilot Model, particularly one that conditions access to statutorily defined 340B pricing on mandatory covered entity participation, is that shifting the point at which 340B status is determined fundamentally alters the operational framework for auditable recordkeeping. The scope and complexity of this change are significant and, to date, likely not fully appreciated.

The statutory prohibitions on duplicated discounts and diversion both reference the condition with "respect to a drug that is subject to an agreement under this section" referring to "the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[8] Until access to the 340B Ceiling price is received by a covered entity, a drug purchased by the covered entity is not a 340B drug and therefore not subject to 340B statutory requirements.

HRSA requires 340B covered entities to maintain auditable records. In a potential rebate model, covered entities would need to crosswalk all pilot model drugs' purchase data, administration, dispense, and claims data to the manufacturer rebate payments. This immense and manual process introduces significant operational burden in maintaining complete auditable records. **A drug's pedigree is not 340B unless and until the covered entity receives a discount.**

At the point a 340B ceiling price is received, covered entities are then required to maintain auditable records. Because the "340B pedigree" of a drug would not be established until the rebate is received, a 340B rebate model will significantly increase the burden on covered entities in the creation and maintenance of auditable records.

To maintain accurate auditable records in a 340B rebate model, health centers and other covered entities would be required to crosswalk purchases to manufacturers' rebate payments, and then

[7] 91 FR 9632 Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation
[8] 42 CFR 447.502

reconcile and record rebates for 340B transactions, creating significant administrative burden and complicating the ability to respond to standard audit data requests.

Because 340B wholesaler accounts will have a mixed pedigree of 340B and non-340B drugs, based on rebates approved or denied by manufacturers, health centers and other covered entities will encounter difficulty replying to HRSA audit requests. Section 5(C) of the Sample HRSA 340B Audit Data Request List[9] requires a list of all 340B drug purchases. Currently, covered entities can download an accurate list of 340B purchases from their wholesaler platforms. In the rebate pilot, wholesalers will not have access to information related to retrospective rebate determinations, so it will fall to the covered entities to create a system to take their wholesaler purchase data and reconcile it to rebate payments to create an auditable purchase record. Given that in the previous pilot proposed by OPA, the rebates were to be paid at the unit level as drugs are dispensed, this makes the process even more complicated and likely will result in situations where only portions of a purchased item are defined as 340B within a single package.

The rebate purchase records will become even more complicated in the event of a 340B program audit. In a HRSA audit, every purchase record for each drug subject to a rebate will have to be traced to a rebate to ensure a rebate was paid, prior to submitting purchases to HRSA. In addition, every targeted claim selection chosen during a HRSA audit for drugs subject to a rebate model will need to have the rebate traced through the manufacturers' chosen pathway to ensure the rebate was paid, effectively changing the drug's pedigree to 340B.

Covered entities will also now be required to perform the additional compliance task of updating the records for every claim processed. Currently, the manufacturers' selected vendor Beacon Channel Management does not provide prescription numbers in the 340B rebate reconciliation files. Instead, health centers will have to comb through reconciliation files and historical upload files to tie together Beacon ID, Claim ID, and prescription number. With health centers having data uploads from clinics, entity-owned pharmacies, and contract pharmacies with upload cadences ranging from daily to bi-weekly, the sheer volume of files that will need to be reviewed to determine a prescription number will grow exponentially as the rebate model continues.

From health center experience with the Medicare Transaction Facilitator, cross-walking a claim can take between 15-30 minutes depending on the availability of data across the two systems. In the case of cross-walking claims to the MTF, we have the advantage of not having to seek the claim "needle" in the file "haystack" and expect the reconciliation process for 340B rebates to be even more burdensome. See attachment "Beacon 340B Rebate Pilot Claim to Payment Reconciliation Basics" for a detail process description.

Once a claim ID and rebate status is identified, the health center must either go and update their records including clinic logs and pharmacy software to the manufacturer assigned pedigree of the drug or have a separate set of information outside of the current medical records, including

[9] https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf

pharmacy software, to serve as 340B auditable records. In the scenario where the health center staff must update the records, this last step will be time-consuming, manual, and burdensome. It also invites the opportunity for human error. In the second scenario, auditable records are no longer in a consistent and reportable place. A third option exists for health centers to pay vendors to reconcile the 340B rebate claims for them, but this option adds even more cost and again has the issue of auditable records no longer being housed in the health center medical records and pharmacy software.

5. Recommendations to Minimize Burden

If HRSA proceeds with any 340B pilot model implementation, burden can and should be substantially reduced by:

- Limiting data collection to the minimum necessary, avoiding routine claim-level submissions where aggregate data will suffice
- Leveraging government-run **neutral clearinghouse mechanisms** rather than manufacturer-controlled platforms
- Establishing uniform national standards for submission requirements, denial categories, and timelines
- Ensuring that participation in rebate-based mechanisms remains voluntary for covered entities and does not condition access to statutory pricing

Conclusion

As safety-net providers, community health centers operate on narrow margins and rely on predictable, prospective 340B pricing to sustain access to care for underserved populations. The 340B Rebate Pilot Model ICR substantially underestimated administrative burden, while shifting financing responsibility to covered entities, effectively threatening program viability and patient access. For these reasons, we respectfully urge HRSA to recognize that the burden estimates in this ICR reflect only a reasonable time allocation for uploading data and fail to represent the additional operation and administrative burden that a rebate will place on covered entities. In reality, it is difficult to fathom that the disparity in administrative burden between covered entities and manufacturers (already greater than an 800% difference when only accounting for time to upload) aligns with the Paperwork Reduction Act's directive to minimize unnecessary burden or 340B statutory intent; surely this is not what congress intended.[10]

> *"In giving these "covered entities" access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*[11]
>
> *"The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of covered entity."*[12]

[10] H.R. REP. 102-384(II)
[11] *Id.*
[12] *Id.*

We thank you again for the opportunity to respond to the Notice. We would appreciate any opportunity to discuss our comments further.

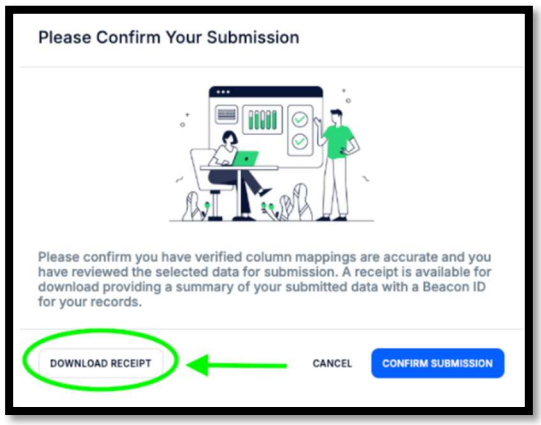
Best Regards,

FQHC 340B Compliance LLC

Felicity Homsted	*Logan Yoho*	*Chelsea Violette*
Felicity Homsted Chief Executive Officer	Logan Yoho Director of Advocacy & Education	Chelsea Violette Chief Operating Officer

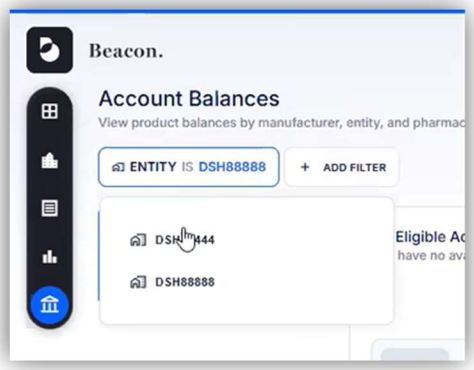
Beacon 340B Rebate Pilot Claim to Payment Reconciliation Basics

Step 1: Download Receipt File Before Submitting Claims



date_of_service	date_prescribed	rx_number	fill_number	ndc	quantity	prescriber_id	service_provider_id	contracted_entity_id	bin	pcn	beacon_id
9/29/25	9/20/25	654323	1	310621030	30	1649230558	1396879094	DSH050305	123456	123456	72b3e9b3335d34f2bbe3075f2b3e993ddbeb76f5a6e1c1fc425accf1da934259
9/29/25	9/20/25	654324	1	310621030	60	1649230558	1396879094	DSH050305	123456	123456	4d77440303cb8b666572571fdcc53fcbf85b666ac48dbd63959b8cce4e0697d5
9/29/25	9/20/25	654325	1	310621030	90	1649230558	1396879094	DSH050305	123456	123456	f7c1e1ac14781c56ecf47a70fc0e151369a4781fd1e923eb0bf0d37b6ce972ff
9/29/25	9/20/25	654326	1	310621030	15	1649230558	1396879094	DSH050305	123456	123456	0e5486c9418e1666576108d979a879391e42ef2841b3cb5e682b292675875d14

Step 2: Download Claim File from Beacon Account Balances Reports

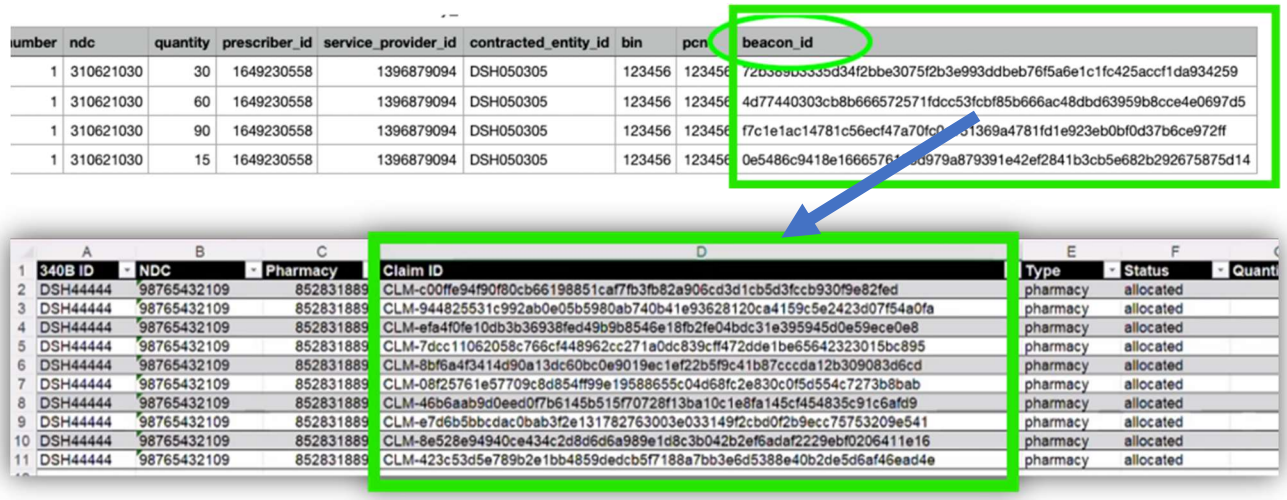


	A	B	C	D	E	F	G	H	I
1	340B ID	NDC	Pharmacy	Claim ID	Type	Status	Quantity	Remaining	Date
2	DSH44444	98765432109	852831889	CLM-c00ffe94f90f80cb66198851caf7fb3fb82a906cd3d1cb5d3fccb930f9e82fed	pharmacy	allocated	5	0	11/15/2025
3	DSH44444	98765432109	852831889	CLM-944825531c992ab0e05b5980ab740b41e93628120ca4159c5e2423d07f54a0fa	pharmacy	allocated	3	0	11/15/2025
4	DSH44444	98765432109	852831889	CLM-efa4f0fe10db3b36938fed49b9b8546e18fb2fe04bdc31e395945d0e59ece0e8	pharmacy	allocated	13	0	11/15/2025
5	DSH44444	98765432109	852831889	CLM-7dcc11062058c766cf448962cc271a0dc839cff472dde1be65642323015bc895	pharmacy	allocated	26	0	11/15/2025
6	DSH44444	98765432109	852831889	CLM-8bf6a4f3414d90a13dc60bc0e9019ec1ef22b5f9c41b87cccda12b309083d6cd	pharmacy	allocated	30	0	11/15/2025
7	DSH44444	98765432109	852831889	CLM-08f25761e57709c8d854ff99e19588655c04d68fc2e830c0f5d554c7273b8bab	pharmacy	allocated	15	0	11/15/2025
8	DSH44444	98765432109	852831889	CLM-46b6aab9d0eed0f7b6145b515f70728f13ba10c1e8fa145cf454835c91c6afd9	pharmacy	allocated	30	0	11/15/2025
9	DSH44444	98765432109	852831889	CLM-e7d6b5bbcdac0bab3f2e131782763003e033149f2cbd0f2b9ecc75753209e541	pharmacy	allocated	25	0	11/15/2025
10	DSH44444	98765432109	852831889	CLM-8e528e94940ce434c2d8d6d6a989e1d8c3b042b2ef6adaf2229ebf0206411e16	pharmacy	allocated	15	0	11/15/2025
11	DSH44444	98765432109	852831889	CLM-423c53d5e789b2e1bb4859dedcb5f7188a7bb3e6d5388e40b2de5d6af46ead4e	pharmacy	allocated	18	0	11/15/2025

Beacon 340B Rebate Pilot Claim to Payment Reconciliation

Step 3: Match Receipt File "Beacon IDs" to Claim File "Claim IDs"

- Claim ID = "CLM-" + Beacon ID
- e.g. Beacon ID = ABCDE123 then Claim ID = CLM-ABCDE123



umber	ndc	quantity	prescriber_id	service_provider_id	contracted_entity_id	bin	pcn	beacon_id
1	310621030	30	1649230558	1396879094	DSH050305	123456	12345	72b389b3335d34f2bbe3075f2b3e993ddbeb76f5a6e1c1fc425accf1da934259
1	310621030	60	1649230558	1396879094	DSH050305	123456	12345	4d77440303cb8b666572571fdcc53fcbf85b666ac48dbd63959b8cce4e0697d5
1	310621030	90	1649230558	1396879094	DSH050305	123456	12345	f7c1e1ac14781c56ecf47a70fc[illegible]1369a4781fd1e923eb0bf0d37b6ce972ff
1	310621030	15	1649230558	1396879094	DSH050305	123456	12345	0e5486c9418e16665761[illegible]979a879391e42ef2841b3cb5e682b292675875d14

	A	B	C	D	E	F
1	340B ID	NDC	Pharmacy	Claim ID	Type	Status
2	DSH44444	98765432109	852831889	CLM-c00ffe94f90f80cb66198851caf7fb3fb82a906cd3d1cb5d3fccb930f9e82fed	pharmacy	allocated
3	DSH44444	98765432109	852831889	CLM-944825531c992ab0e05b5980ab740b41e93628120ca4159c5e2423d07f54a0fa	pharmacy	allocated
4	DSH44444	98765432109	852831889	CLM-efa4f0fe10db3b36938fed49b9b8546e18fb2fe04bdc31e395945d0e59ece0e8	pharmacy	allocated
5	DSH44444	98765432109	852831889	CLM-7dcc11062058c766cf448962cc271a0dc839cff472dde1be65642323015bc895	pharmacy	allocated
6	DSH44444	98765432109	852831889	CLM-8bf6a4f3414d90a13dc60bc0e9019ec1ef22b5f9c41b87cccda12b309083d6cd	pharmacy	allocated
7	DSH44444	98765432109	852831889	CLM-08f25761e57709c8d854ff99e19586655c04d68fc2e830c0f5d554c7273b8bab	pharmacy	allocated
8	DSH44444	98765432109	852831889	CLM-46b6aab9d0eed0f7b6145b515f70728f13ba10c1e8fa145cf454835c91c6afd9	pharmacy	allocated
9	DSH44444	98765432109	852831889	CLM-e7d6b5bbcdac0bab3f2e131782763003e033149f2cbd0f2b9ecc75753209e541	pharmacy	allocated
10	DSH44444	98765432109	852831889	CLM-8e528e94940ce434c2d8d6d6a989e1d8c3b042b2ef6adaf2229ebf0206411e16	pharmacy	allocated
11	DSH44444	98765432109	852831889	CLM-423c53d5e789b2e1bb4859dedcb5f7188a7bb3e6d5388e40b2de5d6af46ead4e	pharmacy	allocated

LifeSpring Health Systems

460 Spring Street

Jeffersonville, Indiana 47130

April 27, 2026

Via Online Submission to: www.Regulations.gov

Chantelle Britton

Director – Office of Pharmacy Affairs (HRSA)

Health Resources and Services Administration

5600 Fishers lane, Mail Stop 14W52

Rockville, Maryland 20857

RE: Information Collection Request: 340B Rebate Model Pilot Program [HRSA-2026-03833 (91 FR 9632)]

Introduction

LifeSpring Health Systems appreciates the opportunity to comment on HRSA's proposed Information Collection Request (ICR) associated with the potential 340B Rebate Model Pilot Program.

As a Community Health Center participating in the 340B Program for approximately 7 years, we utilize Nuvem Rx as our TPA and work exclusively with 340B contract pharmacy arrangements to manage 340B compliance and operations. Our program supports approximately 17,000 patients annually and generates approximately $3.5M (post 340B drug spend) in 340B savings, which are reinvested into opening new clinic locations in rural areas, increase in current patient care services, and absorbing the costs of uncompensated care.

While we support HRSA's goals of improving program integrity and transparency, we have significant concerns regarding the **operational burden, financial implications, and workflow feasibility** of the proposed data collection requirements under a rebate model.

1. Necessity and Utility of the Proposed Information Collection

We understand HRSA's intent to enhance oversight and transparency; however, much of the data proposed to be collected under this ICR is **already captured within existing 340B infrastructure**, including:

- HRSA audits
- Manufacturer inquires and audits
- Manufacturer-required data submissions under current policies via ESP and Truzo
- Medicare Drug Price Negotiation Program reporting
- The Prime Vendor Program

We recommend HRSA clearly demonstrate:

- **What new insights** this additional data collection would provide beyond existing data sources
- Why current data aggregation methods (e.g., through ESP and Truzo) are insufficient

Without this clarity, the necessity of duplicative data submission to manufacturers is not fully justified.

2. Accuracy of HRSA's Burden Estimate

HRSA states that the burden associated with the proposed data collection "may not be significant." Based on our operational experience, we respectfully disagree.

Implementation of a rebate model would require substantial additional effort, including but not limited to:

- Development or modification of data extraction and submission processes
- Integration between TPA systems and manufacturer-specific submission requirements
- Staff training and workflow redesign
- Ongoing reconciliation of submitted claims and received rebates
- Investigation and resolution of discrepancies or denied rebate claims

We estimate the following additional burden:

- **Estimated additional staff hours per month:** 160 – 200 depending on claim volume

- **Estimated FTE impact:** At least 1.5 additional FTEs
- **Estimated annual administrative cost increase:** $225,000 - $275,000
- **Estimated IT/vendor modification costs:** $300,000

These estimates reflect that while the **data elements may exist**, the **processes, formatting, transmission, validation, and reconciliation requirements represent a significant new burden**.

3. Operational Challenges and Workflow Feasibility

The proposed requirement for covered entities to submit claims-level data to manufacturers introduces several operational risks:

A. Increased Complexity and Fragmentation

Covered entities may be required to:

- Submit data to **multiple manufacturers**, each with potentially different formats and requirements
- Manage **varying submission timelines and dispute processes**

This creates fragmentation that is not present in the current centralized TPA model.

B. Reconciliation Burden

Under a rebate model, covered entities must:

- Track each claim submitted for rebate
- Match rebates received to original claims
- Identify and resolve discrepancies

We estimate:

- **Monthly claim volume requiring rebate submission:** 1200 – 1500 per month
- **Estimated reconciliation discrepancy rate:** 65%

This represents a significant ongoing administrative workload.

C. Dependence on Third-Party Administrators

While HRSA notes that data is already maintained by TPAs, it does not account for:

- The need for **new functionality development by TPAs**
- Potential **increased vendor fees**

- Variability in TPA readiness and capabilities

4. Financial Impact and Cash Flow Concerns

A rebate model fundamentally alters the timing of 340B savings.

Under the current model:

- Covered entities receive **upfront discounts**

Under a rebate model:

- Covered entities must **pay higher upfront costs and wait for reimbursement**

We estimate the following potential impact:

- **Average monthly 340B drug spend:** $650,000 per month at the 340B price
- **Estimated portion subject to rebate model:** 40% - 45^
- **Estimated cash flow gap (time between purchase and rebate):** 145 days ***(this number is based on reports from retail pharmacies waiting for payment from the Beacon MFP portal)***

This creates significant financial risk, particularly for safety-net providers operating on narrow margins.

Delays or denials in rebate processing could:

- Disrupt operations
- Reduce available resources for patient care
- Increase financial uncertainty

5. Recommendations to Reduce Burden

To minimize burden and improve feasibility, we recommend:

A. Standardization

- Establish **uniform data submission formats and requirements across all manufacturers**
- Utilize **existing industry standards** wherever possible

B. Centralization via Neutral Data Clearinghouse

- **Utilize a neutral data clearinghouse** rather than a pharmaceutical manufacturer owned platform
- Eliminate data submission to multiple pharmaceutical manufacturer owned platform (duplication of efforts)

C. Automation

- Encourage or require **automated data exchange** using existing TPA systems
- Avoid manual submission processes

D. Alignment with Existing Data Streams

- Align required data elements with:
  - Existing TPA datasets
  - Contract pharmacy reporting
  - Medicare (MFP) negotiation program reporting

E. Clear Timelines and SLAs

- Establish **defined timelines for rebate payments**
- Include **accountability measures for delayed or denied rebates**

6. Enhancing Quality, Utility, and Clarity of Data Collection

To improve data quality and usability, HRSA should:

- Clearly define **required data elements and formats**
- Provide **detailed technical guidance prior to implementation**
- Pilot test submission processes with covered entities and TPAs
- Ensure **data validation standards are consistent across manufacturers**

7. Use of Technology to Minimize Burden

We strongly encourage HRSA to require:

- Integration with **existing TPA platforms**
- Use of **secure, automated data exchange (e.g., APIs, standardized file transfers)**
- Avoidance of duplicative manual reporting systems

Conclusion

While we support HRSA's goals of improving transparency and program integrity, the proposed information collection associated with a 340B Rebate Model Pilot Program represents a **significant operational and financial shift** for covered entities.

We respectfully request that HRSA:

- Reassess the estimated burden
- Prioritize standardization and centralization
- Ensure that any data collection requirements align with existing workflows
- Mitigate financial risks associated with delayed rebate payments

We appreciate the opportunity to provide input and look forward to continued engagement on this important issue.

Sincerely,

Thomasyna Sweed

340B Program Manager

LifeSpring Health Systems

Jeffersonville, IN

From:	LToya Knighten
To:	HRSA Paperwork
Subject:	[EXTERNAL] Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX.
Date:	Monday, April 27, 2026 10:28:34 PM
Attachments:	image.png image.png image.png

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

April 26, 2026

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

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

Dear Director Britton:

Thank you and the team at the Health Resources and Services Administration (HRSA) for providing the opportunity to share our estimated burden on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, we respectively ask that CHCs be exempted from the pilot program.

Variety Care is the largest Community Health Center in the state of Oklahoma. In 2025, we provided quality and affordable health care for 88,750 Oklahomans, in 160+ zip codes across the state.

This letter gives examples of the impacts Variety Care would be faced with if a 340B rebate model is implemented.

<u>Administrative Burden and Cash Flow Instability</u>:
The proposed shift to a rebate-based 340B model would fundamentally weaken Variety Care's ability to serve our patients by introducing unnecessary administrative complexity and unsustainable financial risk.

Administrative Burden

The rebate model creates a significant reconciliation gap that does not exist under the current structure. Our team would be required to track, validate, and reconcile claims across five in-house pharmacy locations to ensure rebates are issued accurately and completely. This is not a minor operational adjustment. It is a fundamental restructuring of how the program must be managed.
To keep pace with these demands, Variety Care would be forced to hire at least one additional full-time employee (FTE) at approximately $56,130, and this FTE would be solely dedicated to rebate administration. Beyond staffing, we anticipate increased annual costs that are currently unbudgeted for external support, including 340B consultants, legal counsel, third-party administrators, software vendors, and reconciliation services. These are dollars that would otherwise go directly toward patient care.

Cash Flow Instability

REBATE SCENARIO #1

SUN	MON	TUE	WED	THU	FRI	SAT
	INVOICE	INVOICE	INVOICE	INVOICE	INVOICE	
		PRESECRIPTION FILLED			PAYMENT DUE	
	PRESCRIPTION PICKED UP BY PATIENT	REBATE SUBMITTED				
					REBATE PAYMENT RECEIVED	

Variety Care operates on a net 7 with our wholesaler. We place orders each day.

REBATE SCENARIO #2

SUN	MON	TUE	WED	THU	FRI	SAT
	INVOICE	INVOICE	INVOICE	INVOICE	INVOICE	
		PRESECRIPTION FILLED	REBATE SUBMITTED		PAYMENT DUE	
					PRESCRIPTION RETURNED TO STOCK AS PATIENT DOESN'T PICK UP	REBATE PAYMENT RECEIVED
	REBATE REVERSAL SUBMITTED					

In this scenario, Variety Care has additional administrative burdens when the prescription is returned to stock and a rebate reversal must be submitted. Each scenario explains here assumes the manufacturer is approving the rebate by day 10.

The rebate model would also create serious cash flow constraints. Variety Care operates on narrow margins and relies on upfront 340B savings to sustain clinical services. Under a rebate structure, the organization would be required to pay full drug acquisition costs upfront and wait for reimbursement, creating delays that are difficult to absorb.

We estimate our days-cash-on-hand would lower by 5-10 days under a rebate model.

Under this structure, we are required to pay the full cost of medications upfront well before any rebate is received. In Scenario #1, medications are ordered mid-week and must be paid to the wholesaler within seven days. However, the rebate process does not begin until after the patient picks up the prescription, and payment is not received until well after the invoice is due. This creates a recurring cash flow gap where Variety Care is effectively financing the program out of pocket. For a community health center, this is not sustainable. It forces us to absorb ongoing financial risk simply to maintain access to medications for our patients.

In Scenario #2, an additional layer of complexity and inefficiency is introduced. Scenario #2 exposes one of the most problematic aspects of a rebate-based model: the need to reverse rebates when prescriptions are not picked up. In this case, a rebate is submitted after the prescription is filled, but the medication is later returned to stock when the patient does not pick it up. This triggers a required rebate reversal that transforms a routine pharmacy workflow into a high-risk compliance event.

Under this model, Variety Care is forced into a continuous cycle of submitting, tracking, and reversing rebate claims. Each step introduces new opportunities for error and significantly increases exposure to audit findings.
This creates several serious risks:

- **Audit Vulnerability:** Every rebate submission and reversal becomes a transaction subject to manufacturer and third-party audit. Any delay, mismatch, or documentation gap could be flagged as non-compliance, even when the underlying issue is a common

and unavoidable occurrence in pharmacy operations.

- **Compliance Exposure:** The burden of accuracy falls entirely on Variety Care. Failure to reverse a rebate in a timely manner could result in allegations of duplicate discounts or program misuse.
- **Manufacturer Disputes:** Rebate reversals increase the likelihood of disputes over eligibility, timing, and repayment. These disputes can delay funds, require extensive documentation, and consume additional administrative resources to resolve.
- **Operational Instability:** Staff must actively monitor prescriptions even after rebates are submitted, adding ongoing workload and increasing the risk of missed reversals. This is a continuous, resource-intensive process.

What makes this especially concerning is that these risks are triggered by routine patient behavior. Prescriptions being returned to stock is a normal and expected part of pharmacy operations. Under a rebate model, however, these everyday occurrences become compliance liabilities.

Impact on Patient Access and Care

The consequences of this model extend far beyond operations. Patient care is directly impacted. The 340B program was designed to allow providers like Variety Care to stretch scarce resources and expand access to care. The rebate model does the opposite.

By delaying savings and increasing administrative costs, it diverts critical resources away from patient services and into overhead. It limits our ability to invest in care coordination, behavioral health, chronic disease management, and other essential programs that our patients rely on.

Closing

A 340B Rebate Model is a direct threat to our financial stability and our ability to serve our community. Any model that delays access to savings, increases administrative burden, and forces health centers to front significant costs is fundamentally misaligned with the mission of the 340B program and should not be implemented.

This is not a sustainable solution. The proposed rebate model undermines the core purpose of 340B. It shifts financial burden onto safety-net providers and creates barriers to care for the very populations the program was intended to support.

Sincerely,

Lou Carmichael
President and CEO
Variety Care

From:	LToya Knighten
To:	HRSA Paperwork
Subject:	[EXTERNAL] Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX.
Date:	Monday, April 27, 2026 10:32:25 PM
Attachments:	image.png

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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. The Stigler Health & Wellness Center (SHWC) is the largest rural Community Health Center (CHC) in Oklahoma. The SHWC currently has 7 healthcare clinics, 3 pharmacies, 2 residential substance use recovery facilities, and 1 dental facility in Stigler. Clinic locations include Checotah, Eufaula, Poteau, Sallisaw, Stigler, Warner, and Wilburton.

In addition to integrated services, SHWC also provides Medication Assisted Treatment (MAT) services including Suboxone treatment and counseling for Opioid Use Disorder.

Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Stigler Health and Wellness Center (SHWC) again requests that CHCs be exempted from the pilot program due to the following impacts:

- Financial Losses: SHWC alone reports an average loss of $355,274.38 from entity-owned pharmacy operations and $100,941.58 for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation. This represents a total of $456,215.96

in administrative burden costs for 2025 alone.

- 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.

- Rural Health Center Breakdown: For rural CHCs, these costs are even more devastating. Rural centers invest nearly one-quarter (25%) of their 340B savings in rural-specific infrastructure, such as mobile clinics and telehealth.

Workforce Impact:

- Staffing Impact: SHWC anticipates needing at a minimum, 1.0 FTE initially to manage the first 10 drugs. As more drugs are added, another FTE will be needed to maintain control of the administrative burden, and 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, SHWC will face an increased administrative burden to monitor rebate claims and payments. Thirty hours per week will be required to report 340B rebate claims to a third-party platform.
- External Vendor Costs: SHWC anticipates an additional $35,000 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. $41,500 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 30,000 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $3.721 million annually.

The In-House Pharmacy: The Burden of IT Integration

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.
- Even with the aid of a Rebate Platform our PMS is not fully equipped to designate which claims are 340B and which are not, regarding the rebate platform. This means that staff will have to make manual adjustments to end of month reports for accounting, calculating risk, losses, and overpay payments. We are now having to use 5 different methods to ensure that claims are being paid and accounted for (Computer Rx, Beacon, MTF, Rx Paradigm, plus our MIP Accounting Software).
- One-Time Integration Costs: We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. As previously mentioned, this was $41,500 for our CHC.
- Ongoing Resource Diversion: Staff who currently manage clinical pharmacy services will be forced to spend 20 hours per week manually pulling “Purchase Files” and “Price Files” to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. SHWC currently partners with 14 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 three 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 rural Eastern Oklahoma, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[1]

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.

SHWC makes medications affordable by applying a Sliding Fee Scale (SFS) discount to all medications available from our wholesaler. This SFS is calculated by taking the lower 340B cost of goods (COG) and adding a minimal dispensing fee, starting at $5.50 for patients at or below 100% of the Federal Poverty Level (FPL). The dispensing fee increases by $1 for each level increase in FPL reported by the patient, ensuring that medication costs remain as low and accessible as possible, while maintaining the integrity of the 340B program.

Stigler Health & Wellness Center, Inc. appreciates the opportunity to respond to this ICR 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 Brooke Lattimore, COO at blattimore@healthwellnessok.com.

Sincerely,

Teresa Huggins, CEO
Stigler Health & Wellness Center, Inc.

Access Care of Coastal Texas

707 23rd Street

Galveston, Texas 77550

April 27, 2026

Submitted via email to: paperwork@hrsa.gov

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

Thank you for the opportunity to comment on HRSA's proposed Information Collection Request (ICR) associated with the potential 340B Rebate Model Pilot Program.

As a Ryan White HIV/AIDS Program-funded center participating in the 340B Program for approximately five years, ACCT provides comprehensive, coordinated care to individuals living with HIV in the Galveston, Texas area. We utilize Nuvem Rx as our Third-Party Administrator (TPA) and rely exclusively on 340B contract pharmacy arrangements to manage program compliance and operations.

Our 340B program supports approximately 550 patients annually, many of whom are uninsured or underinsured and rely on consistent access to life-sustaining antiretroviral therapy. The program generates approximately $2 million in annual savings (net of 340B drug spend), which are directly reinvested into expanding access to care, including opening new clinic locations in rural areas, enhancing clinical services, and absorbing the costs of uncompensated care.

For Ryan White providers, the 340B Program is not simply a financial mechanism, it is a critical tool that enables continuity of HIV treatment, viral suppression, and prevention of transmission within vulnerable populations.

While we support HRSA's goals of improving program integrity and transparency, we have significant concerns regarding the operational burden, financial implications, and workflow feasibility of the proposed data collection requirements under a rebate model, particularly given the time-sensitive and essential nature of HIV treatment.

Necessity and Utility of the Proposed Information Collection

We understand HRSA's intent to enhance oversight and transparency; however, much of the data proposed to be collected under this ICR is already captured within existing 340B infrastructure, including:

- HRSA audits
- Manufacturer inquiries and audits
- Manufacturer-required data submissions under current policies via ESP and Truzo
- Medicare Drug Price Negotiation Program reporting
- The Prime Vendor Program

We respectfully request that HRSA clearly demonstrate:

- What new or unique insights this additional data collection would provide beyond existing data sources
- Why current data aggregation and validation methods (e.g., through ESP and Truzo) are insufficient

Without this clarification, the necessity of duplicative data submission, particularly directly to manufacturers, is not fully justified and may introduce unnecessary administrative complexity without corresponding programmatic benefit.

Accuracy of HRSA's Burden Estimate

HRSA states that the burden associated with the proposed data collection "may not be significant." Based on our operational experience, we respectfully disagree.

Transitioning to a rebate model would require substantial additional effort, including:

- Development or modification of data extraction and submission processes
- Integration between TPA systems and multiple manufacturer-specific submission requirements
- Staff training and workflow redesign
- Ongoing reconciliation of submitted claims and received rebates
- Investigation and resolution of discrepancies or denied rebate claims

We estimate the following additional burden:

- ***Estimated additional staff hours per month: 80-100 hours, depending on claim volume***
- ***Estimated FTE impact: At least 0.5 additional FTE***
- ***Estimated annual administrative cost increase: $85,000–$115,000****
- ***Estimated IT/vendor modification costs: $120,000****

While the underlying data elements may already exist, the processes required to format, transmit, validate, track, and reconcile rebate-related data represent a substantial and ongoing operational burden.

(*-these amounts would be incurred to our post-340B drug spend savings)

Operational Challenges and Workflow Feasibility

The requirement for covered entities to submit claim-level data directly to pharmaceutical manufacturer platforms introduces several significant operational risks:

1. Increased Complexity and Fragmentation

Covered entities may be required to:

- Submit data to multiple pharmaceutical manufacturer platforms, each with different formats, systems, and requirements
- Manage varying submission timelines, validation standards, and dispute resolution processes

This fragmentation is inconsistent with the current centralized TPA model and introduces inefficiencies that increase administrative burden and risk of error.

2. Reconciliation Burden

Under a rebate model, covered entities must:

- Track each claim submitted for rebate
- Match rebates received to original claims
- Identify, investigate, and resolve discrepancies, provided clear resolution options are provided

We estimate:

- ***Monthly claim volume requiring rebate submission: 900 – 1,100 claims***

- ***Estimated reconciliation discrepancy rate: Approximately 60%***

This level of discrepancy would require significant ongoing staff time and resources, diverting focus from patient care.

3. Dependence on Third-Party Administrators

While HRSA notes that covered entities already maintain this data through TPAs, the proposal does not account for:

- Required development of new TPA functionality
- Increased vendor costs
- Variability in TPA readiness and capabilities

Financial Impact and Cash Flow Concerns

A rebate model fundamentally alters the timing of 340B savings, which is particularly concerning for Ryan White providers supporting patients who require uninterrupted access to medication.

Under the current model:

- Covered entities receive upfront discounts, enabling predictable reinvestment into care

Under a rebate model:

- Covered entities must pay higher upfront costs and wait for reimbursement

We estimate the following impact:

- ***Average monthly 340B drug spend (at 340B price): $791,666***
- ***Estimated portion subject to rebate model: 60%–70% (based of MFP list for FY 2027 and FY2028)***
- ***Estimated cash flow gap (purchase to rebate): Approximately 120 days***

This delay, particularly when applied to high-cost antiretroviral therapies, creates significant financial strain.

For Ryan White providers, delays in reimbursement could:

- Limit the ability to expand or sustain services

- Reduce resources available for adherence support and care coordination
- Ultimately impact patient outcomes, including viral suppression rates

Recommendations to Reduce Burden

To improve feasibility and minimize burden, we recommend:

1. Standardization

- Establish uniform data submission formats and requirements across all manufacturers
- Utilize existing industry standards wherever possible

2. Centralization via Neutral Data Clearinghouse

- Utilize a neutral data clearinghouse rather than manufacturer-owned platforms
- Eliminate duplicative submissions across multiple manufacturer-owned platforms

3. Automation

- Require automated data exchange through existing TPA systems
- Avoid manual submission processes

4. Alignment with Existing Data Streams

- Align required data elements with:
    - Existing TPA datasets
    - Contract pharmacy reporting

5. Clear Timelines and Accountability

- Establish defined timelines for rebate payments
- Include accountability measures for delayed or denied rebates

Enhancing Quality, Utility, and Clarity of Data Collection

To improve data quality and usability, HRSA should:

- Clearly define required data elements and formats
- Provide detailed technical guidance prior to implementation
- Pilot test processes with covered entities and TPAs
- Ensure consistent validation standards across manufacturers

Use of Technology to Minimize Burden

We strongly encourage HRSA to require:

- Integration with existing TPA platforms
- Use of secure, automated data exchange (e.g., APIs, standardized file transfers)
- Elimination of duplicative manual reporting systems

Conclusion

While ACCT supports HRSA's goals of improving transparency and program integrity, the proposed information collection associated with a 340B Rebate Model Pilot Program represents a significant operational and financial shift for Ryan White providers.

For organizations serving individuals living with HIV, any disruption in financial stability or administrative capacity has direct implications for patient care and public health outcomes.

We respectfully request that HRSA:

- Reassess the estimated burden
- Prioritize standardization and centralization
- Ensure alignment with existing workflows
- Mitigate financial risks associated with delayed rebate payments

Again, we thank HRSA for the opportunity to provide input and welcome continued engagement on these important issues.

Sincerely,

Access Care of Coastal Texas (ACCT)

Galveston, Texas