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

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

April 20, 2026

Dear Administrator Engels:

On behalf of **Sinai Hospital of Baltimore, Inc.**, we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) "Request for Information: 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. The answer is "no."

As explained below, *any* rebate mechanism will impose enormous costs and burdens on **Sinai Hospital of Baltimore, Inc.** that far outweigh any benefits that might come from it. HRSA's own calculations of costs are extraordinary. More fundamentally, HRSA's desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In reality, HRSA must give primacy to the needs of covered entities so that they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which **Sinai Hospital of Baltimore, Inc.** has relied on for years, is the best way to fulfill that purpose of the 340B program.

The RFI poses 30 questions and encourages commenters to include supporting facts, research, and evidence in their responses. **Sinai Hospital of Baltimore, Inc.** has done its best to provide detailed answers in the limited time available to us. For purposes of estimating costs, we have assumed that any future Rebate Program will include the 10 drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026 Information Collection Request. With the addition of the 2027 drugs, our cost estimate have increased over the estimates we had calculated for the 2026

drugs alone. After all, more drugs and more drug companies means *more* claims to submit, *more* rebates to track and reconcile, *more* money that we will need to float to drug companies while we await our statutory discount, *more* likely disputes over delays and denials, and therefore *less* money that **Sinai Hospital of Baltimore, Inc.** can spend on patient care and comprehensive health care services.

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

- The estimated administrative and operational costs incurred would be inclusive of ongoing expenses and initial start-up expenses. This cost breakdown would include the following:
    - Administrative oversight, training staff, IT data collecting/processing/testing and would estimate 364 hours/year.
    - Additional FTE for billing clerk, cost for initial IT setup/configuration of systems/data feeds
    - Pharmacy resources to support 340B TPA management/reporting
    - Pharmacy resources to manage rebate denials and appeals process.
    - A finance resource to manage AR reconciliation and rebate payments.
    - System for tracking rebates would be an ongoing expense
    - Upfront cash flow carrying costs would be significant and reduce cash on hand.

Staffing Impacts Under a Potential 340B Rebate Program. Sinai Hospital of Baltimore, Inc. does not currently have the staff needed to comply with a Rebate Program.

- The rebate program would require additional full-time staff, possibly an analyst with pharmacy technician license, but until that staff is added to the team, current staff would have to try to manage the

oversite of the program as well as their current functions. This would require reallocating work hours to the rebate program.
    - Recruiting and hiring eligible staff to fill these positions may take 3-6 months.
- The rebate model would require additional FTE to gather data from multiple programs, review and conform data to meet data requirements, submit data, ensure successful upload, review and process any errors in data upload, research the reason if a claim is rejected, re-process claims, ensure the receipt of rebate amounts are correct, and follow through if covered entity does not receive the correct rebate amount.
- The estimates for staffing to manage the IRA drugs under the rebate model is grossly understated. There would be a need for additional resources and hours that exceed HRSA's estimate. The time to train current and new staff on the program data requirements, processes, ensuring accuracy of the data submitted and rebates received, would require more than 5 hours per week. We estimate it would require at least 2-3 hours per day to support the rebate requirements.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Program. Sinai Hospital of Baltimore, Inc. has designed its technological systems and operational infrastructure in reliance on an upfront discount model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems.

- Implementation of a new program that could assist in tracking all requirements of the rebate program would include purchase and implementation, staff training, and execution of program. There would also be a need for an IT platform to ensure secure data transfer, data tracking and auditing of rebates to validate accuracy of expected savings.
- New programs through companies such as Plenful, Bluesight, Pillr, Cencora, etc., would be required and ongoing costs would be incurred for maintenance of the program for each 340B location and ongoing subscription costs.
- There would also be initial one time costs related to implementing the IT system infrastructure (interfaces, testing, etc.).
- Retrieval of medical claims data poses many challenges. The TPA does not have direct interfaces to medical claims. This work must be done manually to perform data extraction. The data often needs to be manually scrubbed and formatted to meet TPA or manufacture data requirements.

Data Collection By Covered Entities. During the prior iteration of the Rebate Program, both HRSA and the drug companies stated that a rebate mechanism would not impose new data-related burdens on 340B hospitals like ours. For example, both insisted that hospitals already provide the required information through 340B ESP. That is incorrect.

- Currently our program through our TPA, pharmacy operating system, and E.H.R to gather data, 340B analyst has to compile data, billing clerk has to review data submitted and trying to resolve denials and delays to ensure accurate rebate amounts received.
- We utilize an outside vendor to conduct annual external audits. We also conduct self audits that are reported up through our internal 340B compliance committee.
- The rebate program would change current data flow and activities. Current TPAs do not have the full functionality to create conforming reports and would require additional manual reporting to comply with the manufacture reporting requirements.
- The pharmacy would work with our IT department to obtain medical claims data as we do not currently have access to this information, and it would require additional resources for this data and manual work for data collections.
- We would need to modify existing data feeds from our EHR working with our IT team to include the medical claims.
- The pharmacy does not have access to medical claims data and would incur costs to add additional resources to assist in data gathering from with IT department as this data has not been a previous requirement to obtain 340B pricing.
- The health plan data and HCPCS code are added data fields that would need to be added.

Payment Timing And Potential Cash Flow Impacts. Unlike the existing upfront discount mechanism, any rebate mechanism will force **Sinai Hospital of Baltimore, Inc.** to effectively provide drug companies interest-free loans as we await the discounts that we are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our institution and the patients we serve.

- Delay of payment would cause decreased gross margins, increase in expenses and carrying costs, additional staff resources to dispute/appeal denials, partial or non-payment of rebates, and potential loss of cost-minus discounts and discounts with our wholesalers for early invoice payments

- Due to additional carrying costs we would need additional cash on hand in order to purchase high-cost drugs that have historically been purchased at an up front discounted 340B price and would now need to be purchased at WAC up front.

Adverse Impacts of These Additional Costs And Burdens. All of these many different costs and burdens add up. Unfortunately, that means that **Sinai Hospital of Baltimore, Inc.** will no longer be able to use our 340B savings as effectively and comprehensively as we did under an upfront discount model. As a result, our patients and community will suffer in concrete ways.

- Deterioration of hospital savings/funds used for patient care needs and support services would diminish our ability to provide added services for our patients.
- Pharmacy staffing and funds to cover patient medication needs upon discharge and hospital infusion centers would be impacted.
- Financial support for various community programs e.g. Case Management/Social Work, and other internal funds used to assist patient care needs could be reduced or removed as the funding for some of these programs are contingent on 340B savings.
- Potential reduction in services for patients in the community causing patients to travel further or create lapses in care.
- The impact to this unprecedented change, would result in likely not stocking specialty medication or being able to offer services to patients with specialized conditions such as HIV, Oncology, and other immunocompromised conditions due to the high cost of purchasing the medications and assuming risks for denials or delays in rebate payment.

Reliance Interests. The RFI expressly invites comment on "reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via 'rebate or discount.'" Respectfully, that framing rests on a flawed premise. The mere existence of statutory authority does not imply that the agency will—or reasonably may—exercise it in a particular manner. That is especially so here, where the 340B Program has, since its inception, consistently provided discounts through upfront pricing rather than post-sale rebates. **Sinai Hospital of Baltimore, Inc.** reasonably relied on this history when designing its internal operations, staffing, third-party contractual relationships, and financial planning for the use of 340B savings—all based on an upfront-

discount model. A fundamental switch now would disrupt these settled reliance interests engendered by the agency's prior policy. Absent any identified problems with the upfront discount model, and given the massive costs that this disruption will impose on 340B hospitals like ours, there is no reason to switch to a rebate mechanism, even in so-called "pilot" form.

Problems With the Beacon IT Platform. Under HRSA's original Rebate Program, the approved drug companies were planning to use Second Sight Solutions' Beacon IT platform to operate the Program. In the few weeks we had to prepare for the start of that Program, we encountered serious problems with Beacon.

- Red-lines or revisions to the TOC, were not allowed and must be accepted as is.
- Data concerns related to working within multiple platforms and general reports to meet data reporting requirements. The timeline and cost to prepare, collect and report in a timely manner of the rebate go-live date. This could take months to a year for Covered Entities to have systems and processes in place to comply.
- Due to the volume of inquiries received by Beacon, questions submitted were delayed in response, and there were areas of data requests in the claims fields that Beacon had not clarified before the program was paused.
- The Beacon Platform T&C cannot be amended. CEs are under duress to comply in order to access savings. There was not a mutual indemnification clause. Liability was assumed by the Covered Entities for all data breach matters. Would recommend a mutual indemnification in TOU.

Efforts To Avoid 340B/MDPNP Duplicate Discounts. 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 **Sinai Hospital of Baltimore, Inc.,** 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 AHA'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.

- There is already a process that manufacturers leverage in the event they identify a potential duplicate discount. We have received requests for reviews and have followed up with the manufacturer to resolve the issue.

For all of these reasons, Sinai Hospital of Baltimore, Inc. respectfully submits that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse.

If, however, HRSA chooses to move forward with this effort, it must allow **Sinai Hospital of Baltimore, Inc.** 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). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem.

We appreciate your consideration of these comments and look forward to working with HRSA on this important issue, which has profound implications for the millions of patients who rely on the 340B Program. Please contact me if you have questions.

Sincerely,

Rose Jose Pharm D.
Chief Operating Officer, Outpatient & Specialty Pharmacy Services

Lisa Polinsky, RPH, MBA
Vice President, Pharmacy and Respiratory Services

Hackensack Meridian *Health*

Via Electronic Submission - http://www.govinfo.gov
The Honorable Thomas J. Engels
Administrator
Health Resources Services Administration
Headquarters
5600 Fishers Lane
Rockville, MD 20857

April 27, 2026

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

Dear Administrator Engels,

On behalf of Hackensack Meridian *Health* (HMH), we thank you for the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed data collection for the 340B Drug Pricing Program (340B Program).[1]

HMH is the largest, most comprehensive, and truly integrated health care network in New Jersey, comprising a network of hospitals that includes three academic medical centers, one university teaching hospital, two children's hospitals, eight community hospitals, a behavioral health hospital, two rehabilitation hospitals and one long-term acute care hospital. Six of our 18 hospitals maintain robust academic medical programs. HMH also has more than 500 patient care locations, including ambulatory care centers, surgery centers, cancer centers, home health services, long-term care and assisted living communities, ambulance services, lifesaving air medical transportation, fitness and wellness centers, rehabilitation centers, urgent care centers, and physician practice locations. HMH has more than 40,000 team members and more than 7,000 physicians within its network and is a distinguished leader in health care philanthropy, committed to the health and well-being of the communities it serves.

As a vital safety-net provider for the State of New Jersey, the 340B Program is indispensable to HMH's mission. The savings generated through the Program are directly reinvested to stretch scarce federal resources, allowing the network to provide critical services to vulnerable patient populations. These services include offering free or low-cost medications, expanding access to specialty care, and supporting clinical services that would otherwise operate at a loss.

Overview of HMH's Comments

HMH appreciates HRSA's commitment to program integrity and transparency; however, HMH is concerned that the proposed data collection framework described in the Information Collection Request (ICR) would create significant operational burdens, introduce new risks to patient care, and undermine

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

the stability of the 340B Program.

HMH supports efforts to strengthen oversight of the 340B Program. However, the ICR would require covered entities (CEs) to implement a claims-level data collection and submission process to manufacturers in order to obtain rebates. While presented as an administrative mechanism, this framework would materially change program operations, create barriers for providers serving vulnerable populations, and introduce significant cash flow uncertainty by delaying reimbursement until after manufacturer adjudication.

HMH urges HRSA to reconsider this approach and instead rely on existing program data and centralized oversight mechanisms rather than provider-driven claims submission. As described below, the proposed framework raises significant operational, financial, and privacy concerns that warrant withdrawal or substantial revision. At a minimum, HRSA should revise the ICR to align with operational realities and develop alternative approaches that strengthen oversight while preserving access and program stability.

Claims-Level Data Collection and Submission Requirements

The proposal would require CEs to collect, validate, and transmit claims-level data to multiple manufacturers. This does not align with existing provider data systems and would require the development of new infrastructure to support ongoing, high-volume data exchange. This would create a significant administrative burden on CEs and require the diversion of resources from patient care. ***HMH urges HRSA to limit data collection to standardized, aggregated reporting or leverage existing claims and audit data already available to the agency, avoiding the need for new provider-side infrastructure.***

Fragmentation of Data Submission and Rebate Processes

The proposal would require providers to interface with multiple manufacturer-specific systems, each with different submission requirements, formats, and timelines. This would create operational inefficiencies, increase the likelihood of data discrepancies, and delay rebate payments. This fragmented approach would be difficult to implement across large health systems and would undermine program stability. ***If HRSA moves forward, HMH urges the agency to establish a single, standardized submission framework or centralized clearinghouse to ensure uniformity, reduce administrative burden, and minimize disputes.***

Patient Privacy and Data Security Concerns

The proposal would require the transmission of claims-level data, including Protected Health Information (PHI), to multiple third parties. This would expand the number of entities receiving sensitive patient data and increase the risk of unauthorized access or misuse. This would also create additional compliance risk under federal and state privacy laws. ***HMH urges HRSA to minimize the transmission of PHI by limiting required data elements, using de-identified or***

aggregated data where possible, and requiring any data exchange to occur through secure, centralized mechanisms rather than direct transmission to multiple manufacturers.

Conclusion

While HMH supports HRSA's goal of ensuring program integrity, the proposed data collection activities would have a chilling effect on participation in the 340B Program. The cumulative impact of these requirements would be increased administrative burden, reduced operational efficiency, heightened risk to patient privacy, and diminished access to affordable medications for patients. These requirements would not advance the goals of the 340B Program and would create barriers to participation for safety-net providers.

Thank you for the opportunity to comment on HRSA's ICR for the 340B Program. We would be pleased to discuss any of the above in greater detail at any time. If you have questions, please feel free to contact me at 201-370-8279 or Sarah.Lechner@hmhn.org.

Sincerely,

Sarah Lechner
SVP, Chief of External Affairs

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 **Vista Community Clinic (VCC),** 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, Vista Community Clinic again requests that CHCs be exempted from the pilot program.**

When VCC first opened in 1972, we set out to provide quality health care to anyone who walked through our doors. Over 50 years later, VCC is still fulfilling that mission of breaking down barriers to healthcare access. Over 65,000 patients in the Southern California region depend on VCC for their primary care. At VCC, we provide healthcare in communities where there are few or no options for care, or where systemic barriers to care have been created.

With very slim margins, our healthcare teams go the extra mile each day to provide high-quality and innovative models of primary care. Our patients are depending on us to pioneer new ways to provide exceptional care with scare federal resources. We are grateful that the 340B Drug Pricing program has enabled us to offer award-winning care and top-tier medications to our patients at an accessible price they can afford. Without the 340B program, VCC would not be able to provide our patients with the care they need and deserve.

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.

For Vista Community Clinic, the impact would be substantial:

- **Scale of Impact:**
  In 2025, we cared for over 65,000 patients and supported their medical needs through 54,827 340B-eligible prescriptions. This represents $4,941,705 in total drug costs, $4,135,274 in pharmacy administrative costs, and $1,826,426 in 340B program management and oversight costs, resulting in over $3.8 million in net 340B savings that directly support patient care and critical services. Any disruption to these savings directly affects access to medications for our predominantly uninsured and Medi-Cal patient population.

- **Existing Administrative Burden:**
  Our current administrative costs are approximately $174,000 annually to maintain a compliant 340B program under the existing model. The proposed rebate model would introduce new requirements—including claims tracking, rebate submission, reconciliation, and dispute resolution—resulting in a significant and unfunded increase in administrative costs.

- **Direct Impact on Patient Services:**
  340B savings support 115 programs across our organization, including: access to healthcare, behavioral health, care coordination, dental services, food and basic needs assistance, HIV services, migrant health, women's health, and youth programs. Any reduction in 340B savings or increase in administrative costs would directly limit our ability to sustain these critical services.

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 **65,000** 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.

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

Workforce Impact:

- **Staffing Impact**: Vista Community Clinic anticipates **additional staffing costs of $155,915** annually to account for the increase in regulatory, 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, **Vista Community Clinic** will face an increased administrative burden to monitor rebate claims and payments. It's estimated, that an additional ten (10) hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Given increased complexity, Vista Community Clinic anticipates an increase of **$35,000 annually** for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, 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 upfront costs to design new internal workflows and create processes to support the demands of a Rebate Program. Approximately, $5,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves over 65,000 patients, the total projected increase in expenses - including labor, IT, and additional vendor costs - is estimated at $190,000 annually.

The In-House Pharmacy: The Burden of IT Integration

Vista Community Clinic operates 2 in-house pharmacies, supporting 17 different clinics located throughout San Diego, Riverside, Orange and Los Angeles counties.. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **8** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC currently partners with 88 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 **88** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model is more costly and complicated to manage, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in **San Diego, Riverside, Orange and LA Counties** with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[2] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[3]

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.[4] Vista Community Clinic estimates it will take an additional 20 hours of implementation time and weekly an additional 8 hours and cost a total of $190,915 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

Vista Community Clinic 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

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

[4] Internal NACHC survey data

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.[5] This patient population relies on affordable medications to manage these long-term conditions.

Only 19% of VCC's patient population has Medicare or Commercial Insurance. This means that 81%, or approximately 53,000 patients under our care, are either uninsured or enrolled in Medi-Cal and many depend on access to reduced-cost medications, sliding fee discounts, and other affordability programs supported by the current 340B program. These vulnerable individuals will be directly impacted by the proposed 340B Rebate Program. VCC will be required to purchase medications at wholesale acquisition cost (WAC) and await rebate reimbursement, which may prevent us from consistently offering 340B-discounted pricing on medications included in the rebate program. This will significantly limit our ability to assist those most in need and materially compromise our ability to provide the level of care and support on which our patients depend.

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,[6] 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.[7] In line with their mission, CHCs offer flat or sliding-scale discounts on

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

prescription drugs to make them more affordable for low-income individuals.[8] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

Vista Community Clinic works to ensure patients have access to needed medications regardless of income by actively using all available tools—including manufacturer vouchers and our Sliding Fee Scale—to reduce costs at the point of sale. **Approximately 18,000 prescriptions, or 45% of all prescriptions dispensed through our in-house pharmacies, depend on these efforts**. A rebate model undermines this work by requiring CHCs to provide discounts without knowing the final net drug cost or when reimbursement will occur, shifting financial risk onto the CHC and weakening the very mechanisms that enable consistent patient access to medications.

Conclusion

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

Vista Community Clinic 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 please contact **Debra Jones, 340B Program Manager at** debra.jones@vcc.org **or Emily Nguyen, Pharmacy Director at** enguyen@vcc.org**.**

Sincerely,

Fernando Sanudo, CEO
Vista Community Clinic

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

Your health.
Your clinic.
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NHC Administrative Office
7320 SW Hunziker Rd. Ste. 102
Portland, OR 97223
Phone: 503.941.3033

April 22, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Neighborhood Health Center (NHC)** 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, Neighborhood Health Center (NHC) again requests that CHCs be exempted from the pilot program.**

[ADD YOUR ORG BOILERPLATE INFO HERE] Neighborhood Health Center (NHC) is a federally qualified health center (FQHC) headquartered in Washington County, Oregon, committed to our mission to *build healthy communities—one neighbor at a time—through patient-centered healthcare, regardless of income or current state of wellness*. **Neighborhood Health Center (NHC)** serves historically underserved communities, including low-income households, communities of color, agricultural workers, as well as individuals experiencing homelessness. **Neighborhood Health Center (NHC)** serves communities across Clackamas and Washington counties through a network of nine clinics and two SBHCs. In 2025, these sites provided primary medical, dental, behavioral health, and pharmacy services to nearly 25,000 patients through 74,000 visits, many of whom face financial, transportation, and other barriers to care.

In Clackamas County, NHC operates three clinics serving both urban and rural populations. Rural communities make up a significant portion of the county, and this is most evident at the Canby clinic, NHC's first co-located and owned site, which served 3,982 patients with 11,727 visits in 2025. Nearly one in seven patients at Canby live in rural communities, with the highest concentrations coming from Canby, Molalla, Aurora, Estacada, Woodburn, and Hubbard. Many

community members face overlapping challenges such as limited transportation options, financial hardship, and lack of insurance, which make consistent access to healthcare especially difficult. Beyond Canby, patients come from across Clackamas County, making these clinics critical access points for a wide range of communities. The Milwaukie clinic provides dental, primary medical, and behavioral health services to 7,502 patients with 18,862 visits, while the Oregon City clinic serves 4,438 patients with 11,758 visits, offering the same suite of services.

In Washington County, NHC's Hillsboro clinic focuses on reproductive health and served 233 patients with 313 visits in 2025. The Tanasbourne clinic provides integrated primary medical, dental, and behavioral health services to 13,566 patients across 36,484 visits. NHC also operates two school-based health centers (SBHCs) that provide well-child care and primary medical, dental, and behavioral health services: the Tualatin High School SBHC served 808 patients with 1,869 visits, and the Merlo Campus SBHC served 503 patients with 661 visits in 2025.

Neighborhood Health Center (NHC) provides care to a highly economically vulnerable population in a service area that is home to nearly 850,000 residents, of whom 21% are low-income and 9% live in poverty. Among the overall population, 6% are uninsured and 26% are enrolled in Medicaid. Additionally, 17% of adults report poor mental health, defined as 14 or more days in the past 30 days when their mental health was not good, and 12% report poor physical health. Housing stress affects 33% of households, and 6% live in households with limited English proficiency (HRSA, 2025).

In 2025, **Neighborhood Health Center (NHC)** served a patient population reflecting these broader community needs, where 61% of patients with reported income were considered low-income. The majority (82%) were insured through Medicaid or Medicare, while 8% remained uninsured. **Neighborhood Health Center's (NHC)** patient base is wide-ranging, including 40% identifying as Hispanic/Latinx, 4% as Black/African American, 6% as Asian, and smaller percentages identifying as Native Hawaiian/Pacific Islander, American Indian/Alaska Native, or multiracial.

Neighborhood Health Center (NHC) also provides critical services to high-need populations, with 10% of patients experiencing homelessness. Additionally, 7% received direct, low-barrier care at its SBHCs. Through its integrated medical, dental, pharmacy, and behavioral health services, **Neighborhood Health Center (NHC)** remains committed to reducing health disparities and improving outcomes for Oregon's most vulnerable communities.

Across all Neighborhood Health Center (NHC) sites, Community Health Navigators (CHN) help patients overcome social and structural barriers to care, connecting 2,660 patients in 2025 to resources such as transportation, food, and housing assistance. An additional 1,978 patients received insurance navigation and enrollment support through Neighborhood Health Center's (NHC) Member and Engagement Services (MES), ensuring patients maintain access to needed care.

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 **Neighborhood Health Center's (NHC)** ability to serve the **25,000** 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. **Neighborhood Health Center's (NHC)** 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**: **Neighborhood Health Center (NHC)** anticipates needing **1.0** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model. **Neighborhood Health Center (NHC) estimates the cost to hire additional staff to be $91,500 for 1 FTE annually.**
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Neighborhood Health Center (NHC)** will face an increased administrative burden to monitor rebate claims and payments. **Neighborhood Health Center (NHC)** estimates that **20 hours weekly** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Neighborhood Health Center (NHC)** anticipates an additional **increased costs related to the Rebate Model** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

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

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: Neighborhood Health Center (NHC)** anticipates high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **Neighborhood Health Center's (NHC)** estimated one-time cost of $ 25,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For **Neighborhood Health Center (NHC)**, which serves **25,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$100,000** annually.

The In-House Pharmacy: The Burden of IT Integration

Neighborhood Health Center (NHC) operates 1 (one) in-house pharmacy in our Canby Clinic in addition to a pharmacy locker in our Tanasbourne Clinic stocked and refilled through delivery services performed by our in-house pharmacy staff. 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. **For Neighborhood Health Center's (NHC) pharmacy software to function correctly and allow for the continuation of 340B pricing to our qualified patients Neighborhood Health Center (NHC) will be required to build and maintain an additional pricing structure separate from the WAC files. This will create an additional administrative burden to maintain accurate pricing files for the correct national drug codes.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools if **Neighborhood Health Center (NHC) is forced to move to a new software vendor or pay increased costs to our existing vendor as additional API build needs increase.**
- **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. My CHC currently partners with **52** 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 **52** 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 Neighborhood Health Center's (NHC)** service area, this would leave our 24,000 patients in **Clackamas and Washington Counties** 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] **Neighborhood Health Center (NHC) currently does not stock NDCS's identified in the rebate model. However, if the rebate model goes into effect the additional upfront cost and reconciliation work would limit Neighborhood Health Center (NHC) from adding medications in the future and would ultimately affect patient care.**

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

Neighborhood Health Center (NHC) 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.

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

[3] Internal NACHC survey data

[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.

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.
  Based on our organization's data, we estimate it would cost **$672,787 annually** to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends $**10,416** to purchase these same drugs at the 340B ceiling price. This represents a **6,360%** increase in upfront capital required for procurement.
- **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. **[DETAILS ON HOW YOUR CHC MAKES DRUGS AFFORDABLE]**
  Neighborhood Health Center (NHC) makes prescriptions affordable by providing medication delivery services within our service area for patients who are unable to travel to the pharmacy at our Canby Clinic. In addition to delivering medications directly to patients' homes, NHC also operates a pharmacy locker at our Tanasbourne Clinic, similar to Amazon pickup lockers. Prescriptions are delivered and securely placed in these lockers for patient pickup, helping make medications more accessible for patients who cannot easily travel to the Canby Pharmacy.

[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

Another way NHC helps make prescriptions more affordable is through the Neighbors Assistance Fund (NAF), which was established with support from private foundations. This fund helps offset the cost of medications for patients who cannot afford to pay for their prescriptions. Because the fund is limited, assistance is dependent on the availability of outside contributions from generous supporters.

Conclusion

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

Neighborhood Health Center (NHC) 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 **Jeri Weeks, CEO, Neighborhood Health Center (NHC) at weeksj@NHCOregon.org**

Sincerely,

Jeri Weeks, CEO
Neighborhood Health Center (NHC)

Winding Waters
Your Health Care Home

April 24, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Winding Waters Medical Clinic** 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, Winding Waters again requests that CHCs be exempted from the pilot program.**

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 **5700** 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.

Workforce Impact:

- **Staffing Impact**: **Winding Waters** anticipates needing **1** 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, **Winding Waters** will face an increased administrative burden to monitor rebate claims and payments. **10-20 hours weekly** will be required to report 340B rebate claims to a third-party platform and to confirm they are received and processed in a timely fashion.
- **External Vendor Costs**: **Winding Waters** anticipates an additional **$20,000** 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. **$20,000** will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees **of $500-$1,000 monthly** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **5,700** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$170,000** annually.

II. Patient Impact

Winding Waters 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.[1] This patient population relies on affordable medications to manage these long-term conditions.

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

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,[2] 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 potentially 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.[3] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[4] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Due to the aforementioned cash flow situation, Winding Waters will likely be faced with decreasing and limiting the sliding scale thereby affecting patient's access to the medications they require.

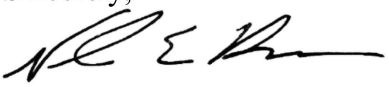
[2] 2025 UDA Data, HRSA (hrsa.gov)
[3] HRSA FAQ
[4] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

In Conclusion

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

Winding Waters sincerely 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 **our Clinical Pharmacy Director Michael Farley at mike.farley@windingwaters.org.**

Sincerely,



Nicolas Powers, CEO
Winding Waters Medical Clinic

CALIFORNIA RURAL INDIAN HEALTH BOARD, INC.

April 17, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of the California Rural Indian Health Board, Inc. (CRIHB), representing 70 federally recognized Tribes and 20 Tribal Health Programs (THPs), we appreciate the opportunity to comment on the Health Resources and Services Administration's (HRSA) Information Collection Request (ICR) for the 340B Rebate Model Pilot Program.

Opposition to the Rebate Model
CRIHB strongly opposes any transition from the current upfront discount structure to a rebate-based model under the 340B Program. Tribal Health Programs rely on 340B to stretch scarce federal resources and maintain access to essential medications for American Indian and Alaska Native patients in rural and medically underserved communities. A rebate model would fundamentally undermine this purpose by requiring providers to absorb significant upfront drug costs while navigating delayed reimbursement.

For Tribal Health Programs operating on limited margins and with little capital reserves, this model introduces significant cash flow risk, increased administrative complexity, and operational instability. It would require additional processes for claims tracking, rebate submissions, denials, reconciliation, and compliance, diverting already limited resources away from patient care.

Most importantly, a rebate model threatens patient access. Any disruption in drug affordability or reimbursement would have immediate consequences for Tribal communities that already face significant barriers to care.

1020 Sundown Way, Roseville, CA 95661
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ICR Burden in the Context of Tribal Health Programs
While this ICR focuses on information collection, the burden cannot be separated from the conditions under which Tribal Health Programs operate, particularly in California, one of the most underfunded IHS Areas in the nation.

- **No IHS hospitals** - all inpatient care is dependent on Purchased/Referred Care (PRC), which is chronically underfunded and routinely exhausted before the end of the fiscal year
- **Severe workforce limitations** - the California Area has among the lowest staffing levels in the IHS system, with approximately 184 Full-Time Equivalents (FTEs) and no recent growth, despite serving over 100 federally recognized Tribes, far below staffing levels in other IHS Areas [1]
- **Longstanding funding inequities** - in *Rincon Band of Mission Indians v. Califano*, federal courts found "no rational basis" for the historical underfunding of California Tribal health systems [2]
- **Lack of federal infrastructure investment** - Tribes have been forced to build and sustain health systems largely without IHS facility support

Against this backdrop, the proposed information collection requirements would impose an additional burden, including:

- Claims-level data submission, tracking, and reconciliation requirements
- Increased staffing needs and diversion of existing personnel
- Costly IT system upgrades and third-party platform integration
- Ongoing administrative complexity due to varying reporting requirements

HRSA's current burden estimates do not adequately reflect these realities and significantly underestimate the impact on Tribal Health Programs.

Request for Tribal Exemption
Given the demonstrated financial, administrative, and operational burden, and the longstanding federal underinvestment in Tribal health systems, CRIHB strongly urges HRSA to:

- Exempt Tribal Health Programs from participation in any 340B Rebate Model Pilot Program; and
- Reevaluate burden estimates to accurately reflect the conditions of under-resourced IHS Areas, particularly California.

[1] U.S. Department of Health and Human Services, *Indian Health Service: Justification of Estimates for Appropriations Committees, Fiscal Year 2027*, FY 2027 Congressional Justification of Estimates for Appropriations Committees

[2] *Rincon Band of Mission Indians v. Califano*, 464 F. Supp. 934 (N.D. Cal. 1979), aff'd sub nom. *Rincon Band of Mission Indians v. Harris*, 618 F.2d 569 (9th Cir. 1980).

This exemption is necessary not only to prevent administrative burden, but to avoid further exacerbating longstanding federal funding inequities and to uphold the federal trust responsibility to Tribal Nations, as reflected in federal law. Congress has declared that it is the policy of this Nation, "in fulfillment of its special trust responsibilities and legal obligations to Indians… to ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy."[3]

The 340B program is critical to Tribal health systems. Imposing a rebate model on already underfunded and infrastructure-limited systems would further destabilize access to care for American Indian and Alaska Native communities.

Thank you for the opportunity to comment. If you have any questions or would like additional information, please contact Cesar Gonzalez-Garcia, Health Policy Analyst at the California Rural Indian Health Board, Inc., at (916) 953-3573 or cgonzalez-garcia@crihb.org.

Sincerely,

Virginia Q Hedrick, MPH (Yurok/Karuk)
Chief Executive Officer
California Rural Indian Health Board, Inc.

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

Executive Administration
520 E. Broad Street
Suite 108
Bethlehem, PA 18018

April 20, 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 ***Star Community Health***, I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, ***Star Community Health*** again requests that CHCs be exempted from the pilot program.

Star Community Health is a Federally Qualified Health Center Look Alike (FQHC-LA also referred to as a Community Health Center or CHC) serving approximately ***52,300 patients*** annually across 15 clinic sites in multiple counties within Pennsylvania and New Jersey. Our patient population includes a high proportion of uninsured, medically underserved, and economically vulnerable individuals, as well as Medicaid beneficiaries.

- Star Community Health operates 5 contract pharmacies.
  - 3,125 total 340B eligible prescriptions
  - Generating ~$478,000 in net 340B savings after program administration costs
  - Recent participation with the 340B ESP portal to un-restrict select manufacturer pricing, Star Community Health has the potential to generate approximately $1.3M in net 340B Savings annually.
  - These savings are directly reinvested into patient care services, including:
    - Sliding fee scale discounts for uninsured and low-income patients
    - Behavioral health integration
    - Chronic disease management programs
    - Care coordination and care gap closure services

- **Financial Losses:** Star Community Health anticipates a loss of **$ 300,000** for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.

- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.
  - **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.

I. Patient Impact

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

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

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

II. Administrative Complexities and Financial Challenges for CHCs

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

340B Rebate Model Operational & Administrative Cost Calculator Description

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

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

administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Sliding Fee Discount**: **Star Community Health** provided **$5,911,987** in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: **Star Community Health** anticipates needing **2** additional FTEs to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, **Star Community Health** anticipates an increase of **$200,000** to costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Workforce Impact

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

- According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.[2]
    - **Star Community Health would require 2 FTEs**
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[3] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities.
    - **Star Community Health estimates the cost to hire 2 FTEs, $180,000 and the upfront costs to exceed $280,000**
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. **Around 20 hours weekly** will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans. The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens.
    - **Star Community Health urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

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

[2] Internal NACHC assessment (99 responses).
[3] Ibid.

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. **$10,000** 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 complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 52,300 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at **$470,000** annually.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across all seven pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[4] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[5]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed in a cost-effective manner that reflects the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[6]

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.
- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address.

A. Financial Challenges

Under the proposed 340B Rebate Model Pilot, CHCs would be required to purchase drugs at full retail price, also known as the Wholesale Acquisition Cost (WAC). This departure from over 30 years of precedent would drastically diminish CHCs' ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow. CHCs will have to wait to receive their rebate

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

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

[6] Internal NACHC survey data

payment ***after*** providing medications to their patients. This change will force CHCs to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

CHCs are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead them to exceed their credit limits with wholesalers, halting their ability to order medications until payments are submitted. While rebates are expected to arrive within 10 days from completed data submissions, the previously proposed rebate pilot allowed covered entities up to 45 days to submit data, meaning the potential time from dispense to rebate can extend to 55 days. Retail pharmacies typically turn their inventory 10-12 times a year (roughly every 30 days).[7] Assuming a best-case scenario of 15 days to the average 30 days for inventory to turn, CHC pharmacies with physical inventory could be waiting 70-85 days from purchase to rebate under a 45-day data submission cadence. Anecdotal reports from CHC pharmacies suggest a planned cadence of 2-week data submissions for entity-owned pharmacy data. Pharmacies with physical inventory submitting data every 14 days would anticipate a purchase-to-rebate payment time frame of 40 to 55 days.

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

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

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, **Star Community Health** may need to reduce:

- **Essential Clinical Services:** To offset the upfront cost of drugs, we may be forced to scale back non-revenue-generating but essential services.
- **Operating Hours:** We may need to reduce our clinic hours.
- **Workforce & Staffing:** The administrative burden of this pilot requires us to divert funds away from clinical staff. For every "Rebate Coordinator" we are forced to hire, we lose the ability to fund additional staff and services.

B. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHCs have suggested that paying for medications upfront at WAC prices

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

would require dipping into limited financial reserves or taking out loans, thereby defeating the purpose of the 340B program.

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

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts.
- **Star Community Health** estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by **$300,000.**

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on **Star Community Health,** the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 34 million patients across the country depend on.

Conclusion

Star Community Health has been a transparent and accountable steward of the existing 340B program and 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. **Star Community Health** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Star Community Health appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue.

Sincerely,

Quynh Hicks
Executive Director
Star Community Health

April 20, 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 Partnership Health Center, I would like to thank the Health Resources and Services Administration (HRSA) for providing the opportunity to **share our estimated burden with HRSA on compliance with the 340B rebate model pilot program. Given the severe administrative, financial, and operational burden a rebate model would place on CHCs, Partnership Health Center again requests that CHCs be exempted from the pilot program.**

At our Health Center, 340B savings are invested in activities that advance our mission to promote optimal health and wellbeing for all through comprehensive, patient-focused, accessible and equitable care. Valuable 340B savings expands access to critical pharmaceutical services such as Clinical Pharmacy within our medical clinic where we provide medication review and reconciliation, education, anticoagulation therapy, and chronic condition management. These services are vitally important to quality care that has a direct impact on positive health outcomes. While unmeasurably important, these services are not typically paid for by insurance, making the use of our 340B savings in this area a focus for our pharmaceutical care. Savings also advance medication assistance navigation, a program that is no cost to patients and assists patients in obtaining life-saving medications that many of our patients would be unable to access without this program. Any remaining 340B savings are directly invested into the Health Center program services such as dental, behavioral health, substance use programs, and social work programs that stabilize patients facing challenging social drivers of health like houselessness, food insecurity, and lack of health insurance.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **18,010** 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**: **Partnership Health Center** anticipates needing **4** 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 our pharmacy fills for the 10 selected drugs, **Partnership Health Center** will face an increased administrative burden to monitor rebate claims and payments. **Nearly 33 hours each week are anticipated** will be required to report 340B rebate claims to a third-party platform. **An additional 124 hours each week are anticipated** to be needed for direct patient navigation for the direct impact to our uninsured patients at the time of filling a prescription.
- **External Vendor Costs**: **Partnership Health Center** anticipates an additional **$1.53M** 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.

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

$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 $650,000 annually** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **18,010** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$1.53M** annually.

The In-House Pharmacy: The Burden of IT Integration

Partnership Health Center operates one extensive in-house pharmacy that serves patient needs across multiple counties in Western Montana. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. **This is the case for Partnership Health Center, that directly serves our community with our in-house pharmacy – filling more than 135,000 essential prescriptions each year.**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **We anticipate initial integration costs could be $50,000.**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **160** hours per week manually pulling “Purchase Files” and “Price Files” to verify that every rebate check matches the statutory 340B price.

II. Patient Impact

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

[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)

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.[4] In line with their mission, CHCs offer flat or sliding-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. **At Partnership Health Center, our sliding fee scale discounts are a direct reflection of the cost related to filling a prescription.** In a rebate model, our cost to purchase medications increases significantly. This has a direct and drastic impact and makes offering meaningful sliding fee scale discounts significantly more limited. Patients who benefit from our sliding fee scale discounts are uninsured and have household incomes less than 200% of the federal poverty level, as has been required by over 30 years of precedent from HRSA guidelines. **We anticipate at least 33% of our 18,010 patients could lose financial access to essential pharmaceuticals that improve and stabilize their health conditions in a rebate model.**

Conclusion

Partnership Health Center strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B

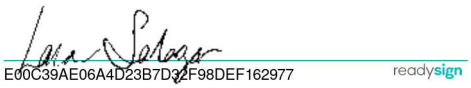
[4] HRSA FAQ

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

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

Partnership Health Center appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Lara Salazar, CEO salazarl@phcmt.org

Sincerely,



Lara Salazar, CEO
Partnership Health Center

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Tel 206.987.7000

Hope. Care. Cure.™

Submitted electronically via www.regulations.gov HHS Docket No. HRSA-2026-0001-0001

April 20, 2026

RE: Public Comment on the Request for Information: 340B Rebate Model Pilot Program

Dear Director Britton:

On behalf of Seattle Children's, I appreciate the opportunity to submit comments in response to the Health Resources and Services Administration's (HRSA) Request for Information (RFI) regarding the 340B Rebate Model Pilot Program. We appreciate HRSA's effort to gather stakeholder feedback on establishing a transparent framework to evaluate the feasibility of a rebate-based mechanism for effectuating the 340B ceiling price, and we support the agency's commitment to early engagement. In response, we respectfully offer the following operational data, financial impact estimates, and recommendations from the perspective of a pediatric safety-net provider.

Seattle Children's is a freestanding, nonprofit, pediatric quaternary care center serving children and families across Washington, Alaska, Montana, and Idaho (WAMI). We operate as a regional safety-net provider, with a payer mix comprised of more than 50 percent Medicaid and public program enrollees. The 340B Drug Pricing Program is an essential financial underpinning that enables us to provide access to highly specialized, resource-intensive care to children across one of the most geographically expansive and underserved catchment areas in the country. These savings directly support access to highly specialized pediatric oncology, transplant, neonatal, rare disease, and infusion services for children who often travel significant distances across the WAMI region to receive care unavailable in their local communities.

While the previously proposed pilot contemplated a framework that was limited in scope to products associated with the Medicare Drug Price Negotiation Program (MDPNP) and did not include drugs with routine pediatric indications, the RFI does not define or limit the scope of any future rebate model, and HRSA has signaled that it may expand any new program to a broader class of drugs. Seattle Children's is deeply concerned by this trajectory. Should HRSA consider expanding the model, we strongly urge the agency to explicitly exclude freestanding children's hospitals from any rebate model implemented under the 340B Program. Freestanding children's hospitals operate under uniquely narrow

service margins, disproportionately high Medicaid payer mixes, and highly specialized drug utilization patterns that make delayed rebate reimbursement materially more disruptive than in broader adult hospital systems.

At a minimum, HRSA should establish a deferment or affirmative opt-in mechanism for these institutions in any future regulatory implementation or programmatic expansion of the model. Unlike large adult hospital systems, pediatric safety-net providers are not positioned to front-load drug acquisition costs or maintain the pharmacy infrastructure required to reconcile complex rebate claims. The cumulative impact of delayed reimbursement, unresolved rebate denials, and heightened administrative burden would represent a structural threat to access for medically complex and underserved pediatric populations.

We appreciate HRSA's inclusion of targeted questions in the RFI regarding the potential implementation of a rebate model. Based on our operational analysis, we respectfully offer the following detailed recommendations and data points to inform your evaluation:

1. Costs to Covered Entities (Sections 1a-1e)

The transition from a point-of-sale discount model to a retrospective rebate model will necessitate significant technical and staffing investments to prevent overcharges and ensure timely payments. This represents a permanent, burdensome shift of our resources from clinical informatics to financial defense.

Current Administrative Infrastructure (Section 1a)

Under the current upfront discount model, Seattle Children's processes 340B transactions through a split-billing platform integrated with our electronic health record and Third-Party Administrator (TPA). Key cost drivers include TPA fees, pharmacy informatics staffing, and ongoing compliance monitoring. While we have not provided a total transaction count in this submission, we are prepared to supplement this comment with additional data upon request.

Incremental Costs Under a Rebate Model (Sections 1b-1d)

Our analysis projects the following incremental costs, distinguishing between one-time implementation costs and ongoing operational burden:

- Staffing & Labor (ongoing): An estimated need for 2.0 additional FTEs (approximately 4,160 hours per year) dedicated specifically to monitoring, reconciling, and negotiating discrepancies, at an annual budgetary impact of roughly $200,000.
- Initial Implementation Burden (one-time, 160 hours): Translating RFI data elements to EHR tables (40 hours), configuring TPA/split-billing logic (60

hours), and running validation and quality assurance to protect Medicaid duplicate discount logic (60 hours).
- Financial System Costs: Estimated at $40,000 for initial module implementation, plus ongoing maintenance fees.
- Operational System Requirements (ongoing): Automated reconciliation software for claims-level matching; procurement interface updates to track unpaid rebates as financial assets on our balance sheets; and enhanced data infrastructure for granular audit logging.

These costs are not theoretical. They reflect the actual investment required to build and maintain the pharmacy financial infrastructure necessary to operate in a rebate environment. We further note that if HRSA were to structure any offset mechanism to address these costs, it would need to account for both the one-time implementation burden and the permanent reallocation of clinical informatics capacity toward financial administration.

Organization-Specific Factors and Access to Drugs (Sections 1e-ii, 1e-iii)

As a freestanding children's hospital with a Medicaid payer mix exceeding 50 percent, Seattle Children's faces structural constrains that distinguish us from large adult health systems. Our pharmacy operations center on high-cost, low-volume specialty drugs for pediatric oncology, transplant, neonatal, and rare disease populations—precisely the drug categories for which delayed reimbursement and rebate denials carry the greatest access risk. Any disruption to the financial flow underpinning these programs directly threatens access for patients with no alternative sources of care.

2. Payment Timing and Cash Flow Impacts (Section 2)

Under our current wholesaler contracts, 340B drugs are purchased at the discounted ceiling price at point of sale. There is no lag between drug acquisition and realization of the 340B benefit. A rebate model would fundamentally alter that timing, requiring us to finance the difference between WAC and the 340B ceiling price—potentially for weeks—while awaiting manufacturer payment. Based on Seattle Children's annual 340B spend, this shift would create a rolling financial float of nearly $250,000 at any given time, disrupting our operating cash flow and threatening our ability to support restricted safety-net program funds.

Seattle Children's does not believe any payment timeline under a rebate model can fully replicate the financial parity of the current upfront discount structure. If HRSA nonetheless moves forward, any payment standard must be accompanied by rigorous enforcement mechanisms to ensure manufacturers uniformly meet their obligations. **A payment deadline without enforcement provides no protection at all.**

3. Rebate Denials (Section 3)

Seattle Children's is particularly concerned that rebate denial processes could function as a de facto post-dispense utilization management mechanism, allowing manufacturers to delay or effectively restrict access to statutory 340B savings through proprietary data requirements, technical edits, or unilateral claim logic. We urge the agency to develop a clearly defined dispute resolution process specific to rebate operations under any contemplated pilot.

While HRSA previously pointed to the existing Administrative Dispute Resolution (ADR) process, that mechanism suffers from prolonged adjudication timelines and is not a practical pathway for providers seeking resolution of real-time rebate denials. Seattle Children's strongly urges HRSA to codify a formal Appeals and Resubmission Process (ARP) featuring:

- A redetermination provision that allows covered entities to resubmit claims flagged for technical or formatting errors without penalty; and
- A neutral third-party arbitration mechanism to resolve disputes, preventing manufacturers from unilaterally denying discounts based on proprietary internal logic.

Furthermore, HRSA must define standard denial reason codes and explicitly establish what constitutes a legitimate versus illegitimate denial. Legitimate denial grounds should be narrow and statutorily grounded. A manufacturer should be permitted to deny a rebate claim where a verified duplicate discount has already been paid under Medicaid on the same dispense—a clear statutory violation—or where the drug was dispensed at a location not listed in OPAIS or to a patient who does not meet HRSA's patient definition. These are the categories of denial that reflect genuine program integrity concerns.

By contrast, HRSA must explicitly prohibit denials that are procedural rather than substantive. A manufacturer should not be permitted to deny a rebate solely because a covered entity submitted standard ANSI 837 data rather than using a proprietary manufacturer portal—process preferences cannot supersede statutory eligibility. Similarly, denying a claim submitted 31 days after dispense while the covered entity is awaiting TPA "sold" status verification is not a legitimate integrity safeguard; it is an administrative "gotcha." HRSA must define clear, enforceable boundaries between these categories so that denial cannot be weaponized as a de facto utilization management tool.

4. Data Collection by Covered Entities (Section 4)

The administrative requirements placed on covered entities must reflect the complexity of hospital pharmacy operations. Seattle Children's recommends that HRSA mandate the use of ANSI X12 837/835 and NCPDP D.0 data standards for all rebate pilot participants. Standardized API integrations must be prioritized over proprietary manufacturer portals to ensure administrative efficiency and data integrity.

We further propose a concrete 90-day grace period for claim submission and data reconciliation. Any window shorter than 90 days fails to account for the necessary lag in pharmacy financial reconciliation and TPA data validation. A vague "reasonable" standard leaves safety-net providers vulnerable to process-based denials.

Data Privacy and Security (Section 4e)

As a pediatric safety-net provider, Seattle Children's is deeply concerned that the data elements required by manufacturers to validate rebates could compromise patient confidentiality. Manufacturers often request granular data that, when applied in the context of rare pediatric conditions, bypasses HIPAA de-identification safeguards. This is possible where otherwise de-identified data elements may nevertheless be sufficient to re-identify individual patients due to low patient volume and highly specialized drug utilization.

We urge HRSA to mandate a Masked Data standard, where only the 340B ID, 11-digit NDC, and a de-identified transaction ID are shared, strictly prohibiting the transfer of patient-specific demographics or prescriber-identifiable information.

5. Manufacturer Efforts to Avoid Duplicate Discounts (Section 5)

As a freestanding children's hospital, Seattle Children's operates with robust systems to prevent 340B-Medicaid duplicate discounts. Our TPA manages virtual inventory split-billing carve-out functionality for Medicaid claims, and our pharmacy team conducts regular reconciliation to verify that no claim received both a 340B discount and a Medicaid rebate. These systems have operated effectively under the current upfront model.

We do not believe a rebate model would meaningfully improve duplicate discount prevention for freestanding children's hospitals. Our existing TPA-based carve-out processes already accomplish this objective. A retrospective rebate model would not materially improve compliance outcomes for institutions like Seattle Children's—it would simply shift financial and administrative risk onto institutions least positioned to bear it, without a corresponding integrity benefit.

6. Required Reporting (Section 6)

We recommend that HRSA require participating manufacturers to report specific operational data to support HRSA's compliance oversight and to allow covered entities to identify and resolve avoidable delays. These reports should include:

- The average time from data submission to rebate disbursement, separating internal processing delays from payment execution;
- Categorized summaries of rebate denial reasons;
- The percentage of claims requiring resubmission prior to payment; and

- Documentation of platform outages or system unavailability that affected claim processing.

These data elements will enable HRSA to identify patterns of non-compliance wand ensure that covered entities can verify timely access to savings that would otherwise have been realized at point of sale. We further recommend that HRSA make manufacturer-level compliance data publicly available on a quarterly basis to promote transparency and accountability.

7. Reliance Interest and 340B Program Integrity (Sections 7, General)

Reliance Interests

Seattle Children's has structured its pharmacy operations, capital planning and safety-net service commitments around the 30-year upfront discount model. Our pharmacy and financial systems were built to receive discounts at point of sale, not to front-load drug acquisition costs and reconcile retrospective rebate claims. These reliance interests are not merely administrative preferences—they reflect decades of operational investment and programmatic decision-making predicated on the reasonable expectation that the upfront discount structure would remain intact absent clear statutory direction to the contrary. Shifting to a rebate model would require Seattle Children's to fundamentally redesign its pharmacy financial infrastructure, at significant cost with no corresponding clinical benefit.

Program Integrity

HRSA has asked whether a rebate model would improve 340B program integrity, including by assisting manufacturers in avoiding duplicate discounts, reducing diversion and increasing pricing transparency. Seattle Children's respectfully submits that a rebate model would not meaningfully advance any of these goals for pediatric covered entities, and could actively undermine them.
On duplicate discounts: as described above, our existing TPA carve-out systems already prevent Medicaid duplicate discounts effectively. On diversion: the highly specialized, low-volume nature of pediatric drug utilization at freestanding children's hospitals does not present the diversion risk profiles that have historically motivated rebate model proposals. On transparency: a rebate model administered through proprietary manufacturer platforms, without standardized data formats or public reporting requirements, would reduce rather than increase transparency from a covered entity perspective.

We therefore urge HRSA to weigh carefully whether the purported program integrity benefits of a rebate model justify its substantial costs for pediatric safety-net providers.

Conclusion

We appreciate HRSA's thoughtful approach to soliciting stakeholder feedback through this RFI and its recognition of the importance of minimizing disruption to the longstanding discount-based model that has served vulnerable patient populations for over three decades. As HRSA evaluates the responses to this RFI and considers whether and how to implement this model, we respectfully request that the agency center its decisions on preserving access for safety-net institutions that, like Seattle Children's, were purpose-built to care for patients who would otherwise go without.

Thank you for your attention to this matter and for your stewardship of the 340B Program.

Respectfully submitted,

Sincerely,

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Submitted via email to paperwork@hrsa.gov

April 22, 2026

Maria G. Button
Director, Executive Secretariat
Health Resources and Services Administration
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5600 Fishers Lane
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Re: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX

Dear Director Button:

The AAMC[1] welcomes this opportunity to comment on the Information Collection Request (ICR) titled "**340B Rebate Model Pilot Program Application, Implementation, and Evaluation"** 91 Fed. Reg. 9632 (February 26, 2026), issued by the Health Resources and Services Administration (HRSA or the Agency). HRSA issued the ICR to collect feedback from the public on its burden estimate of the costs associated with implementing a rebate model to effectuate prices in the 340B Drug Pricing Program. In a separate request for information (RFI), CMS sought feedback on implementing such a rebate model.[2] As the AAMC explained in its separate comments on the RFI, we strongly oppose the adoption of a rebate model for the 340B program, as such a fundamental restructuring of the program's design would jeopardize the ability of academic health systems nationwide to fulfill the 340B program's core purpose of stretching their scarce resources to reach more eligible patients and provide more comprehensive services.[3] In these comments, we focus on HRSA's estimate of the burden associated with collecting data under a rebate model, and as we note, we believe HRSA grossly underestimates the actual burden associated with collecting data under a 340B rebate model program.

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[1] The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 163 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

[2] Request for Information: 340B Rebate Model Pilot Program," 91 Fed. Reg. 7287 (February 17, 2026)

[3] H.R. Rep. No. 102-384(II) (1992).

The 340B program is critical to academic health systems and the patients and communities they serve. 340B hospitals are a vital part of the nation's health care safety net, ensuring access to cutting-edge technology, research, and health expertise for their patients. Nearly 90 percent of AAMC-member short-term non-federal hospitals are 340B eligible and provide highly specialized health care services that are often unavailable in other settings, including oncology services, transplant surgery, trauma care, pediatric specialty care, and treatment for rare and complex conditions. For example, AAMC member hospitals comprise100 percent of all National Cancer Institute (NCI)-designated comprehensive cancer centers, 75 percent of all burn unit beds, 59 percent of all level-one trauma centers, and 64 percent of pediatric ICU beds.[4] AAMC member institutions share a common mission to care for the underserved and train the nation's future health care workforce, making life-saving health care services available to all patients, regardless of their ability to pay. This commitment to high-quality care, regardless of a patient's insurance coverage or socioeconomic status, can create significant financial challenges. Savings from the 340B program help our members to navigate these challenges, supporting their ability to maintain, improve, and expand access to care for their patients. These savings are critical in allowing 340B hospitals to improve the health of their communities, whether through medication management, providing charity care, offering access to healthy food, or expanding care through mobile clinics and community health programs.

As a federal agency, HRSA is required to issue an ICR when it plans to collect information from the public under the Paperwork Reduction Act of 1995. In the ICR, HRSA estimates the annual burden hours stemming from collection of proposed rebate model plans from qualifying drug manufacturers, the ongoing collection of sales data from drug manufacturers, and the collection of data submitted by covered entities to manufacturers to request a rebate in connection with a potential 340B rebate model program. Specific to collection of data from covered entities, HRSA estimates the total annual burden per respondent would be 260 hours, which amounts to 5 hours per week. **This estimate significantly understates the actual time that 340B hospitals will spend on submitting claims data and complying with the requirements of a 340B rebate model.** AAMC member hospitals expect their staff to spend at least 25 to 40 hours a week to submit claims data to a third-party platform, which totals 1300 to 2080 hours annually per hospital and is five to eight times higher than HRSA's estimate.

HRSA states that the burden associated with a rebate model program "may not be significant" because the agency "expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities" (p. 9633). This statement could not be further from the truth. As the AAMC noted in its separate comment letter to HRSA on the 340B rebate model RFI, the administrative costs of complying with a rebate model are substantial and involve more than just submitting claims data to the portal.[5]

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[4] AAMC analysis of FY2023 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2024, and the National Cancer Institute's Office of Cancer Centers, 2024. AAMC membership data, December 2024.

[5] AAMC Comment Letter to HRSA on Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042). Submitted April 20, 2026.

Participating in a rebate model would involve developing new processes and systems to submit and track claims, as well as subsequently reconcile those claims; developing a process for appealing or disputing claims; investing in compliance and audit process changes to prepare for increased audits related to rebate models; staff training and education; and annual vendor fees. Academic health systems have reported that a rebate model would involve extracting data, such as from a third-party administrator and reconciling it with data accepted into the Beacon platform. These types of changes alone, which go beyond the baseline task of submitting claims to a third-party portal, would require the hiring of up to six or more full-time equivalent (FTE) employees dedicated to broader rebate model compliance across the pharmacy, finance, revenue cycle, IT, and compliance functions.

In the ICR, HRSA requests comments on "the necessity and utility of the proposed information collection for the proper performance of the agency's function" and "the accuracy of the estimated burden" (p. 9633). As we note above, the agency's burden estimates are inaccurate and do not comport with the operational realities of how 340B hospitals collect, store, and report information that would need to be submitted through a rebate platform. HRSA should work with 340B program stakeholders to more accurately understand the time and resources that would be required to comply with a 340B rebate model program. Regarding the question of the necessity and utility of the proposed information collection, the AAMC does not believe that a rebate model is necessary for the "proper performance of the agency's function." As the AAMC further explained in its comment letter on the RFI, rebate models are unnecessary to ensure 340B program integrity or to meet HRSA's and the Centers for Medicare and Medicare Services' (CMS') goals of assisting with Maximum Fair Price (MFP) deduplication.[6] Instead of creating additional burden through unnecessary new processes, HRSA should continue to build on existing program integrity tools at its disposal. HRSA could work with CMS to develop more feasible alternative policies to achieve MFP deduplication, such as a prospective approach to MFP effectuation that allows for the purchase of 340B drugs and MFP-eligible drugs at upfront discounts or CMS could use a neutral third-party entity, such as the Medicare Transaction Facilitator, to assist with deduplicating MFP from 340B prices.

Conclusion

Thank you for HRSA's continued support of the 340B program and for ensuring program integrity for all 340B stakeholders. 340B hospitals remain invested in and share HRSA's goal of ensuring program integrity through adopting robust program safeguards. To summarize, we believe HRSA's burden estimate grossly understates the true cost and burden of compliance with 340B rebate models and we believe that the collection of claims data through a 340B rebate model is unnecessary to further HRSA's program integrity goals. We would be happy to work with HRSA on any of the issues discussed or other topics related to the 340B program. If you have questions regarding our comments, please feel free to contact my colleague Shahid Zaman (szaman@aamc.org).

[6] Ibid.

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer
AAMC

cc: David Skorton, M.D., AAMC President and Chief Executive Officer

Submitted electronically 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 20852

Ms. Chantelle Britton
Director
Office of Pharmacy Affairs, Health Resources and Services Administration
U.S. Department of Health and Human Services

Re: Comments on HRSA's Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB # 0906-NEW

Dear Administrator Engels and Director Britton:

On behalf of Denver Health and its hospital, community health centers (CHCs; also known as federally qualified health centers or FQHCs), school-based health clinics and other pediatric and primary care clinics where we serve over 280,000 patients per year, we appreciate the opportunity to comment on the above-captioned notice related to the U.S. Department of Health and Human Services' (HHS) 340B Rebate Model Pilot Program.

Denver Health is a comprehensive health system with nearly 9,000 employees that provides high-quality care for all people. We deliver medical care to one-third of Denver's population annually, proudly serving as the state's premier safety-net hospital, and provide crucial preventative, primary and acute care services. For more than 160 years, Denver Health has been deeply rooted in the health and well-being of the community, providing high-quality clinical care, top-notch education and training for health care workers, and furthering critical research to benefit our patients. We are guided by our mission to serve our community with access to the highest quality and equitable health care regardless of ability to pay.

The federal 340B program is foundational to Denver Health's ability to serve the most vulnerable of patients in the State of Colorado. In 2024, we served more than 82,000 unique patients through the 340B program, as nearly 80 percent of our patients are uninsured or underinsured. Through more than $220 million in pharmaceutical savings in 2025, Denver Health was able to ensure robust care, programs and services for our at-risk patient population. The proposed shift of responsibility from manufacturers to covered entities directly serving patients through a rebate

model threatens to destabilize our safety-net health system's operations and would impact our patients' ability to access life-saving medications.

Based on the previous iteration of this program, just the upfront cost of these pharmaceuticals would be nearly $6 million at any given time over a two-month period for Denver Health without any promise that we would recoup these costs. And even if we do recoup that funding, our health system will be waiting 60-90 days for the refund. We also know that there will be large, additional administrative costs to be able to implement this program, and it is difficult to model that financial impact.

Patient Impact

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

Many drugs selected for the Medicare Drug Price Negotiation Program (MDPNP) for 2026 and 2027, and included in the proposed rebate model, are used to manage chronic conditions prevalent in safety-net health system setting, meaning our patients will be disproportionately affected. Between our hospital and CHCs, we serve a patient population with a higher burden of chronic conditions compared to private practices and large health systems. This patient population relies on affordable medications to manage these long-term conditions.

We are deeply concerned that implementing a rebate model would cause Denver Health's patients to lose access to essential, life-sustaining therapies. For instance:

- Direct oral anticoagulants (DOACs) such as Xarelto and Eliquis are vital for patients with deep vein thrombosis, pulmonary embolism and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives.
- Similarly, the impact on patients requiring SGLT2 inhibitors, such as Farxiga and Jardiance, would be severe. These drugs are a mainstay of primary care for conditions like type 2 diabetes, chronic kidney disease and heart failure, all of which are highly prevalent among our patients. Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[1] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

[1] 3 Packer, M., et al. (2024). Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients with Heart Failure - https://www.ahajournals.org/doi/pdf/10.1161/circulationaha.123.065748

- The United States is amid an alarming mental health crisis, and starting in 2027, the MDPNP will include some behavioral health drugs. Vraylar is an atypical antipsychotic; atypical antipsychotics are the mainstay of treatment for schizophrenia. A rebate model could create barriers for us to provide this drug to uninsured and underinsured patients. Additionally, the 2027 list includes Austedo, a drug used to treat tardive dyskinesia, a common side effect of antipsychotics. Impairing access to these drugs could result in exacerbation of the mental health crisis.
- The impact on insulin access is particularly alarming and directly conflicts with federal requirements, with affordability of insulin being a matter of life or death. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full wholesale acquisition cost (WAC) rather than the discounted 340B price. This makes the price unattainable for the patient and precludes us from fulfilling their legal obligation to offer the required discount at the point of care.

Financially and Administratively Burdensome

Any rebate mechanism will impose enormous costs and burdens on Denver Health that far outweigh any benefits that might come from it. The Health Resources and Services Administration's (HRSA) desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In reality, HRSA must give priority to the needs of covered entities so that they can stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Preserving the upfront discount mechanism, which our safety-net health system has relied on for years, is the best way to fulfill the purpose of the 340B program.

Denver Health fully expects a rebate program, which would include up to 25 high-priced pharmaceuticals that our patients rely on, to be extremely problematic for both our finances and operations. Beyond the upfront cost of these drugs, any rebate program would require us to spend significant sums on new administrative costs. We fully understand that running the 340B program at our facilities has some reasonable administrative costs, and our hiring, operations and program administration are designed around an upfront discount model. A shift to a new kind of discount mechanism demands added funds, and because Denver Health is not a part of a large hospital system, we do not have the administrative and financial bandwidth that some of our counterparts have to increase resources for new staff, software, external vendors, and changes to system interoperability, billing, record keeping and contract pharmacy arrangements.

Denver Health opposes any effort by HRSA or HHS that would create further administrative barriers or burdens to the 340B program. Our health system already has effective controls in place to ensure these discounts are offered only to our patients and we avoid any duplicate discounts. Introducing a rebate model into the management of the 340B program is contrary to the program's intent and the fundamental responsibility of HRSA and HHS to administer this program in the interest of eligible patients.

In closing, a rebate-based model is not necessary to prevent duplicate discounts. The Front Line Hospital Alliance (FLHA) strongly supports development of an alternative pilot program that fixes problems in the 340B program, including a realistic patient definition grounded in clinical care delivery, contract pharmacies that ensure patient discount at the time of dispensing, a changed definition of child site that simplifies the process and allows transparency into payer mix, drug purchases and service to vulnerable patients, and a neutral, HRSA-administered 340B data clearinghouse as a superior alternative. As a FLHA member, we endorse their comments submitted separately which provide more details on alternative pilot program models.

Again, we continue to appreciate the opportunity to provide and submit comments on this very important issue for our safety-net health system. If you have any questions, please reach out to Katie Ryan, Denver Health's Government Relations Director, at katie.ryan@dhha.org or 303-602-2734.

Sincerely,

Donna Lynne, Dr.PH
Chief Executive Officer
Denver Health

Renown HEALTH

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Tuesday, April 14, 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:
340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX

Dear Administrator Engels:

On behalf of Renown Regional Medical Center in Reno, Nevada, we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) "Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation."

As explained below, *any* rebate mechanism will impose enormous costs and burdens on Renown Regional Medical Center that far outweigh any benefits that might come from it. HRSA's own calculations of costs are extraordinary. More fundamentally, HRSA's desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In reality, HRSA must give primacy to the needs of covered entities so that they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which Renown Regional Medical Center has relied on for years, is the best way to fulfill that purpose of the 340B program.

For purposes of estimating costs, we have assumed that any future Rebate Program will include the 10 drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026 Information Collection Request. With the addition of the 2027 drugs, our cost estimate have increased over the estimates we had calculated for the 2026 drugs alone. After all, more drugs and more drug companies means *more* claims to submit, *more* rebates to track and reconcile, *more* money that we will need to float to drug companies while we await our statutory discount, *more* likely disputes over delays and denials, and therefore *less* money that Renown Regional Medical Center can spend on patient care and comprehensive health care services.

Administrative Costs Under A Potential 340B Rebate Program. Any rebate program would require Renown Regional Medical Center to spend significant sums on new

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administrative costs. When we chose to participate in the 340B program, Renown Regional Medical Center understood that we would incur some reasonable administrative costs. We designed our hiring, operations, and program administration around an upfront discount model. A shift to a new kind of discount mechanism demands new resources, imposing considerable additional costs and burdens on our institution that go far above and beyond what we had expected and planned for as a 340B hospital—and far above and beyond what we are experiencing now.

Renown Health's anticipated incremental administrative and operational costs under a 340B Model Rebate Pilot Program—separated into one-time startup expenses and ongoing costs—include the following:

One-time startup expenses

- Increased third-party administrator (TPA) fees for report development and submission **($5,000)**

Ongoing expenses

- Hire at least 1.0 FTE Pharmacy Regulatory Analyst **($83,250/year)** to support rebate program audits, tracking, and dispute management
- Development of a machine-learning solution to track and identify missing rebate payments **($75,000/year)**
- Financial risk and cashflow instability **(>$10,000,000/year)**
    - Under a rebate model, Renown Regional Medical Center would purchase drugs at non340B prices and then wait for retrospective rebates intended to approximate the statutory ceiling price. For a safety-net provider operating on thin margins, this approach creates:
        - Significant disruption to cash flow
        - Greater reliance on working capital or borrowing
        - Increased exposure to denied, delayed, or short paid rebates
        - Reduced ability to reliably forecast resources available for patient care

Unlike manufacturers, safety-net hospitals like Renown Regional Medical Center typically lack the financial reserves needed to absorb prolonged uncertainty or administrative friction in accessing statutorily required discounts.

Staffing Impacts Under a Potential 340B Rebate Program. Renown Regional Medical Center does not currently have the staff needed to comply with a Rebate Program.

- Implementation of a potential 340B Rebate Model Pilot Program would require additional full-time employee(s)
- Renown Regional Medical Center would need to employ **at least 1.0 additional FTE** Pharmacy Regulatory Analyst in order to take on the workload of a potential 340B

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Rebate Model Pilot Program. Specialized pharmacy technician roles similar to this typically take at least six week to recruit and six week to train.

- HRSA's current estimate of only 5 hours per week in additional work (for 25 total drugs, including both the 2026 and 2027 drugs approved under the IRA Drug Price Negotiation Program) is a gross underestimate. There are disparate data sources between in-house pharmacies, mixed-use areas, and contract pharmacies that would require reconciliation and audit prior to data submission.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Program. Renown Regional Medical Center has designed its technological systems and operational infrastructure in reliance on an upfront discount model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems.

- In-house pharmacy claims at Renown Regional Medical Center are managed through an accumulator within the EMR separate from our TPA. Custom reporting would need to be built in order to submit rebate data.
- In addition to the one-time cost of custom report build, Renown Regional Medical Center would have the ongoing cost of pulling and auditing data for a potential 340B Rebate Model Pilot Program prior to submission.
- Medical claims data present a particular challenge for accurate collection and data submission. Renown Regional Medical Center's EMR creates new transaction IDs for prior medication administrations any time a patient's payer is updated. A single medication administration may result in more than ten transaction IDs that would need to be manually reconciled prior to data submission.
- Based on our experience with the Medicare Transaction Facilitator for Maximum Fair Price Drugs we anticipate that we will need to employ a third-party machine learning resource to help identify unrealized rebates and track these from individual claim information. **This solution will add tens of thousands of dollars in additional administrative cost.**

Data Collection By Covered Entities. During the prior iteration of the Rebate Program, both HRSA and the drug companies stated that a rebate mechanism would not impose new data-related burdens on 340B hospitals like ours. For example, both insisted that hospitals already provide the required information through 340B ESP. That is incorrect.

- Renown Regional Medical Center utilizes a TPA for mixed-use and contract pharmacies only. In-house pharmacy claims are managed through an integrated 340B accumulator within our EMR.
- A potential 340B Rebate Model Pilot Program would require new report builds within our EMR and would require data aggregation and audit between the EMR specify data and that data within our TPA on an ongoing basis.

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- In the past, HRSA has suggested that hospitals already submit to drug companies the data required under a rebate model. This is incorrect. Renown Regional Medical Center would need to create and audit new reports within our EMR to submit data from our in-house pharmacies that do not utilize our TPA. Additionally, medical claims data for medication administrations have proven to be particularly challenging to produce accurately and timely based on billing cycle nuances within the EMR.

Adverse Impacts of These Additional Costs And Burdens. All of these many different costs and burdens add up. Unfortunately, that means that Renown Regional Medical Center will no longer be able to use our 340B savings as effectively and comprehensively as we did under an upfront discount model. As a result, our patients and community will suffer in concrete ways.

Renown deploys 340B savings directly to improve patient access to medications and care. A rebate model decouples savings from real-time care delivery and requires Renown to finance safety-net services with restricted or borrowed cash.

Over time, this threatens the sustainability of:

- Medication access programs
- Community clinics
- Charity care and uncompensated services

For a safety-net provider such as Renown, this outcome is inconsistent with the intent of the 340B statute.

Reliance Interests. The recent RFI on the rebate model expressly invites comment on "reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via 'rebate or discount.'" Respectfully, that framing rests on a flawed premise. The mere existence of statutory authority does not imply that the agency will—or reasonably may—exercise it in a particular manner. That is especially so here, where the 340B Program has, since its inception, consistently provided discounts through upfront pricing rather than post-sale rebates. Renown Regional Medical Center reasonably relied on this history when designing its internal operations, staffing, third-party contractual relationships, and financial planning for the use of 340B savings—all based on an upfront-discount model. A fundamental switch now would disrupt these settled reliance interests engendered by the agency's prior policy. Absent any identified problems with the upfront discount model, and given the massive costs that this disruption will impose on 340B hospitals like ours, there is no reason to switch to a rebate mechanism, even in so-called "pilot" form.

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Renown Health has long relied on the statutory up-front 340B discount model as a stable, predictable mechanism to offset unreimbursed and under-reimbursed care.

Renown Regional Medical Center is an **808-bed tertiary care community teaching hospital and the region's only Level II Trauma Center**, serving a patient population with high Medicaid, Medicare SSI, and uninsured representation. **Approximately 35.4% of Renown's patients** are covered by Medicaid or Medicare SSI.

Renown's 340B savings directly support:

- **Uncompensated and charity care**
- Community-based clinics, including a community Medicaid clinic that already operates at an approximate **$1.4 million annual loss**
- Bedside medication delivery programs regardless of ability to pay

In addition, Renown provides approximately **$196.1 million annually in community benefit**, predominantly composed of unreimbursed healthcare services. 340B savings are a critical contributor to Renown's ability to sustain this level of community benefit.

A rebate-based model would undermine these reliance interests by delaying and destabilizing the availability of funds used to support patient care.

Efforts To Avoid 340B/MDPNP Duplicate Discounts. 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 Renown Regional Medical Center, 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 AHA'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.

- Since the inception of Renown Regional Medical Center's 340B program, any potential deduplication issues have been swiftly addressed and corrected (when necessary) through self-disclosure to individual manufacturers or through manufacturer-initiated Good Faith Inquiries.

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For all of these reasons, Renown Regional Medical Center in Reno, Nevada respectfully submits that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse.

If, however, HRSA chooses to move forward with this ill-conceived effort, it must allow **Renown Regional Medical Center** 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). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem.

We appreciate your consideration of these comments and look forward to working with HRSA on this important issue, which has profound implications for the millions of patients who rely on the 340B Program. Please contact me if you have questions.

Sincerely,

Adam Porath, PharmD, BCACP, BCPS, CPEL, FASHP
VP of Pharmacy Services
Renown Regional Medical Center, Reno, Nevada

North Olympic Healthcare NETWORK

April 22, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **North Olympic Healthcare Network ("NOHN"),** 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, NOHN again requests that CHCs be exempted from the pilot program.**

North Olympic Healthcare Network (NOHN) is the Federally Qualified Community Health Center serving nearly 20,000 people in the rural and remote region of Washington State's Olympic Peninsula. We provide integrated, full-spectrum Primary Care, Behavioral Health, Dental care, Vision services, Pharmacy, Care Coordination, Mobile Health, Outreach and Enabling services to everyone in our rural community regardless of their ability to pay.

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 nearly 20,000 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**: **NOHN** anticipates needing **1.5** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **NOHN** will face an increased administrative burden to monitor rebate claims and payments. **20 hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **NOHN** anticipates an additional **$20,000** 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. **$20,000** 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 complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves almost 20,000 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at almost **$104,000** in the first year.

The In-House Pharmacy: The Burden of IT Integration

NOHN operates 2 in-house pharmacies. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

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

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools and anticipate those costs to be at least $20,000 for NOHN.
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **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 **26** 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 **26** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in **Clallam County, Washington** with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[2] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[3]

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.[4]

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

[4] 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

NOHN 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.[5] 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,[6] 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.[7] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[8] A CHC can adjust the cost of health care services, including medications,

[5] 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.
[6] 2025 UDA Data, HRSA (hrsa.gov)
[7] HRSA FAQ
[8] 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. **NOHN has discounted prescription drug prices for patients and provided sliding fee pharmacy discounts to qualifying health center patients by passing 340b savings directly to the patient. These programs have provided access to medications previously unattainable to many patients historically due to cost.**

Conclusion

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

NOHN 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 **Beau J. Brown at bbrown@nohn-pa.org.**

Sincerely,

Beau J. Brown
North Olympic Healthcare Network

PANCARE
OF FLORIDA, INC.

April 12, 2026

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

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

Dear Director Britton:

On behalf of PanCare of Florida, Incorporated, I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 20, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHCs posed by the proposed rebate model. The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on national assessments from NACHC, we know that CHCs are facing staggering impacts:

- **Financial Losses:** Nationwide, CHCs report losses from entity-owned pharmacy operations and savings reduction for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation.
- **Projected Cost Increases:** CHCs anticipate significant increases in operational costs. National data shows that a single mid-sized CHC expects to incur over $3 million in additional costs **annually** to manage the pilot.
    - **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.

PanCare of Florida, Inc. provides affordable primary, dental, pharmacy, vision and behavioral health care to over 54,000 residents across Northwest Florida, regardless of insurance status. We believe affordable health care should be accessible to all individuals.

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

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve the 52 million patients who rely on us.
We strongly urge HRSA to exempt CHCs from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.

II. Patient Impact

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

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

We are deeply concerned that implementing a rebate model would cause CHC patients to lose access to essential, life-sustaining therapies. For instance, **direct oral anticoagulants (DOACs)** such as Xarelto® and Eliquis® are vital for patients with deep vein thrombosis, pulmonary embolism, and atrial fibrillation. For many of our patients, there are minimal – and often less safe – alternatives. This is not an optional therapy but a critical tool for survival, as one study showed that discontinuing these drugs leads to a statistically significant increase in the risk of stroke, heart attack, and death.[2]

Similarly, the impact on patients requiring **SGLT2 inhibitors**, such as Farxiga® and Jardiance®, would be severe. These drugs are a mainstay of primary care for conditions like Type 2 Diabetes, chronic kidney disease, and heart failure, all of which are highly prevalent among our patients.

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[1] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.
[2] Cools F, et al. Risks associated with discontinuation of oral anticoagulation in newly diagnosed patients with atrial fibrillation: Results from the GARFIELD-AF Registry. J Thromb Haemost. 2021 Sep;19(9):2322-2334. doi: 10.1111/jth.15415. Epub 2021 Jul 23. PMID: 34060704; PMCID: PMC8390436.

Research has found that even a 30-day withdrawal of these inhibitors increases the annualized risk of cardiovascular death or heart failure hospitalization.[3] By making these drugs unaffordable, the rebate model would effectively deny our patients access to the most effective therapies for managing their chronic illnesses, leading to a predictable increase in preventable hospitalizations.

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

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

Imposing a rebate model on CHCs would only weaken the safety-net providers that 52 million Americans rely on for health care. CHCs are required to provide sliding fee discounts to patients with incomes at or below 200% of the federal poverty guidelines. The same patients who need access to discounted medical services also depend on CHCs to provide affordable medications. Without the up-front 340B discount, the drugs included in the pilot would become operationally impossible. **This model would create a new and significant barrier, rather than a solution, for our most vulnerable patients, especially those who are uninsured and have limited options for affordable care.**

III. Administrative Complexities and Financial Challenges for CHCs

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHCs but also a duplicative and unnecessary administrative burden. HRSA should exempt CHCs from

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

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

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

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

the 340B Rebate Model Pilot because they will incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NACHC assessment illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHCs will face an increased administrative burden in monitoring rebate claims and payments.

340B Rebate Model Operational & Administrative Cost Calculator Description

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

- **Sliding Fee Discount**: **PanCare of Florida, Inc.** provides sliding fee discounts, through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: **PanCare of Florida, Inc.** anticipates needing **2-3** additional FTEs to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, **PanCare of Florida, Inc.** anticipates an increase to costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Workforce Impact

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

- According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.[7] **We estimate that we will need to add at least 2-3 FTEs to meet the anticipated demand.**
- Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing

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

drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities. **PanCare serves 54,000 unique patients, and we estimate that additional staff will cost at least $100,000 annually.**

- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. **We estimate that at least 80 hours every week** will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **PanCare of Florida, Inc. urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC, which serves 54,000 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated to increase significantly annually.

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

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

- **System Interoperability:** Unlike contract pharmacies that use Third-Party Administrators (TPAs), in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. **Our PMS requires us to manually pull reports that we formulate and comprise ourselves to have the valid data needed. We will then have to use these reports to locate and follow each claim one by one-similar to our process with MFP claims now which has proven very time consuming. This leads us to anticipate $100,000 annual labor cost.**
- **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 **80** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

For CHC contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC currently partners with 61 contract pharmacies to increase access to affordable medications.

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. Our staff must monitor claims across **61** different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in the Florida Panhandle with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

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

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHCs. Because PPS visits are paid at a flat rate, the medications administered in CHCs are often not included on claims billed to payers.
- **Simplified Records:** Because CHCs maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHCs maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC to pay for a standalone software system.
- **Minimal Risk of Duplicate Discounts:** CHCs primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.

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

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

[11] Internal NACHC survey data

- **HRSA should explicitly exclude CADs from any 340B rebate model pilot.** At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHCs and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHCs without corresponding benefits to program integrity or federal oversight.

A. Financial Challenges

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

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

A rebate model also creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[12] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[13] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. **PanCare uniformly offers to all patients a sliding fee discount program. Eligibility for the sliding fee discount program is based on household size and gross household income. The sliding fee discount program will be applied uniformly to all patients. The demand for services continues to increase and in order to serve as many people as possible in the fairest way, PanCare has developed the sliding fee discount program policies and procedures. PanCare also has a policy to never deny a services based on patient's inability to pay. The sliding fee policy and procedure is observed and practiced in all settings of PanCare, including the pharmacy with patient prescription costs.**

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[12] HRSA FAQ

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

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

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

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

340B Rebate Drug Cost Impact Calculator Description

To support CHCs in assessing the financial impact of purchasing drugs at the full WAC price, NACHC worked with its consultant, FQHC 340B Compliance, to create another calculator for all CHCs. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC-specific purchasing data, 340B[15] and WAC pricing data for the first quarter

[14] https://enlivenhealth.co/blog/year-end-business-health-check-key-metrics-every-pharmacy-owner-should-review
[15] https://340bpricing.hrsa.gov/

of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[16] For individual MDPNP Price Applicability Years, the calculator evaluates:

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

Based on our organization's data, we estimate it would cost **$1.3 million annually** to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends **$80,000 annually** to purchase these same drugs at the 340B ceiling price. This represents a **1500%** increase in upfront capital required for procurement.

This increase in costs will have a devastating impact on our organization's ability to maintain an adequate supply of the drugs included in the HRSA 340B Rebate Model Pilot. As previously discussed, our CHC is navigating a difficult financial environment that cannot sustain purchasing drugs at WAC. To cover the upfront cost of purchasing drugs and operationalizing the rebate, **PanCare** anticipates needing to reduce:

- **Essential Clinical Services:** To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services.
- **Operating Hours:** We anticipate needing to reduce our clinic hours 28 hours per week, specifically impacting our evening and weekend hours, which are the only times our working-class and agricultural patients can seek care without losing wages.
- **Workforce & Staffing:** The administrative burden of this pilot requires us to divert funds away from clinical staff.
- **Patient Financial Assistance:** Our ability to provide medications at "zero-pay" or deeply discounted rates under our sliding fee scale will be compromised. If the cash is not in our accounts because it is being held by a manufacturer, we cannot provide the "bridge" support that prevents our **20,000** uninsured patients from rationing their insulin or heart medication.

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

B. Wholesaler Implications

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

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

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHCs are forced to pay invoices before their due dates to remain within their credit limits. Given that CHCs typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHCs often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts.
- **PanCare** estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by **$110,000**.

  Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our organization would be forced to take out a line of credit or utilize limited financial reserves. This is not a sustainable solution. Forcing CHCs into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on **PanCare,** the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 34 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

PanCare of Florida, Inc. urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of a CHC's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed

in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHCs need to understand or contest those decisions.[17]

If a rebate is denied, the CHC takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative **15%** denial rate would result in a net annual loss of **$1.1 million.** This is a sum our CHC cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC mission of serving all patients, regardless of their ability to pay.

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

IV. Reconciliation and Rebate Denials Operational Challenges

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

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;
- Rebate payment timing requirements must apply to both initial and corrected determinations. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism;
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers;
- Manufacturers must bear the burden of establishing that a rebate is not owed;

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

- Rebate determinations must align with statutory patient definition: HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.
- OPA should establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed. This panel should include pharmacists with the necessary subject-matter expertise to understand the complexities of pharmacy software, billing, and data components.

V. Existing CHC Compliance Actions

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

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

Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate harm to CHCs and the patients they serve. The administrative, financial, and operational burdens from such a model would threaten the stability of the safety-net providers that the 340B program was designed to support. CHCs are not the source of misuse in the 340B program; rather, they are national models of compliance.

VI. Establishing a National, Neutral Claims Clearinghouse

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

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**
- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.

- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHCs' participation in the program.
- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHCs to stop purchasing or dispensing MFP drugs altogether.
- **Identify Medicaid Duplicate discounts in Medicaid.** An NCC could provide a standardized national approach to preventing duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states.

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

Conclusion

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

PanCare of Florida, Inc. appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Lori Goodman at lgoodman@pancarefl.org.**

Sincerely,

DocuSigned by:
RThompson
8D74AA5B65B0452...

Robert Thompson, CEO
PanCare of Florida, Inc.

April 23, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Signature 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 Community Health Centers (CHCs), Signature Health again requests that CHCs be exempted from the pilot program.**

Signature Health is a Federally Qualified Health Center (FQHC) located in Northeast Ohio. We serve over 35,000 patients annually at 6 outpatient locations and 4 residential treatment facilities. We primarily serve Medicaid and Medicare patients. Additionally, we have a sliding fee scale available to eligible uninsured and underinsured individuals, so that they may receive services and medications at discounted rates. Signature Health began over 30 years ago as a community-focused behavioral health organization. With a foundation deeply rooted in the treatment of behavioral health conditions, Signature Health provides care to some of the most complex patients in our community. These patients receive services at Signature Health that they would likely struggle to access elsewhere- ranging from counseling and psychiatry, to dental, primary care, and infectious disease treatments. The 340B program plays a vital role in supporting all levels of our operations.

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 35,412 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**: Signature Health anticipates needing 1.5 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Signature Health will face an increased administrative burden to monitor rebate claims and payments. 416 hours annually will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Signature Health anticipates an additional at least $26,000 for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

The In-House Pharmacy: The Burden of IT Integration

Signature Health operates 8 in house, entity owned pharmacies. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. This requires building custom reports out of 4 systems to verify complete and correct information flow – the pharmaceutical wholesaler, our dispensing software, the rebate platform, and our financial accounting

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

software. Ensuring that we received the correct rebate from 1 purchase requires checking these 4 platforms – and would need to be done for EVERY claim.

- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **at** least 5 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 93 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 93 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. Particularly in rural Ashtabula County, this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

II. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Patient Impact

Signature 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.

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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)

III. We Request HRSA Exempt CHCs from the 340B Rebate Model Pilot Program Due to Significant Financial Impact on CHCs Operating on Razor Thin Margins

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half operating with fewer than 90 days of cash on hand, and one in four reporting negative five percent operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.

- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[5] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[6] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. Signature Health offers sliding scale discount on prescription medications, directly passing our 340B savings back to qualified patients by using our actual 340B acquisition cost in the calculation of the patient's cost. We are able to offer medications at the lower costs for patients because we are able to purchase at the reduced 340B cost. A 340B rebate model directly jeopardizes this, as we would no longer have access to upfront reduced medication prices.

Conclusion

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

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[5] HRSA FAQ

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

Signature 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 me at ksullivan@shinc.org.

Sincerely,

Kelley Sullivan Dragar
Signature Health

From:	Alan Witchey
To:	HRSA Paperwork
Subject:	[EXTERNAL] 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Information Collection Request Federal Register Notice
Date:	Thursday, April 23, 2026 3:29:36 PM
Attachments:	image.png Outlook-x12nj4pq Outlook-ccwndf5w Outlook-kasj0ec5 Outlook-04ny5ckp.png

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April 23, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

Samantha Miller

Director of Division of Oversight, Reporting, and Regulatory Compliance

Office of Planning Analysis and Evaluation

Health Resources and Services Administration

5600 Fishers Lane, Room 13N82

Rockville, MD 20857

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

Dear Director Miller:

Damien Center appreciates the opportunity to submit comments to the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) in response to the Request for Information (RFI) regarding a 340B Rebate Model Pilot Program (Rebate Model Pilot).

We strongly oppose any Rebate Model Pilot or any other proposal that would limit covered entities' access to upfront discounts under the 340B program.

We are deeply concerned about the tremendous administrative and financial burdens a rebate model would place on our organization and the damaging impact it would have on our ability to serve our patients – who represent some of the most vulnerable populations in our service area.

As Indiana's leading community health center serving people living with HIV, Damien Center delivers lifesaving wraparound services that have helped our patients achieve viral suppression rates well above the national average. Our ability to provide these services—often at no cost or at a significant discount—depends on predictable, upfront access to 340B savings. Replacing that structure with a rebate-based model would introduce uncertainty, administrative complexity, and cash-flow disruption that would directly undermine our capacity to sustain these outcomes. For nearly three decades, the 340B program has enabled community-based providers like Damien Center to extend care to communities that would otherwise be left behind, while operating under rigorous oversight and reporting requirements. The existing 340B framework is functioning as Congress intended and weakening it would jeopardize patient access with no corresponding public benefit.

Given the harms a rebate model would cause our patients, our organization, and other covered entities, we respectfully request that HRSA abstain from implementing a Rebate Model Pilot and collaborate with the Centers for Medicare & Medicaid Services (CMS) to establish a neutral 340B clearinghouse as an alternative approach to protect 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.

Patient Harm

The comprehensive services that we provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and housing assistance. Because Damien Center, like many clinics, serves clients regardless of their ability to pay, we often receive no insurance payments and depend on the 340B program to underwrite the cost of providing this necessary care to our patients. **Furthermore, we're able to provide these expanded services without any cost to taxpayers.**

A Rebate Model Pilot would make comprehensive HIV and primary care less accessible and more expensive, an outcome that is completely contrary to the intent of the 340B program. Our ability to care for uninsured and underinsured patients depends on receiving 340B savings at the point of purchase. A rebate-based model would delay access to those funds, weakening our capacity to deliver care when reimbursement falls short. We rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating covered entities' access to 340B discounts, the Rebate Model Pilot will erode our 340B savings available to us to cover the cost of care to the uninsured and underinsured. These new, and unnecessary burdens violate the spirit of 340Bs express purpose: "to stretch scarce Federal resources as far as possible, reaching more eligible

patients and providing more comprehensive services."

Additionally, the financial risk and operational burden of a rebate model could drive contract pharmacies to withdraw from participation, restricting patient access to care. If contract pharmacies refuse to enter into agreements with community clinics like ours, access to medications will inevitably be reduced for our patients, many of whom are already face steep barriers such as housing instability, food insecurity, unemployment, and substance use disorder. For infectious disease clinics like ours, adherence to prescribed treatment regimens is an essential component of controlling an individual's HIV disease, and the ability to do so wanes when individuals with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. **Simply put, implementation of the Rebate Model Pilot will set back this nation's fight to end the HIV epidemic.**

Financial Impact of Increased Drug Acquisition Costs

The Rebate Model will increase Damien Center's drug acquisition costs and therefore increase the costs of delivering patient care. Under this model, we'll be forced to pay the full wholesale price for drugs at the point of sale and face a complicated and uncertain rebate process that will create significant cash-flow strain on our small organization. This will threaten our ability to provide low-cost, discounted medications to our patients at a time when healthcare costs are already skyrocketing.

Implementation and Administrative Burden

Since 1992, Damien Center has carefully built processes and workflows to manage the complex nature of 340B compliance and reporting. That's 34 years of institutional knowledge that have all been built on the promise of upfront discounts to covered entities as described by the statute.

Suddenly switching this entire infrastructure to a rebate program violates the spirit of the 340B program as written and upends decades of work. It imposes new management costs on small clinics like ours and does nothing to improve compliance or patient care.

Damien Center will have to invest in new technologies and staff to adapt to these significant changes – all of this under an artificial cash-flow constraint created by this unnecessary change.

We estimate that in 2026 alone this would result in an **additional $213,819** of additional inventory spending. This cost will increase yearly, and in 2028 we estimate that we will spend **over $7,552,618** in additional pharmacy costs and managing the Rebate Model's overhead. By that same year, **our 90 day cash-on-hand impact will increase by $1,763,703** as we wait on uncertain cash rebates.

These costs don't come in a vacuum. The needs of our patients will continue to increase as the general cost of healthcare spirals upward, and we will find ourselves less able to provide effective and low-cost healthcare.

Neutral Clearinghouse as an Alternative

Instead of proceeding with a Rebate Model Pilot, we ask that HRSA instead work with CMS to develop a neutral clearinghouse run by the federal government or a government contractor, to which covered entities, third-party administrators, and/or contract pharmacies retrospectively submit 340B claims data to prevent 340B-MFP duplicate discounts. A 340B clearinghouse model represents the ideal solution for all stakeholders - covered entities, contract pharmacies, manufacturers, and the government – by providing an efficient and coordinated framework that streamlines and enhances compliance, data exchange, and program integrity.

The clearinghouse would match the 340B claims data with patient encounter data to identify and remove those claims from information shared with manufacturers for payment of MFP rebates to providers. Manufacturers would only pay rebates on non-340B claims, thereby preventing duplicate discounts. This approach is not without precedent. CMS already plans to test a clearinghouse-like model that the agency is calling a "340B repository" to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

We appreciate HRSA's consideration of our comments. For further information, please contact **Alan Witchey, President & CEO at awitchey@damien.org**

Sincerely,

Alan Witchey

President & CEO

Damien Center

Alan Witchey *(he/him)*
President & CEO
Damien Center
1420 E. Washington Street
Indianapolis, IN 46201

Phone 317 632 0123 x 266
Web www.damien.org
Email awitchey@damien.org

DAMIEN CENTER

AMERICA'S ESSENTIAL HOSPITALS

April 23, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration (HRSA)
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

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

Dear Administrator Engels:

Thank you for the opportunity to comment on the proposed information collection request (ICR) that the Health Resources and Services Administration (HRSA) plans to submit to the Office of Management and Budget regarding a 340B Rebate Model Pilot Program. For the past two years, we have shared with the agency our serious concerns about rebate models and the harm they would cause to the patients our hospitals serve. These models are not necessary for the proper performance of HRSA's functions and are nothing more than an attempt by drug manufacturers to boost their profits at the expense of safety net providers. Recently, federal courts stopped the implementation of HRSA's rebate pilot because the agency failed to adequately consider the impact on covered entities. **As a result, we are deeply concerned that HRSA issued this ICR about expanding the rebate pilot before reviewing feedback from its recent request for information (RFI) on whether HRSA should implement a rebate model.**

On April 20, we gave detailed responses to the agency's questions based on our members' real-world experience preparing for the rebate pilot. These experiences demonstrate how HRSA substantially underestimated the burden of rebate models. Overall, **we estimated that continuing HRSA's proposed rebate model would result in $1.5–1.6 billion in direct costs and $3.7–$4.6 billion in total costs for hospitals in 2027 alone. These burdens would disproportionately harm essential hospitals, which account for 9% of 340B hospital covered entities but would bear approximately 15% of the added costs.**

America's Essential Hospitals is the leading association and champion for hospitals dedicated to high-quality care for all, including those who face social and financial barriers to care. Since 1981, America's Essential Hospitals has advanced policies and programs that promote health and access to health care. We support our more than 400 members with advocacy, policy development, research, education, and leadership development. Communities depend on essential hospitals for care across the continuum, health care workforce training, research, public health, and other services. Supported by Essential Hospitals Institute, the association's

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research and education arm, essential hospitals innovate and adapt to lead all of health care toward better outcomes and value.

Essential hospitals are committed to serving people in all communities that need access to quality care. Despite making up just 6% of hospitals nationwide, essential hospitals provide 29% of the nation's charity care. About three-quarters of the patients our members serve are uninsured or enrolled in Medicaid or Medicare.[1] In addition, nearly two-thirds of essential hospitals serve rural patients and communities.[2] **The 340B program is instrumental in allowing essential hospitals to stretch scarce federal resources, reach more eligible patients, and provide a wider range of services, exactly as Congress intended.**

Below we summarize our general concerns with HRSA's process for issuing this ICR and specific comments on the ICR questions. America's Essential Hospitals is willing to continue to work with HRSA to support its efforts to oversee and protect the 340B Drug Pricing Program. We hope these comments lead to further, meaningful dialogue with the agency to ensure that the 340B program can continue to work as intended.

Inappropriate Timing of the ICR

Issuing an ICR without a clearly defined program is premature. This action appears at odds with the general message of the district court for the District of Maine to consider stakeholder feedback before moving forward with implementation. Instead, it further illustrates that, as the judge in this case described, HRSA is attempting to "fly the plane before they build it."[3] To comply with the Administrative Procedure Act, HRSA first should consider the RFI comments, then determine whether to pursue a rebate program, and, if so, propose a specific structure with an opportunity for public feedback. **Only after these steps should HRSA solicit input on the model's information collection activities.**

Necessity and Utility of Proposed Information Collection

HRSA requests feedback on whether the proposed information collection is necessary and useful for the proper performance of the agency's functions. As discussed further in our RFI response, we continue to believe that **a rebate model is unnecessary**.

Drug manufacturers have claimed for years that rebate models are the only way to deduplicate 340B discounts from Medicare's maximum fair price.[4,5] That claim was always overstated, and it is now refuted by experience. Since the Medicare Drug Price Negotiation Program (MDPNP) took full effect on Jan. 1, 2026, covered entities, drug manufacturers, and the Department of Health and Human Services (HHS) have implemented tools that allow deduplication while

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[1] Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. essentialdata.info. Accessed March 31, 2026.
[2] America's Essential Hospitals. Policy Brief: Essential Hospitals Ensure Access to Care in Rural Areas. March 2025. https://essentialhospitals.org/policy-brief-essential-hospitals-ensure-access-to-care-in-rural-areas/. Accessed Feb. 19, 2026.
[3] *American Hospital Association, et al., v. Robert F. Kennedy Jr.*No. 2:25-cv-00600-LEW (D. Me. Dec. 30, 2025). https://sponsors.aha.org/rs/710-ZLL-651/images/09113645870.pdf. Accessed March 31, 2026.
[4] Carpenter E, Stancel J. Letter to Thomas Engels on Sept. 8, 2025. https://cdn.aglty.io/phrma/global/resources/import/pdfs/Rebate%20Notice%20PhRMA%20Comments_FINAL.pdf. Accessed April 6, 2026.
[5] Novo Nordisk. 340B Program Policy Update. March 2, 2026. https://340besp.com/resources/novo_nordisk/policy.pdf. Accessed April 6, 2026.

preserving up-front discounts. Reversing course now would disrupt the deduplication infrastructure that already works.

Implementing a rebate program also is an unnecessary waste of agency resources when there are more pressing issues facing the 340B Drug Pricing Program. A bipartisan group of Members of Congress in March 2026 urged the House Appropriations Subcommittee on Labor, HHS, and Education to include bill language barring the use of any fiscal year 2027 funds to implement a 340B rebate model. The group argued explicitly that HRSA's resources would be better directed toward protecting covered entities from actual and ongoing threats to the program.[6]

Inaccurate Estimates of Covered Entity Reporting Burden

HRSA requests feedback on whether its burden estimates are accurate. We strongly disagree with HRSA's claim in the ICR that "the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant." **A rebate pilot program imposes a significant administrative and financial burden on covered entities that far exceeds HRSA's estimated five hours per week.**

According to our members' experience preparing to implement the rebate pilot, hospital staff noted that they would need to hire at least one full-time equivalent (FTE) employee to work on this model full-time (40 hours a week). Many of our largest members have indicated that they would need to hire at least three FTE employees to manage the new process. **Thus, we estimate 40 to 120 hours of additional burden each week.**

These staff would be needed to conduct ongoing monitoring of claim determinations, investigate denials, and initiate formal appeals processes to ensure access to statutorily required discounts. In HRSA's ICR for its previous rebate model, the agency estimated that the pharmacy staff needed to implement a rebate model would cost $132 per hour, similar to estimates our member hospitals provided. **Based on these data, we estimate that the rebate pilot would impose $1.2 billion in total direct staffing costs on all hospitals, including $135.9 million in costs to essential hospitals.**

Even though HRSA has not yet implemented the rebate pilot program, it is important to note that our members are already experiencing economic harm from HRSA's haphazard and illegal attempts to implement rebates in the withdrawn pilot. For example, one member hospital had already allocated **approximately $300,000 in staff labor costs across affected departments to begin implementing a rebate program before it was stopped by federal courts.**

It is also important to note how staffing costs relate to the cash flow challenges a rebate model creates. To mitigate the costs of fronting millions of dollars to drug manufacturers while hospitals wait for rebates, several of our members have reported that they anticipate needing to perform daily claim submission through platforms such as 340B ESP, instead of the weekly or biweekly claim submission process they currently conduct under the existing model of up-front discounts. **This issue underscores why it is premature for HRSA to estimate reporting burden before it considers comments from stakeholders on rebate model design issues that affect how the rebate model will work.**

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[6] Matsui D, Johnson D, Dingell D, et al. Letter to Robert Aderhold and Rosa Delora on March 27, 2026. https://image.email.aamc.org/lib/fe8e13727c63047f73/m/1/3fcab183-aee3-4029-b449-c04925307f27.pdf. Accessed April 15, 2026.

Beyond staffing costs, rebate model implementation would require significant investments in information technology systems and operational infrastructure, as existing systems are inadequate to support claims submission, adjudication, or payment tracking. These costs are not accounted for in the ICR.

Improving Quality, Utility, and Clarity of Drug Manufacturer Applications

If HRSA proceeds with a rebate program, the agency must ensure that it thoroughly evaluates and reviews manufacturer plans before manufacturers are allowed to participate in the rebate pilot program. The ICR indicates that the plans will be evaluated and approved based on requirements published in future guidance. **We urge HRSA to publish such guidance and allow for public comment and collection of information on impact and burden along the lines of this ICR before finalizing the requirements.**

We also urge HRSA to consider lessons from the initial rebate pilot roll out. For example, in HRSA's previously proposed rebate pilot program, the agency limited manufacturer plans to 1,000 words. Such a narrow limit forced manufacturers to consider crucial details and processes only during program implementation, which ultimately resulted in significant differences in pilot effectuation between manufacturers. **We recommend that HRSA allow manufacturer plans to include more specific details of their participation in the pilot.**

HRSA should publicly post the submitted and approved manufacturer plans . Publishing the full plans will enable stakeholders to provide immediate feedback to HRSA if manufacturer demands are unreasonable, assist covered entities in preparing for implementation, and create additional accountability that hopefully will influence the thoughtfulness and quality of manufacturer plans.

Once a manufacturer plan is approved, **HRSA should not allow the manufacturer to make unilateral changes to the terms and details**. Any change to a manufacturer's plan should be subject to a clear review and approval timeline by HRSA.

Improving Quality, Utility, and Clarity of Manufacturer Reporting Data

We appreciate HRSA's intention to collect manufacturer data to monitor manufacturer compliance and assess program effectiveness. The ICR indicates that manufacturers would be required to submit data to the 340B Prime Vendor only once a month. **HRSA should ensure that the frequency of required data submission by manufacturers aligns with proposed reporting requirements for covered entities.** More frequent manufacturer reporting is particularly important at the beginning of pilot implementation to mitigate recurring and easily preventable systematic issues or noncompliance.

Minimizing Information Collection Burden for Covered Entities

The ICR notes that the type and frequency of covered entity data submittals will be defined in future guidance. It is not possible to provide detailed feedback without knowing the actual scope of the collection.

As HRSA considers the scope of data collection under a new pilot, it should limit the permissible claims fields collected to those outlined in the original rebate pilot notice. The expansion of data fields in the withdrawn pilot was deeply troubling, increasing compliance burden and creating opportunities for manufacturers to abuse and misuse data.

HRSA has a duty to safeguard Protected Health Information and to maintain program integrity; it must ensure data are used only for the pilot's stated purpose. **HRSA should explicitly prohibit manufacturers and third parties from using collected data for other purposes.** For example, Beacon Channel Management concerningly suggested it would use claims data to aid in identifying and offsetting rebates across payers like Medicare, Medicaid, and commercial insurers.

Recommendation to Collect Information Related to Pilot Evaluation

The ICR does not include any discussion of anticipated collections related to pilot evaluation. If the agency proceeds with a rebate pilot, HRSA should develop and solicit feedback on a detailed plan for assessing the pilot. HRSA should specify through guidance what data and reports will be collected, define what an effective pilot program entails, and lay out a plan to solicit ongoing feedback from covered entities and stakeholders.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Robert Nelb, at 202-585-0127 or rnelb@essentialhospitals.org.

Sincerely,

Jennifer DeCubellis
President and CEO
America's Essential Hospitals

Finger Lakes COMMUNITY HEALTH
Taking the time to care.

April 23, 2025

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Finger Lakes Community Health (FLCH) is a federally qualified health center under section 330 (e) and (g) Community Health Center/ Migrant Health Center (FQHC) operating 8 full time health center sites, and a full-service school-based health center, which are situated across the region in Cayuga, Ontario, Yates, Seneca, Steuben, and Wayne Counties providing access to comprehensive health care services. As is required by HRSA, FLCH is governed by a Board of Directors that is comprised of a majority of members who are also patients and reflect the demographics of the patients served. FLCH currently employs 210 individuals, with a large percentage of staff hired from the communities served. The demographics of the staff reflect our patients in that many come from the Latino or other communities of color across the Finger Lakes region. The mission of FLCH is "to ensure high quality, comprehensive healthcare in the communities they serve with an emphasis on underserved and special populations." Each of our sites serves a unique population through comprehensive medical, dental, behavioral health, care management, transportation, financial advocacy, and care management services. All designed to address our patients' social care needs which may be impacting their ability to meet their healthcare needs. FLCH has NCQA (National Committee for Quality Assurance) PCMH (Patient Centered Medical Home) Level 3 recognition at all of our sites.

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 **27,885** 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**: **Finger Lakes Community Health** anticipates needing **.5** additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, **Finger Lakes Community Health** will face an increased administrative burden to monitor rebate claims and payments. **An additional 15 hours** will be required to report 340B rebate claims to a third-party platform and reconcile the rebates to ensure full capture of our entitled discounts.
- **External Vendor Costs**: **Finger Lakes Community Health** anticipates an additional **$65,870** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select

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

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

- **One-Time Implementation Costs:** We anticipate high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows.
- **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 **27,885** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $**122,500** annually.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My Finger Lakes Community Health currently partners with **5 pharmacy groups** 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 **45 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 New York State,** 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.

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

[3] Internal NACHC survey data

II. Patient Impact

Finger Lakes Community Health has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies 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. Eligible Patients of Finger Lakes Community Health can purchase medications under our Sliding Fee Discount Program at any Walgreen's location. Under the FLCH Sliding Fee Discount Program patients receive

[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

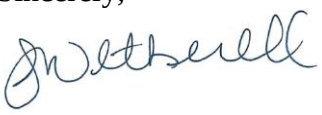
medications at a percentage of actual drug cost based on income and family size, plus a very small dispensing fee of $1.50 per prescription. Patients under the Sliding Fee Discount Program are not limited to 340B eligible drugs only, but, can use the Sliding Fee Discount on any prescription they have. The 340B savings received on Commercially Insured patients help to cover the cost of the discounts provided.

Conclusion

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

Finger Lakes Community 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 Lawreen Duel, Chief Administration Officer @ lawreend@flchealth.org.

Sincerely,



Jamie Wetherell, CPA
Chief Financial Officer
Finger Lakes Community Health

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April 23, 2026

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

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

Dear Administrator Engels:

I am writing on behalf of the Biotechnology Innovation Organization (BIO) to offer comments regarding the Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request (ICR) Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906–NEW.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

As we have noted to HRSA in multiple letters, [1,2,3] the rapid expansion of the 340B Program has shifted it away from its intended purpose of serving vulnerable patients. Instead, covered entities and their for-profit pharmacy and third-party administrator (TPA) partners now exploit the program to generate substantial profits for

[1] BIO Letter to HRSA regarding 340B Rebate Models, October 10, 2024.
[2] BIO Comments to HRSA regarding 2025 340B Rebate Pilot, September 5, 2025.
[3] BIO Comments to HRSA regarding RFI on 340B Rebate Pilot, April 20, 2026.

themselves. [4,5] From 2015 to 2021, purchases under the Program grew an average of 24% per year.[6] By the end of 2024, 340B Program sales at list prices reached $147.8 billion, growing 16.7% year over year, driven in part by growth in the use of contract pharmacies.[7] Reflecting the incentives in the 340B program, this exponential growth is shown in data from IQVIA, which shows 340B purchases at list price in 2024 (from December 2023 to January 2025) grew by 174.6%, compared to only 53.3% growth for non-340B purchases.[8] The 340B Program is now the second largest federal drug program—behind only Medicare Part D.

As we have noted in our previous letters, [9,10,11] BIO strongly supports allowing all 340B manufacturers—consistent with the statute[12]—to offer their covered outpatient drugs at or below the ceiling price through either a discount or a rebate. Rebate models, in particular, can improve program efficiency and provide a more effective mechanism to prevent prohibited duplicate discounts. However, we believe a 340B Rebate Pilot focusing on the selected drugs under the Medicare Drug Price Negotiation Program (DPNP) –Initial Payment Applicability Years (IPAY) 2026 and 2027 drugs as has been described in the ICR –is a good first step toward widely used rebate models for all drugs.

Our comments are summarized as follows:

- A 340B Rebate Pilot should begin as soon as possible, as the implementation of the non-duplication requirements of the IRA in Medicare significantly intensifies the already complex challenge of identifying and deduplicating 340B claims across overlapping programs.
- 340B Covered entity (CE) estimation of the associated burden of a 340B Rebate Pilot is unsupported and grossly exaggerated.
- Appropriate data fields in a 340B Rebate Pilot should include purchase data fields in order so manufacturers may validate claims.
- A 340B Rebate Pilot should be assessed by an independent evaluator to clearly evaluate the program's success.

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[4] "340B Covered Entity Report: Report to the Legislature," Minnesota Department of Health, February 27, 2026. https://www.health.state.mn.us/data/340b/docs/2025report.pdf (Accessed: April 9, 2026)
[5] "Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program," Majority Staff Report, April 2025. https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf (Accessed: April 9, 2026)
[6] Fein, Adam, "What I (and Others) Told the Senate about the 340B Drug Pricing Program." Drug Channels, August 8, 2023. Accessed September 14, 2023. https://www.drugchannels.net/2023/08/what-i-and-others-told-senate-about.html
[7] Martin, Rory, Ph.D., and Karne, Harish, M.S., "The Size and Growth of the 340B Program in 2024," White Paper, IQVIA, 2025. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-update-on-340b-growth-in-2024-white-paper-2025.pdf
[8] Martin, 340B Growth, IQVIA, 2025.
[9] BIO Letter, October 10, 2024.
[10] BIO Comments, September 5, 2025.
[11] BIO Comments, April 20, 2026.
[12] Section 340B(a)(1), Public Health Service Act.

- HRSA must guarantee confidentiality and security of information as much of the required information in a 340B Rebate Pilot would be commercially sensitive and proprietary.

A 340B Rebate Pilot Should Begin As Soon As Possible

The implementation of the IRA's non-duplication requirements for Medicare Maximum Fair Prices, which took effect January 1, 2026, together with Medicare Part B and Part D inflation rebates, significantly intensifies the already complex challenge of identifying and deduplicating 340B claims across overlapping programs. IQVIA estimates show that Medicare accounts for approximately 40% of 340B-eligible volume for self-administered drugs (Part D) and 36% for physician-administered drugs (Part B),[13] underscoring Medicare as a prominent site of potential duplicate discount exposure. A BRG analysis finds that fewer than 0.5% of MFP claims are self-identified as 340B by pharmacies, even though Medicare Part D prescription drug event (PDE) data show that approximately 10–12% of claims for the selected drugs are actually subject to 340B pricing.[14] In effect, pharmacies flag fewer than 5% of 340B claims, the analysis also reveals that these trends suggest manufacturers would be solely responsible for preventing an estimated $5 billion in duplicate discounts in Part D by 2027.[15] This is in addition to the duplicate discount exposure in Medicaid, It is estimated that 3% to 5% of Medicaid rebates are duplicate discounts. In FY 2024 this equates to approximately $1.7 billion to $2.9 billion. [16,17] In this environment of increasing complexity of identifying and resolving duplicate discounts, it is imperative that a 340B Rebate Pilot be implemented as soon as possible.

Estimated Burden

Regarding the associated burden on covered entities (CEs), we reiterate our previous comments.[18] Manufacturers have already made substantial investments to build and operationalize rebate model platforms, including education and tools for CEs and third-party administrators (TPAs). Any one time or up-front implementation costs are routine for 340B pricing and inventory models, which covered entities have repeatedly assumed when implementing their preferred

[13] "Can 340B Modifiers Avoid Duplicate Discounts in the IRA?" IQVIA. February 2023. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf (Accessed: March 28, 2026)
[14] Blalock, Eleanor, "Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027," BRG, April 2026. https://media.thinkbrg.com/wp-content/uploads/2026/04/03101442/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027.pdf (Accessed: April 9, 2026)
[15] Ibid.
[16] "The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark," Drug Channels blog, Drug Channels Institute, March 18, 2022. https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html (Accessed: March 30, 2026)
[17] MACPAC, January 2026. https://www.macpac.gov/wp-content/uploads/2026/01/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2024.pdf
[18] BIO Comments, April 20, 2026.

models, and are minor compared to the significant financial benefits CEs receive from the 340B program. Assertions that a rebate pilot would impose more than $400 million in annual costs[19] are wildly overstated. Many of the relevant implementation expenses were already incurred in advance of the original January 1, 2026, Pilot launch.

Claims about data burden are similarly overstated. CEs already collect and maintain the required data through standard 340B qualification and accumulation processes. Providing this information for rebate purposes adds little to no new administrative or financial burden—a conclusion HRSA itself has acknowledged:

> "...*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.*"[20]

The data elements required under the 2025 Rebate Model Pilot are already routinely captured in payer claims, used in standard 340B operations, retained for audit compliance, and—under certain contract pharmacy and claims data arrangements—shared with manufacturers.

CMS itself has acknowledged that a small number of TPAs process most 340B claims and that they often determine 340B eligibility in as little as 24 hours.[21] Covered entities' existing reliance on TPAs to qualify claims and manage data reporting enables rapid submission of 340B rebate claims and ensures 340B rebate payments can flow within standard wholesaler payment timelines.

While CEs argue that rebate models would require them to "float" funds, empirical analysis does not support this claim. IQVIA's modeling shows that financing costs under a 340B rebate model at entity-owned pharmacies are comparable to those under current replenishment models.[22] At contract pharmacies, cash flow is actually improved: rebate-model interest costs are significantly lower than those associated

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[19] American Hospital Association Letter to HRSA, September 30, 2025. https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program (Accessed: March 30, 2026)
[20] Pages 9632-9633, *Federal Register*, Vol. 91, No. 38, February 26, 2026.
[21] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, page 232, October 2, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (Accessed: March 25, 2026)
[22] Sun, et al. IQVIA White Paper "How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program." December 2, 2025. https://www.iqvia.com/locations/united-states/library/white-papers/how-will-a-rebate-model-impact-cash-flow-in-the-340b-drug-pricing-program (Accessed: March 25, 2026)

with common credit-based and virtual replenishment approaches ($0.18 versus $0.54 and $0.81, respectively).[23]

Data Elements

The ICR describes the data processes and fields that would be necessary for a 340B Rebate Pilot to operate efficiently, as well as the reporting that would be potentially expected under the Pilot. We reiterate from our comments to HRSA under the Request for Information (RFI) issued on February 17, 2026,[24] we believe it is essential that CEs provide manufacturers accurate and complete claims data. A manufacturer can only adjudicate a 340B claim upon verification that it constitutes a valid 340B transaction, has been submitted by an eligible covered entity, and that the covered entity purchased the drug on which a rebate is being requested. The necessary data for an effective 340B Rebate Pilot fall into distinct categories: pharmacy claims, medical claims, and purchase data. These data fields should be as follows:

Pharmacy claims data fields (as was included in the original Rebate Model Pilot) should be:

- Date of service;
- Date prescribed;
- Rx number;
- Fill number;
- 11-digit National Drug Code (NDC);
- Quantity Dispensed;
- Prescriber ID;
- Service provider ID;
- 340B ID;
- Rx Bank Identification Number (BIN); and,
- Rx Processor Control Number (PCN).

Medical claims data fields (as was included in the original Rebate Model Pilot) should be:

- Service provider ID;
- HCPCS Code;
- 11-digit NDC;
- Quantity;
- Date of service;
- Rendering Physician ID;
- Claim number;
- 340B ID;

[23] IQVIA White Paper, December 2, 2025.
[24] 91 *Federal Register,* 7287

- Health Plan ID;
- Claim Line Number; and
- Unit of Measure.

Purchase Data fields (for all 340B claims) should be:

a. Wholesaler/distributor name;
b. Account number;
c. Invoice date;
d. Invoice number;
e. Package units;
f. Ship-to pharmacy NPI;
g. 340B ID; and
h. 11-digit NDC.

Manufacturers must have access to purchase data to verify that drugs were purchased by eligible 340B CEs and at the correct price. Given frequent changes in WAC pricing—and the fact that many CEs do not purchase at WAC—robust purchase details are indispensable to ensuring rebate claims are accurate and appropriate. Without this information, manufacturers have limited ability to validate rebates. As we have raised in prior correspondence, at the beginning of the Pilot there is a significant risk that CEs could submit rebate claims for products that have already received the 340B discount through replenishment.

It is also critical to recognize that purchase data and claims data are distinct and serve different validation functions. Key identifiers, including the 340B ID and NDC-11, must therefore be included in purchase data—not merely embedded within claims data—to enable meaningful verification and protect the integrity of the rebate process.

Independent Evaluator

The ICR states that manufacturers "will be required to submit data to the 340B Prime Vendor monthly to evaluate program integrity and to provide greater transparency in the 340B Program."[25] The ICR also states that the "data will also support the ongoing assessment of any 340B Rebate Model Pilot Program." The evaluation of the rebate pilot must be done by an independent evaluator, and not by Apexus, the Prime Vendor. Apexus, a for-profit company, is currently under Congressional investigation for conflicts-of-interest.[26] As was pointed out in a *New York Times* investigative report, Apexus has significant incentives to aggressively expand the 340B program

[25] 91 *Federal Register*, 9632-9633
[26] Letter from Senator Bill Cassidy, MD to Christopher Hatwig, MS, RPh, FASHP, President of Apexus, February 1, 2026.

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and drive the utilization of more expensive drugs, particularly oncology.[27] Has we have stated in our previous comments,[28] HRSA should work with other government partners to evaluate the model. We urge HRSA to collaborate with HHS OIG and CMS to set clear, transparent criteria for assessing any rebate model and potential changes. OIG can offer insights from past program recommendations, while CMS offices including the Center for Program Integrity, the Medicare Drug Rebate and Negotiations Group, and the Center for Medicaid and CHIP Services should help evaluate effectiveness, compliance with the IRA, and Medicaid nonduplication requirements.

Confidentiality of Information

We are deeply concerned that the ICR has not included any mention of protections to ensure confidential and proprietary information would be kept secure. Much of the information required for the 340B Rebate Pilot would be commercially sensitive and proprietary, and as such must be kept confidential and secure by HRSA and its contractor(s). Disclosure must be prohibited, including the protections under the Federal Trade Secrets Act[29] and exemption 4 of the Freedom of Information Act (FOIA).[30]

* * *

Thank you for your consideration. We believe a 340B rebate model will improve the integrity and efficiency of the 340B Drug Program, which will help reorient the program in a way that will truly help patients. If you have questions, please contact me at 202-962-9200 or at jgeisser@bio.org.

Sincerely,

/s/

Jack Geisser
Vice President
Health Policy

[27] Gabler, Ellen. "How a Company Makes Millions Off a Hospital Program Meant to Help the Poor," NY Times (January 15, 2025).
[28] BIO Letter, April 20, 2026.
[29] 18 U.S.C. § 1905
[30] 5 U.S.C. § 552(b)(4)

TO: Mr. Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services

Ms. Chantelle Britton
Director
Office of Pharmacy Affairs, Health Resources and Services Administration
U.S. Department of Health and Human Services

FROM: Colorado Community Health Network
DATE: Apr. 23, 2026

RE: Comments on HRSA's Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB # 0906-NEW

Colorado Community Health Network (CCHN) is the membership association for the state's 21 Federally Qualified Health Centers (FQHCs, also known as Community Health Centers or CHCs), which includes nineteen grantees and two Look-Alikes. As covered entities, all 21 CHCs participate in the 340B Drug Discount Program, providing access to affordable pharmaceuticals through onsite or contract pharmacies. CCHN does not believe that a rebate model is an appropriate or efficient manner to operate the 340B program, as it pulls CHCs' limited funding and staff time away from patients and towards management of the rebate model. A rebate model damages the integrity of the program and inhibits patient access to affordable prescription medications.

The Information Collection Request (ICR), OMB # 0906-NEW, published by the Health Resources and Services Administration (HRSA) represents a fundamentally flawed perspective of the burden, staff time, and resources that compliance with a rebate model would impose on covered entities, including CHCs. CCHN will provide a Colorado perspective as to the actual cost of participating in a 340B rebate model on CHCs in this letter to better inform HRSA's estimates and understanding. CCHN believes that a rebate model will be catastrophic to the health care safety net in Colorado, and across the country, and devastate low-income, vulnerable patients' access to affordable medications and integrated health care services. **We request that HRSA exempt all CHCs from any 340B rebate model, including the pilot program being explored in HHS Docket # HRSA-2026-03042.**

Data collected by CCHN from fifteen CHCs, which are representative in size and location of the 21 CHCs in Colorado, demonstrates the enormity of the burden, far above the five additional

hours estimated by HRSA. This burden includes substantial staffing impacts and administrative and operational changes to account for the data compilation and collation, data reporting, and tracking of the rebates throughout the process. As defined in the ICR, burden, in this context, means “the time expended…to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems…for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.”

Of the fifteen CHCs that responded, 87% indicated it would require more staff time and dollars to manage the rebate model than their current pharmacy program. To sufficiently and adequately track the submission of the data and the receipt of rebates across in-house and contract pharmacies, those CHCs estimate spending, on average, nearly $100,000 annually in additional staff time and cost, ranging from roughly $10,000 for a small, rural CHC to upwards of $500,000 for a large, urban CHC.

Additionally, CHCs report that it would take an additional 1,962 hours on average per CHC, to compile, calculate, and collate the necessary data, submit the rebate data, reconcile the received rebate with the expected amount, contest any incorrectly denied rebates or follow-up on delayed rebates, and audit their 340B program. This is nearly one full time equivalent staff on average, with estimated burden ranging from 130 more hours per year for a small CHCs up to more than 6,200 hours for larger CHCs, far more than the HRSA estimate of five additional hours per year.

On average, using 2025 drug purchasing as a proxy, CHCs would need to account for an average upfront cost increase of $11.6 million if the rebate model was expanded to all 340B drugs. According to data CCHN calculated in 2024, with a rebate model imposed on the ten drugs subject to the Medicare Fair Price negotiations, CHCs would need to account for an upfront cost increase exceeding 7,000%, which does not include any increased revenue or resources spent on hiring or reallocating and retraining staff, implementing new and upgraded technological systems, and dedicating time to tracking and accounting for rebates.

With any additional revenue or reserves tied up to account for this astronomical increase and no guarantee of a return on the investment, along with the need to pull funds from other areas of the clinic’s operations – including staffing, services, and even clinic locations – to simply maintain compliance with a rebate model, the burden to account for this increase in staff time and cost, and the impact on CHC patients’ access to care and medications, is mind-boggling. It is incomprehensible to impose a rebate model with this level of burden on local, nonprofit and public CHCs when 70% of CHCs in Colorado had negative or breakeven financial operating margins in 2024 and 2025 and it is anticipated a similar number of CHCs will face this financial challenge in 2026.

Thank you for considering our feedback on the true cost that managing and participating in a 340B rebate model pilot program would have on CHCs. This proposed program would not be a simple operating change or a cost rearrangement; it would lead to a drastic, catastrophic detriment in how CHCs operate pharmacy programs, fund staff, health care services, and programs, and support their patients. **We reiterate our request for HRSA to exempt all CHCs from this pilot program, and any 340B rebate model in the future.** If you have any questions, please reach out to myself, Ross Brooks, President and CEO of CCHN, at rbrooks@cchn.org, or Suzanne Smith, Health Center Operations Director of CCHN, at suzanne@cchn.org.

Ross Brooks
President and CEO, Colorado Community Health Network