NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS®

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:

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

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

The 340B program is foundational to CHC's ability to serve the most vulnerable members of our community. However, the proposed shift of responsibility from manufacturers to safety-net providers directly serving patients through a rebate model threatens to destabilize CHC pharmacy operations nationwide. Based on information from CHCs, the hours and dollars spent complying with a rebate program would be staggering.

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

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect CHCs' ability to serve their patients. They operate on razor-thin margins, and these additional costs are not an option for many entities. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. We will face an increased administrative burden in monitoring rebate claims and payments.

To support CHCs in assessing the financial and operational impact of current manufacturer restrictions and an anticipated rebate model, NACHC worked with FQHC 340B Compliance to create an Operational & Administrative Cost Calculator.[3] The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support cost forecasting. CHCs have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, including requirements for clinic-administered drugs and entity-owned pharmacies. A rebate model will require a significant increase in already-strained operational capabilities.

Workforce Impact:

- **Staffing Impact**: According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.[4]
    - Additionally, several CHCs estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[5] One midwestern CHC, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities.
    - For IT needs specifically, one mid-sized CHC in Alaska stated that the administrative time required to set up new IT processes to establish data feeds, run financial reports, and decipher Beacon claims will result in at least one FTE employee at $120,000 and another $100,000 for investment in IT systems. For another large health center in Alabama, the estimated logistics will require an additional one to two FTE if the program grows to manage the reconciliation and continued burden.
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. Thirty-nine percent of CHCs estimate it will take their staff more than 20 hours to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans; another 38% estimate between 15 to 20 hours, and 23%

[3] https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/
[4] Internal NACHC assessment (99 responses).
[5] Ibid.

believe it will take 5 to 10 hours to meet reporting requirements with this pilot program.[6] The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens.

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires both staff and changes to the workflow and software. HRSA should consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers can select different software platforms, like current contract pharmacy policies, the CHC administrative burden would increase substantially.

- **One-Time Implementation Costs:** CHCs anticipate high upfront costs to adapt their pharmacy software, pay for custom dashboard modifications, and design new internal workflows, all of which will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, CHC TPAs and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.

The In-House Pharmacy: The Burden of IT Integration

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

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

[6] Internal NACHC assessment (out of 101 responses).
[7] Internal NACHC assessment (out of 101 responses).
[8] Internal NACHC assessment (99 responses).

The Contract Pharmacy: The Burden of Network Coordination

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

- **TPA Reliance and Fees:** Navigating manufacturers' varying requirements across multiple contract pharmacies requires high-level TPA intervention. CHCs anticipate that TPAs will pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.
- **Verification Latency:** The rebate model creates a reconciliation gap. CHC staff will have to monitor claims in their entity-owned pharmacies, if applicable, and work with their different contract pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** Because this model shifts the financial risk to the pharmacy, many CHCs fear their contract partners will opt out of the 340B program entirely rather than manage the administrative headache. This would leave patients in our area with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[10] 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.[11]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed to be cost-effective and reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[12]

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

II. Patient Impact

NACHC has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving medications. The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a

[9] https://www. nachc.org/wp-content/uploads/2026/01/Pharmacy-Survey_Expanding-Access_V2.pdf
[10] Vulnerability Index Approach to Identify Pharmacy Deserts and Keystone Pharmacies | Pharmacy and Clinical Pharmacology | JAMA Network Open | JAMA Network
[11] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2024.00192?journalCode=hlthaff
[12] Internal NACHC survey data

higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[13] 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,[14] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

III. Financial Challenges

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. Many CHCs are currently under financial strain, with nearly half of CHCs operating with fewer than 90 days of cash on hand, and one in four reporting approximately negative five percent (-5%) operating margins. This rebate model creates significant financial challenges, including:

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[15] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[16] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size.

Conclusion

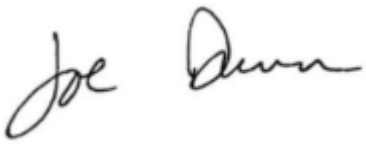
NACHC strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. A 340B rebate program represents a departure from the original intent of the 340B program—to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. A rebate model would create significant cash flow challenges, forcing CHCs to make difficult

[13] 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.
[14] 2025 UDA Data, HRSA (hrsa.gov)
[15] HRSA FAQ
[16] Such discounts are subject to potential legal and contractual restrictions. https://bphc.hrsa.gov/compliance/compliance-manual/chapter9#footnote10

decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHCs would need to make significant investments in IT infrastructure and staff to comply with rebate requirements and track rebates. It would also create a new barrier for patients, especially uninsured patients, who depend on the up-front 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. NACHC believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

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

Sincerely,



Joe Dunn
Chief Policy Officer

340B HEALTH

April 27, 2026

Submitted via Email: paperwork@hrsa.gov

HRSA Information Collection Clearance Officer
Room 13N82
5600 Fishers Lane
Rockville, MD 20857

RE: Information Collection Request (ICR) Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Dear HRSA Information Collection Clearance Officer:

On behalf of our more than 1,600 member hospitals and health systems that participate in the federal 340B program, 340B Health appreciates the opportunity to respond to the Health Resources and Services Administration's (HRSA) notice published in the Federal Register on February 26, 2026, requesting public comment on a proposed data collection pertaining to a 340B rebate model program.[1] We are writing to provide input on the significant burdens that 340B hospitals would incur under a rebate model—burdens that HRSA has substantially underestimated in the ICR.

340B Health continues to urge HRSA to preserve the longstanding upfront discount model that manufacturers have used for more than 30 years to meet their legal pricing obligations under 340B.[2] Unlike rebates, upfront discounts have a well-established record of allowing 340B hospitals and other safety-net providers with limited resources to expand access to care for low-income and underserved patients, consistent with Congress's intent in creating the 340B program. By HRSA's own estimate, a rebate model covering 25 drugs would impose at least $500 million in additional costs on 340B covered entities (CEs) just to

[1] Health Resources and Services Administration, Notice, 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW, 91 Fed. Reg. 9632 (Feb. 26, 2026).
[2] *See* 340B Health, Request for Information (RFI): 340B Rebate Model Pilot Program (HHS Docket No. HRSA–2026–03042), Apr. 20, 2026, https://downloads.regulations.gov/HRSA-2026-0001-2437/attachment_1.pdf; *see also* 340B Health, 340B Rebate Pilot Program (HHS Docket No. HRSA–2025–14619), Sept. 8, 2025, https://www.340bhealth.org/files/FINAL-340B-Health-Comments-Rebate-Pilot9.8.25.pdf (noting our position, which we have presented in federal court as intervenors in drugmakers' lawsuits against HRSA and the Department, that the 340B statute mandates upfront 340B discounts and stating that 340B's legislative history demonstrates that any rebate authority Congress provided to HRSA was intended to be used for the benefit of CEs – not drugmakers). We note that our comments responding to HRSA's RFI notice suggest several changes HRSA should make if it proceeds with a rebate model, including those that do not directly pertain to the information collection proposed by HRSA, and therefore are not addressed in here.

submit rebate claims data to drugmakers.[3] This estimate reflects an extraordinary burden on safety-net providers, many of whom operate on narrow or even negative margins.[4] However, the actual impact of rebate requirements on CEs is likely far greater, as HRSA significantly understates the costs CEs would incur under a rebate model.

HRSA's underestimation of the actual burden and expenses a rebate model would likely impose on CEs appears to stem from an incorrect assumption that the data required for rebates would be comparable to information that CEs already share with manufacturers or third-party vendors (TPAs). As discussed below, that assumption is wrong and leads to a material understatement of the burden.[5] HRSA's estimate also does not account for substantial burdens and costs CEs would be forced to incur to test, implement, maintain, and audit entirely new rebate systems.

At a minimum, HRSA should not proceed with a rebate model unless and until it develops a more accurate assessment of the associated burden and costs. HRSA should also identify the specific information that CEs would be required to submit to obtain rebates and that information should be subject to public notice-and-comment. Anything less would deny CEs a meaningful opportunity to evaluate and comment on the accuracy of HRSA's burden estimate and prevent HRSA from being able to consider the true costs of a rebate model.

I. The Burden for 340B CEs Would Far Exceed HRSA's $500 Million Estimate

A. Hospitals Provide Far Less Data to Manufacturers and Third-Party Administrators Than HRSA's Estimates Assumed

HRSA estimates that CEs would incur at least $500 million in additional annual costs, driven by more than 3.7 million hours of labor that pharmacists would spend solely on submitting data to a

[3] *See* 91 Fed. Reg. at 9633; *see also* Supporting Statement A, 340B Rebate Pilot Program application, Implementation, and Evaluation, OMB Control No. 0906-0111-Extension) (calculating each hour of burden pertaining to CE data submission under HRSA's withdrawn rebate pilot notice as imposing $132 (a pharmacist's hourly wage rate). Under this assumption, HRSA estimates that CEs would incur more than $500 million in annual labor costs just to submit rebate claims data to drugmakers for 25 drugs subject to Medicare Part D negotiated pricing – 10 in 2026 and 15 beginning in 2027 (3,796,000 hours × $132 = $501,072,000). We calculated this cost using HRSA's original methodology because HRSA has not yet released any supporting statements, instructions, or underlying instruments pertaining to the proposed data collection discussed here.

[4] Dobson DaVanzo & Associates, LLC. 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress. July 2020. https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf.
HRSA estimates that the rebate model for 25 drugs by 13 drug companies would impose 3.8 million hours of labor on CEs. 91 Fed. Reg. 9632, 9633 (Feb. 26, 2026).

[5] We are disappointed that HRSA continues to make unsupported assumptions about CEs and rebate claims data that contribute to significant underestimates of the burden and costs of rebate claims data submissions. *See* 340B Health Comments to HRSA (Oct. 29, 2025), responding to 90 Fed. Reg. 44197 (Sept. 12, 2025), https://www.340bhealth.org/files/FINAL-340B-Health-Rebate-Pilot-ICR-Letter-to-HRSA10.29.25.pdf (stating that HRSA's estimates that CEs would spend only two hours per week submitting data to manufacturers are based on incorrect assumptions that CEs will readily be able to generate the pharmacy claims data that HRSA had approved manufacturers to collect under HRSA's withdrawn rebate pilot notice).

third-party vendor (TPA) to obtain rebates for 340B drugs.[6] HRSA assumes the data required under a rebate model would be comparable to information CEs already submit through existing vendor relationships or already provide to manufacturers under manufacturers' contract pharmacy policies and "requests" for in-house pharmacy claims data.[7] HRSA offers no evidence to support these assumptions, while hospitals have provided information directly contradicting them.

HRSA bases its estimates on the assumption that hospitals already provide the data necessary for rebates to TPAs and/or manufacturers. This is false. Less than one-third of hospitals reported to 340B Health in a recent survey that they are actually providing data for 340B drugs dispensed through their in-house retail pharmacies to retain pricing under manufacturer contract pharmacy policies."[8] Nearly every hospital (89%) reported that if they were required to submit claims data for their in-house pharmacy dispenses, the burden would be substantially higher than having to submit data only for contract pharmacy dispenses.[9]

A rebate model would require data for all hospital dispenses of a unique drug, which hospitals currently do not do. Hospitals usually submit data to their TPAs only for certain wholesaler accounts – those where some of the patients seen are not likely to be 340B-eligible. In fact, nearly half (47%) of hospital respondents to 340B Health's survey do not share data for all their 340B locations with their third-party vendors, and the vast majority of hospitals (87%) report that they would incur moderate to substantial costs if they had to do so.[10] Hospitals report needing to add one additional account per each "clean site" that does not currently submit data to a split-billing vendor and will incur new costs to do so. HRSA did not take this factor into account for its rebate estimates and has underestimated hospital costs of submitting data from locations in the hospital for which data has not previously been shared with TPAs or manufacturers.

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[6] 91 Fed. Reg. 9632, 9633 (Feb. 26, 2026).

[7] *Id.* HRSA also states that data is comparable to data for claims dispensed under the Medicare Drug Price Negotiation Program. Part D plans – not CEs - submit this data to manufacturers. Regardless, there are key differences in the data fields used to effectuate pricing under the MDPNP for Part D drugs and the data hospitals would have been required to submit under the Rebate Pilot. Hospitals had concerns about having to report BIN and PCN under the Rebate Pilot because these fields are not always readily available from contract pharmacies and are not required to provide BIN and PCN to manufacturers under the MDPNP.

[8] 340B Health Member Survey – Costs and Burdens of Submitting 340B Claims Data to Pharmaceutical Companies, Summary Results, Apr. 1, 2026. We understand "in-house pharmacy claims requests" to refer to demands by manufacturers such as Eli Lilly and Novo Nordisk for CEs to submit claims data for all 340B dispenses, including in-house retail and hospital pharmacies, as a condition of accessing 340B pricing. The minority of hospitals that are submitting claims data to a manufacturer(s) under that type of policy likely only recently began submitting such data considering the data submission timelines for those policies.

[9] *Id.* Further, one in five hospitals that responded to 340B Health's survey does not submit any claims data to manufacturers-not even contract pharmacy claims data.

[10] *Id.* Sharing data from new locations will require ongoing costs related to submitting data to third party vendors from locations that do not currently do so, such as "clean sites" that use only 340B drugs and thus have no standard business reason to send data to their split-billing vendors. There are also permanent ongoing costs related to maintaining the equipment and regularly auditing each location to ensure that the systems are working correctly. None of these appear to have been factored into HRSA's estimate of the burden.

It is not surprising that hospitals report workloads that far exceed HRSA's estimate of just five hours per week per CE. In recent comments submitted in response to HRSA's RFI, multiple hospitals stated that rebates would require hiring additional full-time staff, diverting existing personnel, and/or hiring third-party vendors to manage aspects of the rebate claims process.

University of Washington, which operates two 340B hospitals, commented:

> *"UW Medicine anticipates the need for seven additional FTEs in the initial year of the pilot, with an additional seven FTEs required annually as more drugs are incorporated into the 340B rebate model. These resources would support data submission, rebate tracking, payment validation, dispute management, and escalation through HRSA's Administrative Dispute Resolution (ADR) process. Notably, these estimates do not include the additional time and resources required from data analysts, IT teams, and accounting staff who would be continuously engaged in supporting data extraction, reconciliation, financial tracking, and reporting associated with this process. These estimates also do not reflect the time and expense of internal and external resources needed to dispute rebate denials."*[11]

UMass Memorial Medical Center, a DSH in Massachusetts, explained that implementing a rebate system would impose substantial ongoing operational costs by requiring:

- *"Significant investment in new data infrastructure and reporting capabilities*
- *Additional full-time staff or reallocation of existing staff to manage rebate submissions, reconciliation, and dispute resolution*
- *Increased reliance on third-party vendors to support data aggregation, validation, and compliance*
- *Ongoing auditing and monitoring to ensure accuracy and mitigate risk of denied rebates."*[12]

Johnson County Hospital, a critical access hospital in Nebraska, expressed concern about the administrative and financial burdens of the rebate process and that it might need to hire additional staff or have to reallocate existing staff to handle these responsibilities:

> *"We anticipate an extreme administrative burden with the amount of work that will be required to prepare and submit claims data, track rebate data, validate/audit receipt of rebates, interface with the manufacturers' vendor and/or manufacturers to address errors and pursue payment for denied rebates. For staffing with a rebate model we anticipate at a minimum that we would have to reallocate time from our finance department, 340B department and a possible part to full-time new employee dedicated just to tracking this process. If this process proves beyond our abilities with all of these staff hours, we may have to pay an additional third-party vendor to help manage the burden."*[13]

[11] UW Medicine RFI Comments, https://downloads.regulations.gov/HRSA-2026-0001-1860/attachment_1.pdf
[12] UMass Memorial Medical Center RFI Comments, https://www.regulations.gov/comment/HRSA-2026-0001-2064
[13] Johnson County Hospital RFI Comments, https://www.regulations.gov/comment/HRSA-2026-0001-1537

B. Hospitals Provide Fewer Data Fields to Manufacturers than HRSA's Estimates Assumed

Not only do hospitals currently submit data to far fewer outside parties than HRSA estimated but they also submit far less data. HRSA's withdrawn rebate pilot required hospitals to submit BIN and PCN information for all retail claims. Hospitals have not been required to submit that information to manufacturers and TPAs in the past. Importantly, this information is not regularly available for drugs dispensed by contract pharmacies.

HRSA's withdrawn pilot also required hospitals, for the first time ever, to submit extensive data for medical claims for drugs administered in hospital outpatient settings. Data for medical claims, which account for most 340B drug spend, has never been routinely submitted to manufacturers by the 340B hospital industry and any medical data submitted to TPAs is on a much lower scale. Compared to the HRSA's rebate program requirements, the mixed-use charge data hospitals currently transmit to split-billing vendors to distinguish 340B (outpatient) drugs from GPO (inpatient) drugs is significantly more limited and can be generated and shared shortly after administration. HRSA's burden and cost estimates fail to account for this.

Submitting complex medical claims data is no easy feat. Standard hospital operations do not allow for immediate submission of medical claims data because payers require that all services furnished during a hospital stay, which can span days, weeks or months, appear on a single, consolidated bill, delaying submission until all departments report their charges to the hospital billing department. Though 340B applies only to outpatient departments, many payers bundle payments for outpatient services into payments made for inpatient services, requiring that the entire stay in the hospital be complete before submitting the consolidated bill. Even for visits that are conducted entirely on an outpatient basis, the requirement that the bill contain all services provided during the stay can results in the claim being submitted weeks after 340B drugs were administered to the patient. Hospitals highlighted that this issue is particularly acute in surgical and observation areas and warned delaying rebates until after claim submission could result in significant financial strain. HRSA's burden and cost estimates fail to account for this reality.

As explained by UMass Memorial Medical Center:

> *"Hospitals would [] face delays in submitting claims data for physician-administered drugs, which are processed through medical billing systems and may not be finalized for weeks after administration. This contradicts assumptions that claims data submission can occur quickly and efficiently and further delays rebate recovery, exacerbating financial strain."*[14]

II. HRSA's Estimates Do Not Reflect the Full Operational and Administrative Burdens a Rebate Model Would Impose on 340B CEs

HRSA's burden and cost estimates are unduly narrow, focusing solely on the act of data submission while overlooking the significant additional burdens and costs CEs would incur to

[14] UMass Memorial Medical Center RFI Comments, https://www.regulations.gov/comment/HRSA-2026-0001-2064

develop, implement, and maintain the systems required to support that submission. Hospitals would need to build and rigorously test new software to ensure integration with existing electronic medical record (EMR) systems. Hospitals have hundreds of different accounts for their main hospital, various clinics and the pharmacies that they own and operate whose billing systems could be significantly disrupted because of changes hospitals may need to make to have the required information to request rebates.

The ongoing demands of routinely maintaining and auditing these systems to ensure they are working properly further compound the burden. Even minor changes to an EMR system can unintentionally disrupt connections or data flows under a new rebate system, introducing risks of data errors or failures. To mitigate these risks, hospitals must implement regular maintenance and auditing processes. This creates a sustained operational obligation that is technically complex and resource intensive. By not accounting for these, HRSA's estimates do not reflect the full scale of the burden a rebate model would impose on 340B hospitals.

Nor do HRSA's estimates account for the significant administrative burden and cost for safety-net providers under rebate models that are expected to stem from having to interface with the manufacturers' vendor that would administer approved rebate models. HRSA is aware of the numerous challenges 340B hospitals have reported when working with 340B ESP to access 340B pricing under manufacturers' restrictive contract pharmacy policies.[15] A majority of hospitals that have submitted contract pharmacy claims data to 340B ESP report having to hire new staff (58%) or redeploy existing staff (62%) to manage this process including various issues that arose.[16] These challenges, which hospitals continue to experience, would contribute to the burden of rebates even for hospitals that already submit contract pharmacy claims data to manufacturers, expect on a much larger scale, as rebates would apply to 340B dispenses of the drugs across all settings and would not be limited to contract pharmacy.[17] This further undermines HRSA's assumptions that CEs would spend only 5 hours per week on the claims data submission and that the process would impose "minimal burdens" on CEs.

[15] See e.g., 340B Health Letter to HHS and HRSA, Significant Administrative and Financial Burdens Imposed on Hospitals Sharing 340B Claims Data Under Manufacturer Contract Pharmacy Restrictions, May 10, 2022, https://www.340bhealth.org/files/340B-Health-Letter-to-HHS-on-Burdens-of-Manufacturer-Claims-DataConditions5.10.22.pdf; 340B Health, 340B Rebate Pilot Program (HHS Docket No. HRSA–2025–14619), Sept. 8, 2025, https://www.340bhealth.org/files/FINAL-340B-Health-Comments-Rebate-Pilot9.8.25.pdf

[16] 340B Health Member Survey – Costs and Burdens of Submitting 340B Claims Data to Pharmaceutical Companies, Summary Results, Apr. 1, 2026. These issues include delayed responses or errors by 340B ESP and/or the manufacturer(s) resulting in the hospital not receiving 340B discounts that they were otherwise entitled to, thereby harming the hospital (85%) and having to conduct follow-up with TPAs, wholesalers, and 340B ESP after pricing dropped for NDCs and contract pharmacies without explanation (95%).

[17] As UR Medicine explained in its RFI comments to HRSA, it is not uncommon for their hospitals to experience challenges with data submission to 340B ESP, including receiving threats of pricing revocation despite complying with the manufacturers' policies. UR Medicine RFI Comments, https://www.regulations.gov/comment/HRSA-2026-0001-2287

III. The Public Cannot Evaluate Burden Under This ICR Because HRSA Has Not Identified the Specific Data Fields Required

HRSA does not identify the "specific data" that it will require CEs to submit to manufacturers.[18] Hospitals faced the same challenge under HRSA's rebate pilot. Experience shows that without that information, hospitals cannot evaluate the burden of submitting this data, as required under the Paperwork Reduction Act.[19]

Hospitals' experience preparing for the rebate pilot—before a federal court halted implementation on January 1—highlights the need for clear, upfront requirements regarding the data necessary to request rebates. HRSA's initial pilot notice did not include the medical claims data fields that were ultimately added to the rebate pilot, resulting in many hospitals informing 340B Health that would not be able to furnish all of the required fields by January 1.

Not only must HRSA identify the required data fields, it must provide sufficiently clear guidance on the information required for each field. HRSA failed to do this under the rebate pilot. Though HRSA's rebate pilot website listed certain approved data elements for pharmacy and medical claims, it failed to define any of the fields, leaving hospitals to rely on vague descriptions and inconsistent, evolving interpretations from manufacturers' rebate vendors. This lack of clarity created significant confusion, particularly for medical claims data.

Hospitals expressed concerns that they may not be able to submit appropriate data for the rebate pilot data field categories of "health plan" or "health plan ID" as required under HRSA's rebate pilot to identify individual payers and plans for medical claims, as this information did not populate in their systems. Hospitals often use clearinghouses to finalize billing for medical claims and submit to payers. These clearinghouses use their own data to route to the correct payer. Many hospitals were unable to set up a mechanism to transmit these fields by the expected start date of January 1, even after dedicating extensive resources and involving multiple internal teams (e.g., information technology, pharmacy, business intelligence, and systems integration) to find a solution. Of those that located the data in their systems, only some had time prior to HRSA announcing it was pausing the Rebate Pilot to evaluate whether the data could be integrated into files sent to TPAs for rebate claims submissions without disrupting their existing billing systems. A significant number of hospitals also reported concerns to 340B Health that the rebate pilot data field categories of "claim number" and "claim line number" pertaining to rebate requests for medical claims could be too onerous for hospitals to comply with.[20]

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[18] 91 Fed. Reg. 9632, 9633 (Feb. 26, 2026) (stating that

[19] 5 C.F.R. § 1320.8(d)(1)(ii) (requiring that before submitting a collection of information to OMB for approval, that agencies provide 60-day notice in the Federal Register, and otherwise consult with members of the public and solicit comment to evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information).

[20] Definitions provided by the manufacturers' vendor for the following fields caused significant confusion and were later updated after hospitals had already expended resources evaluating the original definitions provided: "claim number" defined by the manufacturers' vendor as "the claim number as assigned by the healthcare provider" and "claim line number" as "the line number of the claim." Beacon Channel Management, FAQ Document on file with 340B Health. The manufacturers' vendor also advised that the rebate data submitted should be "final," leading many hospitals to understand that these data fields must be populated by the same numbers that are used on the medical

Hospitals struggled to obtain clear and consistent information pertaining to the information required for rebate submissions, significantly increasing the cost and complexity of developing IT systems capable of submitting the required claims data. Hospitals—many of which operate hundreds of billing accounts across hospitals, clinics, and owned pharmacies—were forced, on an accelerated timeline, to determine whether their systems captured the necessary data or whether substantial operational changes would be required, all without prior testing or validation. In practice, hospitals expended considerable effort analyzing only a small subset of the fields. These challenges remain unresolved and, if not resolved, would impose substantial and ongoing implementation burdens on hospitals that are not reflected in HRSA's estimates.

HRSA must identify the specific data elements required and provide clear definitions so CEs can understand what must be submitted. This information should then be subject to public notice and comment. Otherwise, stakeholders cannot meaningfully evaluate or comment on the accuracy of HRSA's burden estimate nor on the proposed collection's "quality, utility, and clarity" as required under Paperwork Reduction Act rules.[21] Compounding this concern is the massive scope of data that manufacturers have asked HRSA to allow them to collect, including purchase and encounter data categories—that would impose substantial additional burdens on CEs if they were required to furnish it.[22]

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claim submitted to the payer. Not only would this cause significant delays in hospitals' ability to submit rebate requests, but many hospitals reported that their existing software systems would be unable to meet this requirement without a complete overhaul. The manufacturers' vendor later confirmed to 340B Health that hospitals would not be required to tie "claim number" and "claim line number" to numbers listed on the claim that was submitted to the payer.

[21] In addition to violating 5 C.F.R. § 1320.8(d)(1), we believe that HRSA has not complied with 5 C.F.R. § 1320.8(d)(2) because HRSA failed to make the proposed collection of information—specifically, the draft instruments and related instructions—available for public review during the 60-day comment period. Because the proposed collection and instructions were not in the 60-day Federal Register Notice, HRSA was required to take one of two steps: (1) to provide more than 60 days' notice to allow for the "timely receipt" of the materials, or (2) to clearly explain how and from whom the public can request and obtain them during the comment period. HRSA has satisfied neither alternative requirement. First, it has not extended the comment deadline. Second, an email on file with 340B Health to the HRSA Paperwork Team requests copies of the information collection plans and draft instruments for the proposed data collection and HRSA's response, also on file, states that the forms are not yet final and will be available upon publication of OMB's 30-day notice. Though HRSA said in the ICR notice that stakeholders can contact HRSA to request more information on the proposed collection or obtain a copy of the information collection plans and draft instruments, merely offering a process that yields no access during the comment window does not satisfy 5 C.F.R. § 1320.8(d)(2), which requires that the public be able to actually obtain the materials in time to comment on them.

[22] *See e.g.,* J&J RFI Comments, https://downloads.regulations.gov/HRSA-2026-0001-2226/attachment_1.pdf, (requesting purchase data in addition to pharmacy and medical claims data); AbbVie RFI Comments, (requesting pharmacy, medical claims data and purchase data, stating that "verifying the purchase of each individual unit is critical to a successful Rebate Model."); Sanofi RFI Comments, https://downloads.regulations.gov/HRSA-2026-0001-2020/attachment_1.pdf, (requesting that manufacturers participating in the rebate pilot be permitted to collect "health care encounter data to verify that those receiving drugs dispensed in connection with a 340B claim are in fact patients of the relevant covered entity.").

Thank you for considering our comments. Please contact Maureen Testoni, President and Chief Executive Officer, at maureen.testoni@340bhealth.org, or Amanda Nagrotsky, Vice President of Legal and Policy, at amanda.nagrotsky@340Bhealth.org, if you have questions or would like to discuss our comments.

Sincerely,

Maureen Testoni
President and Chief Executive Officer
340B Health

Amanda Nagrotsky
Vice President of Legal and Policy
340B Health

April 27, 2026

HRSA Information Collection Clearance Officer
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear HRSA Information Collection Clearance Officer:

Big Bend Cares submits these comments in response to HRSA's request for public comments on the Information Collection Request (ICR) burden estimates associated with the proposed 340B Rebate Model Pilot Program. Big Bend Cares is a Ryan White HIV/AIDS Program grantee and community-based healthcare provider serving low-income and uninsured individuals living with HIV across North Florida. We operate more than 50 active contract pharmacy locations and maintain an in-house pharmacy program. Our 340B program generates approximately $15.0 million in annualized revenue and $2.75 million in net savings annually, which directly funds HIV/AIDS patient services that are not separately reimbursed through Medicaid or commercial insurance.

We write specifically to address the ICR burden estimates and to urge HRSA to substantially revise them to reflect the true administrative burden that a rebate model would impose on small Ryan White and safety-net covered entities.

I. HRSA's Burden Estimates Are Significantly Understated for Ryan White Grantees

HRSA's ICR estimates approximately 5 hours per response for covered entities participating in a 340B rebate model. Based on our operational experience, we believe this estimate materially understates the actual burden that would be imposed on Ryan White grantees and similarly situated small safety-net providers.

Our current 340B compliance infrastructure already requires:

- Split-billing software
- Third-party administrator (TPA) oversight — currently costing Big Bend Cares approximately $300,000 annually
- Wholesaler reconciliation and dispensing fee reconciliation — approximately $1.61 million annually
- Chief Pharmacy Officer oversight and audit-ready documentation maintained for six years

A rebate model would require entirely new operational workflows on top of this existing infrastructure, including:

- **Claim-by-claim rebate submissions** across multiple manufacturer platforms (e.g., Beacon, SecureAccessRx, and others), each with differing data format requirements, submission timelines, and adjudication standards
- **Tracking, reconciling, and appealing denials** across dozens of separate manufacturer adjudication systems
- **Staff time for monthly rebate cycle management:** claims preparation, submission, denial management, and reconciliation — we estimate 15–20 hours per monthly cycle per manufacturer platform, not 5 hours total
- **New software systems** and vendor/legal/consulting expenses
- **Dedicated FTE:** We estimate 1.5–2.0 additional FTEs would be required at $75,000–$110,000 annually

In total, we estimate incremental annual administrative burden costs of $400,000–$500,000, representing 15–20% of our current 340B net savings. These costs would translate directly into reduced patient services.

II. Frequency and Volume of Collection Is Understated

The burden of rebate administration is not a single annual event. Under a rebate model, submissions would be required monthly — and potentially more frequently — for each manufacturer participating in the pilot. With more than 50 contract pharmacy locations dispensing drugs across multiple manufacturers, the volume of submissions, tracking, and reconciliation would be substantial.

We urge HRSA to revise the ICR to reflect:

- **Monthly submission cycles** per manufacturer (not a single annual count)
- **Multiplatform burden:** different manufacturers use different platforms, each with unique submission formats, credentialing requirements, and adjudication timelines
- **Denial management time:** we estimate denial resolution requires an additional 3–5 hours per denial event, and denial rates from manufacturer rebate platforms have historically been significant for covered entities

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III. Cash Flow Burden Is a Form of Administrative Cost Not Reflected in the ICR

HRSA's ICR burden analysis does not appear to account for the financial carrying cost created by a shift from upfront discounts to rebates. For Big Bend Cares:

- The difference between WAC and 340B pricing on our drug spend can approach $6 million annually
- Under a rebate model, we would be required to purchase at WAC, creating a minimum 25–30 day financing gap between payment and rebate receipt
- Floating one month of that differential — approximately $500,000 — exceeds our current unrestricted cash reserves

- If just 10% of rebates are delayed beyond 60 days or denied on technical grounds, we would lose approximately $275,000 in working capital directly supporting HIV/AIDS patient services

These financing burdens represent real organizational costs — including potential line-of-credit fees or operational curtailments — that should be reflected in any accurate burden estimate.

IV. Patient Data Submission Burden Raises Additional Costs

A rebate model would require submission of detailed patient-level data — including patient identifiers, dates of birth, prescriber NPIs, dispense dates, NDCs, quantities, days supply, and contract pharmacy NPIs — directly to manufacturers on a claim-by-claim basis.

Managing this data submission creates additional ICR burden through:

- **Data preparation, de-identification review, and quality control** prior to each submission
- **Legal and compliance review** to ensure HIPAA compliance and data minimization
- **Cybersecurity safeguards** for transmitting sensitive data involving a medically vulnerable, stigmatized population to commercial entities
- **Breach monitoring and incident response planning** across multiple manufacturer platforms

These data-related burden hours are not reflected in HRSA's current estimates and should be added to any revised ICR.

V. Recommendations to Reduce Burden

If HRSA proceeds with a pilot, we recommend the following measures to minimize administrative burden on small covered entities:

1. **Standardize submission formats** across all participating manufacturers — a single electronic submission portal managed by HRSA or a designated neutral third party
2. **Limit required data elements** to those strictly necessary to identify duplicate discounts: NDC, dispense date, payer type, and claim adjudication status
3. **Extend submission timelines** — at minimum 30 days after month-end to allow for complete reconciliation
4. **Mandate automatic approval** for claims not adjudicated within 10 business days
5. **Provide advance HRSA technical assistance** including templates, vendor-neutral system standards, and plain-language guidance to reduce implementation costs for small providers
6. **Conduct a formal independent burden study** with real-world input from Ryan White grantees, FQHCs, and other small safety-net entities before finalizing any ICR estimates

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Conclusion

Big Bend Cares respectfully urges HRSA to substantially revise its burden estimates for the 340B Rebate Model Pilot Program ICR to reflect the actual operational, staffing, financial, and data compliance costs that would be imposed on Ryan White grantees and small safety-net covered entities. The current estimates do not capture the monthly frequency of submissions, multiplatform complexity, cash flow carrying costs, or patient data management burden. Accurate burden estimates are essential for informed policymaking and for ensuring that the 340B Program continues to serve its statutory mission of expanding access to affordable medications for vulnerable populations.

We appreciate HRSA's engagement on this issue and welcome continued dialogue.

Sincerely,

Ray Akrayi

Chief Pharmacy Officer
Big Bend Cares
2201 South Monroe Street
Tallahassee, Florida 32301
850-656-2437

AltaMed

April 27, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of AltaMed Health Services Corporation (AltaMed), 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, AltaMed again requests that CHCs be exempted from the pilot program.**

For over 55 years, AltaMed has operated as a nonprofit federally qualified health center (FQHC), providing high-quality, comprehensive, and affordable primary and preventive care across Southern California. We serve more than 700,000 individuals with integrated medical, dental, behavioral health, pharmacy, vision, and other essential services—often acting as the only accessible source of care for hardworking individuals and families. Our pharmacies further expand access with affordable medications, lower-cost generics, diabetes management, and free delivery, particularly in underserved communities. As such, we strongly urge HRSA to exempt Community Health Centers from the 340B Rebate Model 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 patients who rely on

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us. For AltaMed in particular, this change would affect approximately over 1 million 340B transactions, impacting more than 100,000 patients. 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**: AltaMed anticipates needing two additional FTEs—equivalent to 4,160 hours per year—to address the increased regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, AltaMed anticipates an additional increase of $15,000 in costs, along with a $5,000 monthly fee for external support venders. 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 high upfront costs to adapt our pharmacy software, pay for custom dashboard modifications, and design new internal workflows. $15,000 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. We estimate these recurring costs will be at least $5,000 annually, representing a permanent expense that reduces our 340B savings.
- **Total Cost:** For AltaMed, which serves approximately 100,000 patients receiving prescriptions through the 340B program, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at least $144,000 annually.

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

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The In-House Pharmacy: The Burden of IT Integration

AltaMed operates 11 dedicated pharmacy locations throughout Los Angeles and Orange 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 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, including an additional $15,000 in costs to AltaMed.

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 100 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 100 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 Southern California with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already, 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.

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.

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

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(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

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

Conclusion

AltaMed 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

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

AltaMed 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 Bertha Alisia Guerrero, Associate Vice President of Government Affairs at beguerrero@altamed.org.

Sincerely,

Berenice Nuñez Constant
Senior Vice President of Government Relations and External Affairs
AltaMed Health Services Corporation

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APRIL 24, 2026

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

RE: 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 Hawai'i Island Community Health Center (HICHC), 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, Hawai'i Island Community Health Center again requests that CHCs be exempted from the pilot program.

In 2022, Bay Clinic and West Hawai'i Community Health Center, both nonprofit Federally Qualified Health Centers, merged to form Hawai'i Island Community Health Center. This bold and strategic unification created an integrated, island-wide system dedicated to delivering high-quality, comprehensive care across Hawai'i Island. Our mission is to advance health equity for all, guided by our core values of compassion, respect, humility, advocacy, and excellence.

The 340B Drug Pricing Program is essential to fulfilling this mission. It enables HICHC to stretch scarce federal resources, reinvest in patient care, and provide comprehensive services regardless of a patient's ability to pay. Through our sliding-fee-scale discount program, we saved patients more than one million dollars in direct medication costs last year alone. These savings also sustain a wide range of critical services, including clinical pharmacy support, behavioral health, school-based health centers, mobile health units, dental care, women's health, medication mail order and delivery, durable medical equipment, prior authorization processing, and prescription refills by protocol. These services are vital to ensuring that patients, especially those in rural and underserved communities, receive the care they need without financial barriers.

The **proposed 340B Rebate Model Pilot** would fundamentally undermine Hawai'i Island Community Health Center's ability to operate sustainably and serve nearly 39,700 patients who

rely on affordable access to life-saving medications. By shifting financial risk and administrative responsibility from manufacturers to safety-net providers, the rebate model would impose an **estimated $199,000 in annual recurring costs** for increase in expenses including labor, IT, and carrying costs. In addition, the rebate model would impose and **estimated $90,000 in upfront and integration expenses** for HICHC based on NACHC estimations. Lastly, the rebate model would necessitate an estimated **1.25 additional FTE in HICHC staffing** and disrupt both in-house and contract pharmacy operations. **These burdens would erode over one million dollars in annual patient medication savings,** threaten compliance with federally required sliding-fee discounts and insulin affordability mandates, and force CHCs to divert limited resources away from direct patient care. Collectively, the rebate model represents not a technical modification, but a structural threat to care access, financial stability, and health equity for the rural and underserved communities on Hawai'i Island.

1 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 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: HICHC anticipates needing 1.25 additional FTEs to account for the increase in operational, administrative, and compliance burden created by a rebate model.
- Number of Hours: Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, HICHC will face an increased administrative burden to monitor rebate claims and payments. HICHC estimates that an additional 10 hours per week will be required to report 340B rebate claims to a third-party platform.

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

- External Vendor Costs: HICHC anticipates an additional $9,350 monthly 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. HICHC estimates that $17,000 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 $8,500 monthly to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- Total Cost: For our CHC, which serves 39,700 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $199,000 annually.

The In-House Pharmacy: The Burden of IT Integration

HICHC operates an In-House Pharmacy which offers mail order and deliver services across Hawaii island for eligible HICHC patients. The rebate model is not a simple accounting change; it is a significant technological disruption. To remain compliant, in-house pharmacy systems will require costly customization to provide real-time, accurate information at the pharmacy counter.

- System Interoperability: Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. The HICHC in house pharmacy uses PioneerRx, which does not have native 340B rebate-model reporting capabilities. To comply with the proposed rebate infrastructure, HICHC would be required to take on the administrative burden of creating customizable reports to meet 340B rebate-model reporting requirements.
- One-Time Integration Costs: We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. HICHC is anticipating integration costs as high as $75,000 per NACHC estimation.
- Ongoing Resource Diversion: Staff who currently manage clinical pharmacy services will be forced to spend 10 hours per week manually pulling “Purchase Files” and “Price Files” to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with thirty-five pharmacies to increase access to affordable medications.

- TPA Reliance and Fees: Navigating manufacturers’ varying requirements across multiple contract pharmacies requires high-level TPA intervention. We anticipate that our TPAs will

pass on the costs of developing rebate-tracking modules to us through increased per-claim fees.

- VERIFICATION LATENCY: The rebate model creates a reconciliation gap. Our staff must monitor claims across thirty-five 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 our region, this would leave patients across much of Hawai'i Island without 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.

TOTALS: FINANCIAL AND ADMINISTRATIVE BURDEN SUMMARY

- ANNUAL RECURRING COST: The rebate model for HICHC the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$199,000 in annual recurring costs.**
- UPFRONT EXPENSES: The rebate model is estimated to require more than **$90,000 in upfront and integration expenses** based on NACHC estimations.
- ADDITIONAL STAFFING: the rebate model would necessitate an estimated **1.25 additional FTE in HICHC staffing** and disrupt both in-house and contract pharmacy operations.

[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

2 PATIENT IMPACT

HAWAI'I ISLAND COMMUNITY HEALTH CENTER HAS SIGNIFICANT CONCERNS ABOUT THE IMPACT A 340B REBATE MODEL PILOT WOULD HAVE ON OUR MOST VULNERABLE PATIENTS' ACCESS TO LIFE-SAVING MEDICATIONS.

The majority of drugs selected for the MDPNP for 2026 and 2027, and included in the proposed rebate model, manage chronic conditions prevalent in primary care settings. CHCs serve a patient population with a higher burden of chronic conditions compared to private practices, with studies showing a significantly higher prevalence of illnesses like diabetes, hypertension, and obesity.[4] This patient population relies on affordable medications to manage these long-term conditions.

The impact on insulin access is also alarming and directly conflicts with federal requirements. With over 3 million Americans relying on CHCs for essential diabetes care,[5] insulin affordability is a matter of life and death. Furthermore, Executive Order #14273 conditions future Section 330(e) funds on CHCs providing low-income patients with access to discounted insulin. No current operational method exists to provide discounted medications in a rebate model. In the proposed model, the wholesaler price file would reflect the full Wholesale Acquisition Cost (WAC) rather than the discounted 340B price, making the price unattainable for patients and precluding CHCs from fulfilling their legal obligation to offer the required discount at the point of care.

3 FINANCIAL CHALLENGES

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

- PURCHASING DRUGS AT THE WAC PRICE UPFRONT: Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing operating hours. We are particularly worried that the need to purchase drugs at full WAC will cause cash flow issues and potentially lead CHCs to exceed credit limits with wholesalers, halting their ability to order medications until payments are submitted.
- SLIDING FEE SCALE: A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of project.[6] In line with their mission, CHCs offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income

[4] Richard P, Ku L, Dor A, Tan E, Shin P, Rosenbaum S. Cost savings associated with the use of community health centers. J Ambul Care Manage. 2012 Jan-Mar;35(1):50-9. doi: 10.1097/JAC.0b013e31823d27b6. PMID: 22156955.
[5] 2025 UDA Data, HRSA (hrsa.gov)
[6] HRSA FAQ

individuals.[7] A CHC can adjust the cost of health care services, including medications, based on a patient's income and family size. HICHC provided approximately $1,500,000 in sliding fee discounts, provided through discounted medications at our Entity Owned Pharmacy. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.

4 CONCLUSION

HAWAI'I ISLAND COMMUNITY HEALTH CENTER STRONGLY URGES HRSA TO EXEMPT CHCS FROM ANY 340B REBATE MODEL PILOT PROGRAM.

A 340B rebate program represents a significant departure from the original intent of the 340B statute to allow safety-net providers to "stretch scarce Federal resources" and expand access to comprehensive care. A rebate-based structure would create substantial cash-flow challenges, forcing CHCs to make difficult decisions about staffing levels, essential services, and even the range of medications they can afford to stock. In addition, CHCs would be required to make major investments in IT infrastructure, data-tracking systems, and personnel to comply with rebate processing and reconciliation requirements.

A rebate model would also create new barriers for patients, particularly uninsured individuals who rely on the up-front 340B discount to access affordable medications. Under a rebate system, it would be operationally impossible to provide the sliding-fee-scale and deeply discounted medications that CHCs are required by law to offer. As a result, patients with the fewest resources would face the greatest harm.

HICHC believes that a 340B rebate pilot would disproportionately impact the patients served by CHCs and other safety-net providers, undermining access to care and threatening the stability of essential community-based services.

Hawai'i Island Community Health Center appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot, and we look forward to continued engagement with HRSA on this critical issue. If you have any questions, please contact HICHC's Vice President of Pharmacy Services, Dr. Melissa Bumgardner, at MABumgardner@hichc.org.

SINCERELY,

Richard Taaffe

_____

TAAFFE, RICHARD J.
CHIEF EXECUTIVE OFFICER,
HAWAI'I ISLAND COMMUNITY HEALTH CENTER

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

palmetto health council, inc.

643 Main Street
Palmetto, Georgia 30268

April 24, 2025

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

Re: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB No. 0906-NEW)
Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of Palmetto Health Council, Inc., a Georgia-based Federally Qualified Health Center (FQHC), we respectfully submit the following comments. Our health center serves approximately 9,000 patients annually across eight clinical sites located in Meriwether, Pike, Lamar, Carroll, Coweta, and South Fulton counties. The population we serve faces significant socioeconomic challenges. Approximately 35.0% of our patients are uninsured, 34.9% are Medicaid beneficiaries, and 65.9% live at or below 200% of the Federal Poverty Level. While we operate within small, diverse communities with moderate income levels, persistent barriers to care remain—particularly for uninsured, multilingual, and older residents.

We appreciate the opportunity to provide comments regarding the proposed information collection requirements associated with the 340B Rebate Model Pilot Program. Given the significant administrative, financial, and operational burden this model would impose, we respectfully request that Community Health Centers (CHCs) be exempted from participation in the pilot program.

The 340B Program is foundational to our ability to serve vulnerable populations and stretch scarce federal resources. At Palmetto Health Council, we dispense approximately 18,000 prescriptions annually. The program generates approximately $400,000 annually, which is reinvested into essential patient services including free medication delivery, dental services, behavioral health programs, care coordination, medication access programs, and many other critical clinical services. A shift to a rebate model fundamentally disrupts this structure by transferring financial and operational responsibility from manufacturers to safety-net providers.

Under the proposed model, we would be required to purchase medications at full Wholesale Acquisition Cost (WAC) and wait for rebates, creating immediate and material cash flow strain. We estimate an increase in monthly inventory spend of approximately $110k, requiring additional working capital of $440k to sustain operations. For organizations like ours operating on thin margins and serving 9,000 patients, this creates significant financial instability and may force reductions in services, staffing, or medication access. The risk of delayed or denied rebates further compounds this issue and introduces uncertainty into an already complex system.

Operationally, the rebate model introduces a parallel claims lifecycle that does not exist today. We would be required to identify eligible claims post-dispense, submit claims-level data across multiple manufacturer platforms, track rebate payments, reconcile discrepancies, and manage disputes. Based on our current operations, we estimate the need for 1.5 additional FTEs, approximately 40 hours per week dedicated to rebate tracking and reconciliation, and an increase of $180k annually in administrative costs. We also anticipate $150k in vendor-related expenses, including third-party administrators, consultants, legal support, EMR and pharmacy system upgrades, and reconciliation tools.

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

Clinic-administered drugs present an additional layer of complexity, as many are not captured in traditional claims data due to bundled payment structures. This would require new systems, workflows, and manual processes to convert existing documentation into rebate-eligible formats. We estimate this will require 500 hours and approximately $75k annually to support, driven by system integration, training, and manual data conversion.

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

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

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

Conclusion

For these reasons, Palmetto Health Council strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. The proposed model will create significant operational and financial challenges while undermining the very purpose of the 340B Program. We believe this approach will disproportionately harm safety-net providers and the patients they serve. We appreciate the opportunity to provide comments and welcome continued engagement on this critical issue. If you have any questions, please contact me at t.brown@yourtownhealth.com.

Sincerely,

Tara Brown, DMD, MBA
Chief Executive Officer
Palmetto Health Council, Inc.
t.brown@yourtownhealth.com
(404) 929-8824

April 17, 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: AID Upstate Comments in Response to: "340B Rebate Model Pilot Program Application, Implementation, and Evaluation" Information Collection Request Federal Register Notice

Dear Director Miller:

AID Upstate appreciates the opportunity to submit comments to the Health Resources and Services Administration (HRSA) in response to the above-referenced information collection request (ICR) Federal Register Notice ("FRN") dated February 26, 2026. The purpose of this comment is to express our alarm that HRSA is proposing a rebate model in the ICR that is unnecessary and so highly burdensome. In the FRN and in its previous Rebate Model Pilot Program ICR, HRSA drastically underestimates the burden of such a collection, and fails to consider less burdensome alternatives that would enhance the collected information.

As demonstrated by the data and information we provide below, we are deeply concerned about the tremendous administrative and financial burdens a rebate model would place on our patients, our organization, and other covered entities. We respectfully urge HRSA to refrain from implementing a Rebate Model Pilot and instead collaborate with the Centers for Medicare & Medicaid Services (CMS) to develop an alternative approach that prevents manufacturers from providing a covered entity access to both the 340B ceiling price and a maximum fair price (MFP) rebate on the same drug claim.

AID Upstate is deeply concerned that the proposed 340B Rebate Model would jeopardize our ability to continue providing comprehensive HIV care to our patient population in Upstate South Carolina. As a Ryan White Part B sub-grantee, our federal funding alone is insufficient to support the full scope of medical and supportive services we currently provide to more than 1,500 individuals and families affected by HIV. Our 340B program is essential to sustaining these services. Our patient population is growing due to both new HIV diagnoses and in-migration to the region, which has already placed significant strain on our clinical capacity. The additional financial and administrative burden associated with implementing a rebate model—combined with the risk of delayed or denied rebate payments—would create serious cash flow challenges and could force us to scale back or potentially close our medical clinic. This would result in thousands of patients losing access to their medical home. The healthcare system in the Upstate is not equipped to absorb this level of displacement. Loss of access to care would disrupt treatment for people living with HIV, leading to decreased medication adherence, loss of viral suppression, and increased risk of HIV transmission. These outcomes would reverse significant public health gains and place additional strain on already limited regional healthcare resources. In summary, the proposed rebate model introduces financial uncertainty and administrative complexity that threaten the stability of safety-net providers like AID Upstate and, most importantly, the continuity of care for vulnerable patients. For AID Upstate, the rebate model does not represent a minor administrative change—it represents a fundamental threat to our ability to deliver care

AID Upstate is a 501(c)(3) nonprofit organization providing comprehensive HIV medical care, prevention, and supportive services to individuals in Anderson, Greenville, Oconee, and Pickens Counties of South Carolina. Founded in 1987 in response to the HIV/AIDS epidemic, we are a Ryan White Part B sub-grantee through the South Carolina Department of Public Health and a recipient of CDC prevention funding. As a Ryan White-funded provider, AID Upstate qualifies for participation in the 340B Drug Pricing Program. We use 340B program savings to support and expand access to care through our medical practice, which includes primary care and infectious disease services, medical case management, and an on-site contract pharmacy. These resources allow us to provide comprehensive, coordinated care to more than 1,500 individuals, as well as PrEP services—including testing, clinical care, medications, and navigation—for individuals at risk of HIV. Prior to participation in the 340B program, our organization did not operate a medical clinic, and patients faced significant barriers to timely care. Today, 340B enables us to deliver accessible, high-quality services that improve health outcomes and reduce HIV transmission in our region.

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

Financial Impact of Increased Drug Acquisition Costs

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

Implementation and Administrative Burden

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

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

Patient Harm

The comprehensive services that Ryan White clinics like our organization 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 Ryan White clinics often receive no insurance payments for these services, they depend on the 340B program to underwrite the cost of providing this care to their patients. Importantly, the 340B program allows Ryan

White clinics to provide these expanded services without any cost to taxpayers. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

A Rebate Model Pilot would have an inevitable adverse impact on our patients. Increased financial and administrative costs from the Rebate Model Pilot will reduce the resources on which we rely both to care for existing patients and to identify additional patients in need of care. 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 burdens directly contradict the purpose of the 340B program -- to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Additionally, contract pharmacies may be less willing to distribute drugs to patients on behalf of covered entities due to the cumbersome and financially straining rebate process. If contract pharmacies refuse to enter into agreements with entities, access to medications will be limited for their patients, many of whom are already difficult to treat due to barriers such as housing instability, food insecurity, unemployment, and addiction. For Ryan White clinics like ours, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, 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 AIDS epidemic.

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

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

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

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

HRSA's assumption that the data will be comparable to information that covered entities already collect is inaccurate and results in HRSA's low burden estimate. To help HRSA adequately evaluate the Rebate Model Pilot Program costs, we have presented our estimate of the impact that the Rebate Model Pilot Program would have on our organization below.

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	11,301	4 minutes
Time Spent Disbursing Rebate Payments to Correct Covered Entity	11,301	1 minute
Time Spent Disputing Rebate Claim Denials	1,130	12 minutes

Start-Up Cost for Rebate Model Implementation:

Cash on Hand for Upfront Drug Acquisition Costs	$900,000
Purchase of Additional Equipment	$50,000
Hiring and Training of Additional Staff	$40,000 – $75,000

Annual Lost Wages for Rebate Model Implementation:

Category of Employee	Number of Hours Spent	Hourly Wage Rate	Total Cost
Finance / Billing Staff	200	30	$6000.00
Pharmacy / 340B Coordination Staff	300	35	$10500.00
Clinical / Case Management Staff	150	28	$4200.00
		Total	**$20700.00**

* * *

We appreciate HRSA's consideration of our comments. For further information, please contact Greg Campbell, MPA, Chief Operations Officer, 864-250-0607 (ext. 6315).

Sincerely,

Gregory L Campbell
Chief Operations Officer
AID Upstate

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

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

Dear Administrator Engels:

On behalf of Howard County Medical Center, 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 Howard County Medical Center in St. Paul, Nebraska**,** 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 Howard County Medical Center in St. Paul, Nebraska, 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. Howard County Medical Center in St. Paul, Nebraska, 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 estimates 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 Howard County Medical Center in St. Paul, Nebraska, can spend on patient care and comprehensive health care services.

Administrative Costs Under A Potential 340B Rebate Program. Any rebate program would require Howard County Medical Center in St. Paul, Nebraska, to spend significant sums on new administrative costs. When we chose to participate in the 340B program, Howard County Medical Center in St. Paul, Nebraska, 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. There will be additional man hours, each day and week, that will need to go into the drug selection during ordering. Along with tracking the new inventory to make sure the rebates are appropriately applied and received. This can be estimated for over 20 hours a week. Furthermore, with the use of new software, more time will need to be spent by staff to train and learn processes. Our IT team will need to work with the pharmacy to make sure correct data is being submitted to the programs that will run the claims. Additionally, a process will need to be developed for challenging denials and following up on the status of these claims. Howard County Medical Center only employees one on-site pharmacist and technician during the work week. All these changes will create a heavy burden on the current staff. It will take away daily hours to provide the outstanding patient care we strive every day to achieve.

Staffing Impacts Under a Potential 340B Rebate Program. Howard County Medical Center does not currently have the staff needed to comply with a Rebate Program. Howard County Medical Center currently employes 1 full-time pharmacist and 1 full-time technician. When the rebate program starts, it will take away vital time to complete daily tasks to keep the pharmacy running. Furthermore, it will hinder patient care. The one full-time pharmacist acts as the staff pharmacist, inventory manager, and pharmacy director. When the rebate model starts, the pharmacist will need to devote at least half of the hours of the day to the model. This will have to include making sure purchasing and inventory is correct, submitting data for claims, and rectifying claims. Additionally, following up on claims that need corrected or making sure rebates are correct and being deposited to the hospital account.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Program. Howard County 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. The pharmacist

will now have to spend time with the IT department working on data claims submission. This just won't be uploading the claims data to the new platform that is required, it starts with making sure the correct data is being created. The pharmacist and COO generate all the reports used for the 340B program currently.

Adverse Impacts of These Additional Costs And Burdens. All of these many different costs and burdens add up. Unfortunately, that means that **Howard County 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.

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. **Howard County 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.

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. Our facility could not enter our bank account information. It took us well over a month to get things figured out. Beacon's advice was just deleting the account and re-enter it. No other help was offered at the time. The hospital had to create a whole new account with the bank. This took time out of the CFO's busy schedule to get approval from the board and then go to the bank to set up a new account.

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 **Howard County 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.

For all of these reasons, Howard County Medical Center 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 **Howard County 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,

Cali Roberg
Pharmacy Director
Howard County Medical Center

April 27, 2026

VIA EMAIL (paperwork@hrsa.gov)

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Rockville, MD 20857

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

Dear Ms. Miller:

Eli Lilly and Company (Lilly) appreciates the opportunity to respond to the proposed Information Collection Request (ICR) related to the application, implementation, and evaluation of HRSA's proposed 340B Rebate Model Pilot Program.[1] As a member of the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and Biotechnology Innovation Organization (BIO), Lilly supports their comments on the ICR and encourages HRSA to consider their input. In addition, Lilly offers the following prioritized comments and recommendations on matters of specific interest to the company.

As discussed in our comments in response to HRSA's separate Request for Information (RFI) on the 340B Rebate Pilot,[2] Lilly supports the original intent of the 340B program to benefit underinsured and uninsured patients but has instead witnessed the program grow into a profit center for large hospital systems and their for-profit partners. Lilly believes that the 340B Rebate Model Pilot is a sensible first step in that direction and we are submitting these comments addressing proposals related to the pilot from the proposed ICR.

I. Manufacturers Eligible to Apply

The ICR indicates the agency intends to only include products selected for Inflation Reduction Act (IRA) "negotiation" in 2026 and 2027 for participation in the 340B rebate pilot.[3] Combined with the first 340B rebate pilot being limited to drugs subject to MFP in 2026, it is clear HRSA views rebate models as a key tool for complying with the statutory prohibition on duplicate discounts in the Medicare Drug Price Negotiation Program. However, administering 340B prices via rebates is clearly the best way to address all statutorily prohibited duplicate discounts. As discussed in our RFI response and elsewhere, Medicaid duplicates, particularly Medicaid Managed Care, have been an issue for years and are only growing in number as covered entities continue to expand their 340B usage. Additionally, CMS is only currently **estimating** Part D inflation rebates and 340B duplicate discounts; the statute requires actual identification and de-duplication.[4] Rebate models provide a holistic solution to all duplicate discount areas, not just those with MFP.

HRSA should also consider the impact of only including MFP products on the integrity of its evaluation. The MFP effectuation process itself is new and untested, having only been launched four

[1] 91 Fed. Reg. 9632 (Feb. 26, 2026).
[2] *Available at* https://downloads.regulations.gov/HRSA-2026-0001-2394/attachment_1.pdf
[3] 91 Fed. Reg. at 9632.
[4] 90 Fed. Reg. 49,266, 49,740-48 (Nov. 5, 2025).

months ago, and limiting the rebate pilot to just MFP duplicates risks muddying the waters on the source of any potential issues in that process. For example, pharmacies have already noted that there are issues with MFP refunds being delayed.[5] Hospitals have also complained about MFP refunds being denied due to the claim being identified as 340B,[6] which is ironic given that these same hospitals oppose both submission of claims data and 340B rebate programs, which would ensure timely payment and accurate identification of duplicates. In any event, the MFP refund process is already subject to complaints related to 340B duplicates and limiting a 340B rebate to only MFP products risks having those pre-existing issues falsely attributed to the 340B rebate pilot.

To operate an effective pilot and improve the utility of the ICR overall, HRSA should consider including non-MFP manufacturers in any rebate pilot, so it can develop data based on a controlled comparison group to determine if any issues are related to the MFP process or are with the 340B rebate process. Lilly does not have any products subject to an MFP until 2028, and the agency has yet to either approve or deny our 2024 proposal to launch a cash replenishment model, and therefore including our company in a rebate pilot would allow HRSA to effectively isolate MFP and non-MFP related effectuation issues.

II. Submission and Evaluation of Manufacturer Reporting Data

Lilly urges HRSA to not require manufacturers to submit data and reports under the rebate pilot to Apexus, the 340B Prime Vendor as the ICR proposes. The Prime Vendor's statutory role under the 340B statute is limited to "the distribution of covered outpatient drugs."[7] Evaluating a rebate pilot—an exercise that is fundamentally about program integrity, duplicate discount prevention, and the accuracy of claims-level data—falls well outside that statutory mandate. Channeling manufacturer reporting through Apexus would effectively expand the Prime Vendor's role beyond what Congress authorized and insert an unauthorized intermediary between manufacturers and the agency charged with administering the program.

The choice of data custodian is not a neutral administrative detail either; it directly affects the "quality, utility, and clarity" of the information HRSA will rely on to evaluate the pilot. Apexus has a well-documented history of mismanagement and conflicts of interest in its administration of the 340B, as detailed by the fact its parent company is owned by hospital covered entities, the recent *New York Times* investigation into the program,[8] and the pending Senate investigation into its role as Prime Vendor.[9] Given that track record, and given that the pilot's findings will shape the future of rebate-based 340B compliance, in order to preserve the integrity and credibility of the 340B rebate pilot Apexus should not be involved in the collection of data or evaluation of that data. Instead HRSA should

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[5] *NCPA Asks CMS for Expedited Payments and Other Corrections to MDPNP Following Survey of Independent Pharmacies that Finds Cash Flow Problems* (Feb. 27, 2026), *available at* https://ncpa.org/newsroom/news-releases/2026/02/27/ncpa-asks-cms-expedited-payments-and-other-corrections-mdpnp.
[6] Letter from America's Essential Hospitals to Administrator of Centers for Medicare & Medicaid Services (Mar. 5, 2026), *available at* https://essentialhospitals.org/wp-content/uploads/2026/03/Deduplication-Issue-Letter-to-CMS.pdf.
[7] 42 U.S.C. § 256b(a)(8).
[8] NY Times, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor* (Jan. 15, 2015), *available at* https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html.
[9] *See* Letter from Senate HELP Committee to Christopher A. Hatwig, President, Apexus, LLC (Feb. 1, 2026), available at https://www.help.senate.gov/imo/media/doc/26-02-01_chairman_cassidy_letter_to_apexus_finalpdf.pdf.

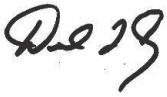
only work with government partners to evaluate the model, such as the Center for Program Integrity under CMS that has experience with these types of program integrity projects.

Furthermore, the ICR specifically invites comment on "automated collection techniques or other forms of information technology" that could minimize reporting burden.[10] We suspect that the proposed rebate vendors would be willing and able to transmit automated, standardized reports directly to HRSA from their existing rebate platforms systems, obviating any need for Apexus to serve as a middleman in the data collection process. A direct, automated rebate platform-to-HRSA reporting channel would reduce burden on manufacturers, shorten the data pipeline, and give HRSA cleaner and more timely information than a Prime Vendor–mediated process could provide. We encourage HRSA to inquire with the rebate vendors on the possibility of such a direct reporting process.

III. Conclusion

We appreciate HRSA's consideration of these comments, as well as those from PhRMA and BIO as it proceeds towards launching a 340B rebate pilot. As always, Lilly remains committed to working with HRSA and other stakeholders to fix the 340B program and believes a rebate model is a key first step in that direction.

Sincerely,



Derek L. Asay
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[10] 91 Fed. Reg. at 9633.