Venice Family Clinic

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April 20, 2026

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

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

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

Venice Family Clinic is a nonprofit community health center that provides comprehensive, high-quality primary health care to 45,000 people in need annually, regardless of their ability to pay or immigration status. The Clinic serves people from the Santa Monica Mountains through the South Bay in Los Angeles County. The Clinic has a network of clinic locations and Early Head Start centers located in Venice, Santa Monica, Mar Vista, Inglewood, Culver City, Redondo Beach, Carson, Gardena and Hawthorne, plus mobile clinics and multiple street medicine teams. **The Clinic's comprehensive care includes primary care, mental health services, dental care, street medicine for people experiencing homelessness, vision services, substance use treatment, prescription medications, domestic violence counseling, HIV services, healthy food distributions, health education, health insurance enrollment, child development services and more.**

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 **39,701** 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**: Venice Family Clinic anticipates needing .5 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, Venice Family Clinic will face an increased administrative burden to monitor rebate claims and payments. Between 5 to 7 hours will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: Venice Family Clinic anticipates an additional $41,340 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.

- **Total Cost:** For our CHC, which serves 39,701 patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $95,122 annually.

The In-House Pharmacy: The Burden of IT Integration

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

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

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 **111 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 111 different pharmacy locations to ensure rebates are paid correctly.
- **Risk of Pharmacy Exodus:** The model shifts financial risk to the pharmacy, potentially causing contract partners to opt out of the 340B program entirely rather than manage the administrative headache. In Los Angeles County area**,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

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

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

II. Patient Impact

Venice Family Clinic has significant concerns about the impact a 340B Rebate Model Pilot would have on our most vulnerable patients' access to life-saving

[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

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

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

III. Financial Challenges

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

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

[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

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

IV. California Case Study: State Medicaid Implementation Will Compound the Harms of the Rebate Model

The rebate model does not exist in isolation—it will be interpreted and operationalized by state Medicaid agencies in ways that HRSA cannot control. California provides a concrete example of how state-level implementation guidance can multiply the burdens on CHCs far beyond what the federal pilot alone would impose.

When HRSA previously proposed the rebate pilot, California's Department of Health Care Services (DHCS) issued guidance for California's Medicaid Pharmacy Program, Medi-Cal Rx, requiring pharmacies to delay Medi-Cal billing until after manufacturer rebate reconciliation is complete. This means a CHC dispensing a rebate-model drug to a Medi-Cal patient would have to: purchase at WAC, dispense the drug, submit data to the rebate administrator (Beacon), receive the rebate, and only then submit a retroactive Medi-Cal claim—with a required return to the Beacon platform to reconcile records. A single prescription becomes a five-step, multi-system process.

This approach creates three serious, compounding harms for CHCs:

- **Patient safety risks.** Medi-Cal Rx real-time adjudication performs critical safety checks at the point of dispensing—eligibility verification, prior authorization, drug utilization review, and duplicate therapy screening. Delaying billing bypasses these safeguards entirely. Medications could be dispensed to patients who are ineligible, have a coverage conflict, or receive a duplicate fill at another pharmacy—with no real-time safety net to catch it.
- **Unsustainable upfront cost burden.** The rebate model already forces CHCs to carry the full WAC cost upfront—but California's multi-step billing process extended that carrying period significantly. Because Medi-Cal reimbursement cannot be submitted until after the rebate is received from Beacon, CHCs would need to finance WAC purchases through the entire sequence: dispensing, Beacon data submission, rebate receipt, retroactive Medi-Cal billing, and final reconciliation. For specialty drugs that can exceed $10,000 per unit, this is not a minor cash flow inconvenience—it is a structural financial burden. CHCs already operate on a national average margin of negative 2 percent. Requiring these providers to front escalating WAC costs for extended periods, with no guarantee of timely or full reimbursement, is financially unsustainable.

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

- **Unsustainable administrative burden.** CHCs must manually track claims across multiple systems and stages—interim cash claims, Beacon submissions, rebate receipts, retroactive Medi-Cal rebilling, and Beacon reconciliation—all within DHCS's six-month timely filing window. For CHCs without sophisticated technology platforms, this is entirely manual work and creates significant risk of missed deadlines, lost reimbursement, and audit exposure.

If the rebate model moves forward, CHCs in states that adopt guidance like California's will face a cascade of additional harms beyond their control. HRSA must take these compounding harms into consideration.

Conclusion

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

Venice Family Clinic appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Isabela Mihai (Chief Compliance Officer - IMihai@mednet.ucla.edu) and Fred Dolgin (Chief Operation Officer – FDolgin@mednet.ucla.edu).

Sincerely,

Signed by:
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