November 12, 2025

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

RE: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0111—Extension.

Submitted via paperwork@hrsa.gov.

Dear Director Britton:

The National Association of Community Health Centers (NACHC) is the leading national membership organization dedicated to promoting Community Health Centers (CHCs) (also known as Federally Qualified Health Centers) as the Employer, Provider, and Partner of choice in all communities, as well as the foundation of the primary health care system in the United States. **NACHC appreciates 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, NACHC again requests that CHCs be exempted from the pilot program.**

For 60 years, CHCs have provided high-quality, affordable, comprehensive care – including primary, preventive, dental, behavioral health, pharmacy, vision, and other essential health services to nearly 34 million patients annually at over 17,000 locations across rural and non-rural communities. This includes over 10 million rural residents (at least 1 in 5), more than 20 million (at least 1 in 3) in poverty, and more than 6 million (at least 1 in 5) uninsured people. CHCs serve at least 1 in 10 Americans and up to 1 in 7[1] yet account for only 1% of total U.S. healthcare spending, saving Medicaid and Medicare billions annually by reducing costly emergency, inpatient, and specialty care.[2] Research shows that every dollar invested in primary care yields a 13-to-1 return in overall health system savings.[3]

In addition to medical services, CHCs provide dental, behavioral health, pharmacy services, and other "enabling" or support services that facilitate access to care for individuals and families in medically underserved communities, regardless of insurance status or ability to pay. NACHC maintains its role

[1] https://www.weitzmaninstitute.org/the-hidden-patient-base/
[2] 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/
[3] https://www.oregon.gov/oha/HPA/dsi-pcpch/Documents/PCPCH-Program-Implementation-Report-Final-Sept-2016.pdf

as the national voice for CHCs and believes that high-quality primary health care is essential in creating healthy communities. The collective mission and mandate of NACHC and the 1,512 CHCs across the country are to close the primary care gap and provide access to high-quality, cost-effective primary and preventive medical care.

Workforce and Information/Technology Burden Concerns

Recent data collected by NACHC illustrates that CHCs will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHCs will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. While we appreciate the pilot program's intention not to allow manufacturers to charge covered entities to participate, we expect that CHCs will incur significant operational costs.

- 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 an increase in costs exceeding $3 million annually, including the upfront annual costs of purchasing the drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHCs operate on razor-thin margins, and these additional costs are not an option for many entities.
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHCs will face an increased administrative burden in terms of monitoring rebate claims and payments. 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 pilot program.[6] The lack of standardization and likely varying requirements from each manufacturer will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing both costs and operational burdens. **NACHC urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Administrative and Financial Burden Concerns

NACHC remains concerned that a rebate model would create administrative complexities and financial challenges for Community Health Centers. Under the proposed 340B Rebate Model Pilot, CHCs would be required to purchase drugs at full retail price, also known as Wholesale Acquisition Cost (WAC). This departure from over 30 years of precedent would impact CHCs' ability to purchase drugs due to the uncertainty of waiting for a manufacturer to approve a rebate, thereby constraining the CHC's cash flow. As you know, CHCs rely on the revenue generated from the 340B Program to provide affordable healthcare services and medications to uninsured and underinsured

[4] Internal NACHC assessment (99 responses).
[5] Ibid.
[6] Internal NACHC assessment (out of 101 responses).

patients. Lack of access to these upfront discounts, along with the high IT/infrastructure costs, will disproportionately impact CHCs and trickle down to patients. It's important to note that many CHCs are already under financial strain, with the median cash-on-hand at around 100 days and one-quarter reporting operating margins of -4%.

A specific concern that CHCs have raised is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some have suggested that paying for medications upfront at WAC prices would require dipping into limited financial reserves or taking out loans, which would defeat the core purpose of the 340B program. Another complication is that the rebate amount may not match the initial discount offered to the patient, creating unpredictable financial losses. CHCs must estimate the rebate amount and could potentially undercharge or overcharge patients due to confusion.

Additionally, we urge HRSA to strengthen safeguards against rebate denials or delays under the 340B Rebate Program, as the current lack of clarity would impose significant financial and administrative burdens on CHCs. The current framework allows manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHCs need to understand or contest those decisions. The use of a vague "other" category for denial reasons only adds to the confusion. It leaves providers guessing about compliance requirements that they are never clearly told exist.[7] These unpredictable denials often rely on flawed assumptions or automated processes that fail to account for routine pharmacy operations and can create serious cash flow issues, particularly for CHCs that operate on thin margins and depend on timely reimbursement to sustain services for medically underserved populations.

Moreover, NACHC strongly urges HRSA to create a formal complaint process, such as a stakeholder group or advisory panel, to ensure covered entities have a formal mechanism to report systemic issues with manufacturer rebate denials, escalate disputes, and provide ongoing feedback to HRSA throughout the pilot program. CHCs should not be forced to shoulder additional compliance burdens or navigate a murky appeals process with no guarantee of a rebate. A more robust procedure is essential to holding manufacturers responsible for unjustified denials and ensuring that CHCs can continue delivering care without undue administrative and financial strain. Without due process, CHCs will have to make difficult decisions on how to utilize their limited financial resources, which could result in cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

Furthermore, a rebate model would create confusion about its interactions and impact on a CHC's ability to offer sliding-fee discounts at the point of purchase. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[8] In alignment with their mission, CHCs often implement flat discounts or sliding fee discounts to make prescription drugs 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. **The proposed 340B Rebate Model Pilot would have a direct impact on CHCs' ability to offer patients steeply discounted medications at the point of sale by requiring them to**

[7] 90 Fed. Reg. 38166 (Aug. 7, 2025).
[8] HRSA FAQ.

purchase at full WAC pricing upfront. CHCs' pharmacies, entity-owned and contract pharmacies, will not have access to the 340B price when the patient needs the medication. This will create a very unpredictable process for determining the level of discount and pricing for a patient's medication, as the 340B price will no longer be reflected in the pharmacy software from the wholesaler's price catalog, since initial purchase prices will be at WAC.

Additionally, **Executive Order #14273 conditions future Section 330(e) funds on health centers providing access to discounted insulin and injectable epinephrine** to qualifying patients. There is currently no operational method to provide these discounted medications in a retrospective rebate model. In the proposed model, the wholesaler price file would reflect the full WAC price rather than the discounted 340B price. This makes the price unattainable for the patient and **precludes health centers from fulfilling their legal obligation to offer the required discount at the point of care.**

NACHC also harbors concerns about contract pharmacies' willingness to participate, given the uncertainty around rebates or the operationalization of replenishment inventory accounting systems under this pilot program. Nearly 90% of CHCs rely heavily on contract pharmacies to ensure patients have access to affordable medications, especially in underserved areas.[9] However, unclear guidance on how these pharmacies will participate in rebate, reimbursement, and claims processes, combined with the lack of clarity around the use of replenishment inventory systems, creates serious uncertainty and operational challenges for CHCs. Without clear guidance, many contract pharmacies may be unable or unwilling to participate in the program, threatening CHCs' ability to maintain these vital partnerships. This would directly impact patients by limiting access to essential medications, particularly in rural and low-income communities. **NACHC urges HRSA to provide additional guidance to contract pharmacies to minimize the administrative burden on community pharmacies that lack the financial infrastructure to wait for rebate determinations.**

Exempt CHCs from the Rebate Pilot Program

For over three decades, the 340B program has enabled CHCs to purchase outpatient medications at significantly reduced costs, enabling them to provide affordable and sometimes free medications to millions of low-income and uninsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHCs.

NACHC data indicates that without discounted or free medications, a substantial portion of CHC patients—up to 3 million or more—would lose access to essential treatments.[10] A change of this nature will also have an immediate and direct impact on patients at the pharmacy counter. It would limit the range and volume of drugs CHCs can afford to stock, directly contradicting the program's goal of increasing access to affordable medications. Since 90% of CHC patients are at or below 200% of the federal poverty level, they rely on discounted medications from their local CHC.[11] The proposed 340B rebate model would severely restrict access to essential medications for CHC patients, who disproportionately suffer from chronic conditions like diabetes, heart disease, and kidney failure. Without the upfront 340B discount, many CHCs would be unable to provide affordable, life-

[9] https://www.nachc.org/resource/340-b-a-critical-program-for-health-centers/#:~:text=Starting%20in%20August%202020%2C%20pharmaceutical,than%20any%20other%20patient%20population.
[10] https://www.hcadvocacy.org/wp-content/uploads/2023/02/NACHC-340B-Report-Summary-June-2022.pdf
[11] Ibid.

sustaining therapies such as insulin, DOACs[12], and SGLT2 inhibitors[13], ultimately jeopardizing patient health. **We strongly urge HRSA to exempt CHCs from any rebate model to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients.**

Adding additional requirements under the proposed pilot would significantly weaken the ability of CHCs to provide affordable medications, especially to the most underserved CHC patients who rely on the up-front 340B discount to afford their treatments. Several manufacturers have already proposed denying claims that do not comply with their contract pharmacy criteria. NACHC has grave concerns that HRSA's legal authority will not protect CHCs from manufacturers' unilateral business practices, similar to the contract pharmacy restrictions, that continue to impact CHCs across the country. **For this reason, NACHC urges HRSA to deny manufacturers' requests to participate in the 340B Rebate Model Pilot Program if they have existing contract pharmacy restrictions**.

Conclusion

NACHC strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. This pilot, as currently proposed, 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. This 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 will need to make significant investments in IT infrastructure and staff to comply with rebate requirements, as well as track rebates. It also creates 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. We believe this pilot will cause disproportionate harm to patients served by CHCs and other safety net providers.

NACHC appreciates the opportunity to respond to this information collection request 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 Vacheria Keys, Vice President of Policy & Regulatory Affairs, at vkeys@nachc.org.

Sincerely,

Joe Dunn
Chief Policy Officer

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

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