



ADVOCATES FOR
COMMUNITY
HEALTH

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:

Advocates for Community Health (ACH) is a member organization focused on advocacy initiatives to affect positive change for community health centers (CHCs), the patients they serve, and the entire nation's health care system. Our 45 members represent 23 states, Puerto Rico, and the District of Columbia. On behalf of our member CHCs and the 4 million patients they serve, ACH appreciates the opportunity to provide comments to the Health Resources and Services Administration (HRSA) on the information collection necessary to implement 340B rebate model pilot program. Given the substantial administrative, financial, and operational strain a rebate model would create, **ACH strongly recommends that CHCs be exempt from the pilot program.**

CHCs are a cornerstone of delivering comprehensive primary care – serving about 34 million patients annually. Health centers often serve as the main, and sometimes only, source of care in many rural and underserved areas. For these patients, preventive services are critical to avoiding costly hospitalizations, detecting disease early, and improving long-term health outcomes. Despite only accounting for 1% of the total U.S. healthcare spending, CHCs provide care to at least 1 in 10 Americans. This saves both Medicaid and Medicare billions annually by reducing emergency room visits, hospitalizations, and specialty care costs.

Beyond primary care, CHCs provide comprehensive services, including dental, behavioral health, and pharmacy care, supported by programs that remove barriers to access for underserved individuals and families, regardless of income or insurance.

As a recognized leader and a national voice for CHCs, ACH urges HRSA to exempt community health centers from the pilot program because of the significant burden outlined below.

1. The Information Collection required for a rebate model would require CHCs to hire additional staff and expend valuable resources.

ACH is concerned that most CHCs lack the workforce and IT infrastructure that is needed to absorb the administrative and financial requirements of the 340B rebate pilot program. Health centers already devote significant time navigating contract pharmacy restrictions, and the proposed model would further strain these limited resources. To comply with multiple manufacturer rebate systems, CHCs would also need to develop and implement new IT infrastructure and hire or reassign staff to manage complex data submission requirements, payment reconciliations, and dispute processes for denied rebates. The increased administrative effort needed to effectively manage this program would also divert staff away from serving patients and delivering critical services.

Through a member survey, the National Association of Community Health Centers found that:

- 47% of CHCs would need 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 resulting in additional costs of \$30,000 to \$200,000 annually.
- Nearly 80% of CHCs estimate it will take their staff more than 15 hours to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans.

2. The drug purchase model places a financial burden on CHCs.

CHCs have raised specific concerns that purchasing drugs at full Wholesale Acquisition Cost (WAC) could lead many organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are made. Some have suggested that paying for drugs upfront at WAC prices would force CHCs to pull funds from already limited reserves or take on short-term debt. This directly contradicts the intent of the 340B program which is to help safety-net providers stretch scarce federal resources. Others are concerned that the rebate amount may not align with the original discount offered to patients, which may result in unpredictable financial losses. CHCs would need to estimate rebate values in advance, which could result in patients being inadvertently overcharged or undercharged at the point of sale.

3. The model makes sliding fee scales more burdensome to implement.

This model would introduce uncertainty regarding CHCs' ability to provide sliding fee discounts at the point of purchase. Under existing statute and regulation, CHCs must offer sliding fee discounts for all required and additional health services within their HRSA-approved scope of project.¹ Consistent with their mission, CHCs frequently use flat or sliding scale discounts to make prescription

¹ HRSA FAQ.

drugs more affordable for low-income patients, adjusting costs based on household income and family size.

The proposed 340B Rebate Model Pilot would directly undermine this ability by requiring CHCs to pay full Wholesale Acquisition Cost (WAC) prices upfront. As a result, both entity-owned and contract pharmacies would lose access to 340B-discounted prices at the time patients fill their prescriptions. This structure would make it extremely difficult for CHCs to determine appropriate discount levels, as pharmacy software would no longer display 340B pricing from wholesaler catalogs. This would then create an unpredictable and administratively burdensome process that ultimately limits patients' access to affordable medications.

Additionally, [Executive Order 14273](#) ties future Section 330(e) funding to a health center's ability to offer discounted insulin and injectable epinephrine to eligible patients. Under a retrospective rebate structure, there is currently no practical way to deliver these discounts at the point of sale. 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.

4. HRSA must clarify the role of contract pharmacies in implementing the model to prevent additional burden on CHCs.

This model introduces uncertainty surrounding contract pharmacy participation. ACH urges HRSA to issue comprehensive guidance for contract pharmacies to ensure consistency in participation and to reduce administrative burdens on community pharmacies that lack the financial capacity to absorb delays in rebate determinations. Most CHCs rely heavily on contract pharmacies to ensure patients have access to affordable medications, especially in underserved areas. However, the lack of clear guidance on how contract pharmacies will engage in the model's rebate, reimbursement, and claims processes, and the ambiguity about the use of replenishment inventory systems, creates significant uncertainty and operational challenges for CHCs. Without specific direction from HRSA, many contract pharmacies may be unable or unwilling to participate in the program, jeopardizing CHCs' ability to sustain these critical partnerships. Such disruptions would have direct consequences for patients, reducing access to essential medications, especially in rural and low-income communities.

Conclusion

ACH strongly urges HRSA to exempt CHCs from the 340B Rebate Model Pilot Program. The proposed pilot represents a fundamental departure from the original intent of the 340B program: to enable safety-net providers to "stretch scarce Federal resources" to expand access and deliver more comprehensive care. The proposed model would impose severe financial constraints on health centers which would force them to make difficult decisions regarding staffing levels, service offerings, and the availability of essential medications. In addition, compliance with the rebate model would require substantial new investments in IT infrastructure, data systems, and personnel to manage the tracking

and reporting requirements. Most critically, the pilot would raise new patient barriers who rely on the immediate 340B discount at the point of sale. By eliminating this up-front discount, CHCs would face operational barriers to applying sliding fee scales and providing deeply discounted medications, as required by law. Ultimately, this pilot would disproportionately harm the very patients and communities the 340B program was designed to support.

ACH 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. For more information, please contact me at apearskelly@advocatesforcommunityhealth.org and/or Stephanie Krenrich, Senior Vice President of Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amanda Pears Kelly', with a stylized, flowing script.

Amanda Pears Kelly
Chief Executive Officer
Advocates for Community Health