



ADVOCATES FOR
COMMUNITY
HEALTH

September 5, 2025

Tom Engels
Administrator
Health Resources and Services Administration
5600 Fishers Ln, Rockville, MD 20852

Re: HHS Docket No. HRSA-2025-14619

Dear Administrator Engels,

Thank you for the opportunity to provide feedback on the 340B Rebate Model Pilot Program as announced by the Health Resources and Services Administration (HRSA) in the Federal Register on July 31, 2025. On behalf of Advocates for Community Health (ACH), 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, we write to express our deep concern with the 340B Rebate Model Pilot Program.

Our 45 members serve over 3 million patients across 22 states, Puerto Rico, and the District of Columbia. **On behalf of our members and their patients, we urge you to prohibit manufacturers from applying their rebate models to federally qualified health centers.**

ACH members are committed to strict compliance with 340B guidance and regulations and strongly support increased transparency and accountability within the 340B program. However, after careful review and extensive discussion with our members, we have serious concerns that the Pilot Program as currently drafted is simply not feasible or sustainable for CHCs. We have provided thorough rationale to support this recommendation below.

1. *The Pilot Program puts patients at risk and could reduce the availability of vital services.*
 - a. CHCs exemplify the original intent of the 340B program, which is “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (H.R. Rep. No. 102-384(II), at 12 (1992)). Under HRSA rules, CHCs are required to reinvest all program

income back into the operations of the health center ([45 CFR § 75.307](#)) which means every dollar of 340B savings is going directly back into underserved communities. Further, all CHCs are required to provide all patients who need it a sliding fee scale to access all services, including pharmaceuticals ([Compliance Manual, chapter 9](#)).

- b. ACH members leverage the program to maintain rural sites of care; expand access to services that prevent chronic disease; and treat more uninsured patients. Decreasing 340B savings will result in health centers having to scale back or end many of these essential programs.

2. *The premise of the Pilot Program, as it applies to CHCs, is false.*

- a. The Pilot Program is targeting a Medicare issue, but applies to all payers.
 - i. HRSA notes that the agency has received inquiries from manufacturers related to different proposed rebate models for the 340B Program, “**primarily to address 340B and Maximum Fair Price (MFP) deduplication**, but also to facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion.” By this analysis, it seems as if HRSA is most concerned with the MFP deduplication, given the scope of the pilot.
 - ii. If this is the case, the pilot should not apply to all payers, especially when it comes to Medicare. Only 11% of health center patients are covered by Medicare ([HRSA](#)).
 1. Even within the Medicare population, ACH does not support any retrospective approach to reconciling MFP and 340B pricing, and it is not the best solution to the relatively minor issue posed at health centers. As the [American Hospital Association has outlined](#), prospective purchasing is possible and compliant.
- b. The Pilot Program assumes a lack of existing oversight by HRSA.
 - i. Since 2012, CHCs have undergone regular oversight audits from HRSA, and consistently conduct their own internal audits for compliance with all federal guidance and regulation.
 - ii. CHC purchases under the 340B program represent just 5.4% of overall covered entity purchases ([OPA](#)). Even if one accepts the premise that a rebate model might achieve some marginal compliance improvement, it is simply not worth the risk of foundational impact to thousands of safety net providers across the country. CHCs are already facing workforce shortages, forthcoming

losses of Medicaid revenue, and other challenges. The additional compliance and administrative burden to potentially only see a marginally small increase in compliance is not worth the risk to health centers and their patients.

3. *The Pilot Program could severely disrupt clinical care.*
 - a. CHCs play a critical role in sustaining access to care and providing essential medications for patients - especially rural and underserved areas. CHCs that are unable to build the internal systems necessary to participate in these models, or cannot float the necessary cash, may be forced to limit prescribing certain medications, some of which lack viable alternatives.
 - b. ACH is concerned that this model prioritizes convenience for larger for-profit corporations, instead of preserving CHCs ability to provide affordable and timely access to essential medications.

4. *The Pilot Program increases administrative burden and financial risk on health centers that are already stretched thin.*
 - a. The increased administrative burden and financial risk CHCs would have to undergo to participate in the pilot is expected to be significant, and will limit their ability to provide high quality and comprehensive care to using 340b savings.
 - b. Health centers will have to add senior level staff with the experience and sophistication to track rebates across multiple different models, third party administrators (TPAs), and contract pharmacies. They will need to submit data reports, and submit disputes when manufacturers ultimately do not comply. These staff also need to coordinate with finance departments in an entirely new, and unnecessary, way. The need to hire these staff takes away from resources that could be dedicated to patient care.

5. *The Pilot Program may impact uninsured access to affordable medications.*
 - a. If the program transitions to a rebate program, CHCs may also face difficulty offering a sliding fee scale to uninsured patients. More specifically, if a CHC assumes a 340B eligible drug and provides a sliding fee scale based on that purchase price, but a rebate isn't paid, CHCs cannot go back to charge the patient more; they will have to absorb that cost. CHCs may have to restructure how they are offering sliding fee scales depending on their cash flow reserves.

6. *The Pilot Program offers no protections for health centers when a manufacturer does not pay a rebate.*
 - a. The notice states “Covered entities are also afforded opportunities to raise concerns with OPA if there are issues with rebate delays and denials,” but does not specify what those opportunities are, does not offer a guaranteed turnaround time for resolution, or how HRSA will enforce a manufacturer’s requirement to pay a rebate.
 - b. ACH is concerned that with current operating margins, without a guaranteed way to recoup funds, CHCs could be forced into terrible decisions on staffing and patient care.

7. *Offering rebate models at the package size puts cash-strapped health centers at a significant disadvantage.*
 - a. If manufacturers only offer rebates at the package size, health centers could potentially incur tens of thousands of dollars in costs while waiting for the ability to submit a rebate claim.
 - b. With contract pharmacy arrangements, the health center will also be waiting on any potential revenue from payers as well.
 - c. Health centers that do have in-house pharmacies are much smaller, and cannot achieve economies of scale with other drugs like larger entities.
 - d. Finally, to accommodate package size rebate systems, health centers would have to invest in new physical and virtual inventory systems to accommodate this model.

Through this Pilot Program, HRSA is asking the primary care safety net—on which more than 32 million patients rely—to participate in a model that depends on the cooperation of manufacturers who have expressed interest in ending the 340B program. Furthermore, community-based providers will have to invest in costly overhaul of their internal and external systems without guarantee that their rebate requests – to which they are legally entitled – will be paid. As currently drafted, this model prioritizes the convenience and financial success of larger and most profitable corporations instead of the original intent and integrity of the program to allow health to invest 340B savings back into the patients they serve. In conclusion, ACH strongly urges HRSA to prohibit manufacturers from applying their rebate models to federally qualified health centers.

Thank you again for the opportunity to provide feedback. ACH welcomes the opportunity to serve as a resource and partner in supporting the development of a model that fully considers the best interests of CHCs and the patients they serve. 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'. The signature is fluid and cursive, with a large initial 'A' and a long, sweeping underline.

Amanda Pears Kelly
Chief Executive Officer
Advocates for Community Health