



ADVOCATES FOR
COMMUNITY
HEALTH

March 10, 2025

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

Dear Administrator Engels,

Congratulations on your return to the Health Resources and Services Administration. On behalf of Advocates for Community Health (ACH) and the members and patients we represent, we welcome you back for your second tenure as Administrator and look forward to working with you.

Established in 2021, Advocates for Community Health (ACH) is a nonpartisan, nonprofit membership organization of community health centers dedicated to forward-thinking and ambitious federal policy and advocacy on behalf of health centers, their patients, and their communities. Our 41 members represent 20 states, Puerto Rico, and the District of Columbia. Our members serve 3.5 million patients, providing high-quality, comprehensive primary health care, mental health services, preventive care, and social services to patients most in need. We look forward to partnering with you on a range of issues to ensure that our nation's primary care safety net continues to thrive.

We are writing today about the 340B program, a vital lifeline for health centers, enabling them to serve more patients, and provide more services, at more sites. As you know, several pharmaceutical manufacturers are seeking to proceed with a "rebate model" in the 340B program, under which covered entities must pay the full price for drugs upfront and wait through an adjudication process run by the manufacturer to determine if they receive the 340B discount in the form of a rebate.

ACH strongly supports HRSA's most recently communicated position on this issue, which is that the rebate model is not allowable under the 340B statute. We urge you to continue the enforcement mechanisms that your agency has deployed to date and defend the original discount model in court.

There are challenges CHCs can expect to encounter if a rebate model is in place:

1. **Revenue cycle challenges.** Community health centers, non-profit organizations that accept all patients regardless of insurance coverage or ability to pay, operate with extremely small margins. Each organization has to monitor their cash flow carefully. Because the 340B program is often a vital component of a health center's business model, having to wait even a few weeks to receive a delayed discount could alter their ability to pay staff, purchase

necessary equipment, and make other decisions essential to running a busy clinical practice.

2. **Challenging operational changes.** Having to adapt to a rebate model, rather than an upfront discount as designed by the 340B statute, would require each health center to use an accumulator, which is separate software that tracks 340B purchases and may be burdensome to implement. In addition, health centers may have to start using a split inventory, which creates the extremely challenging process of reconciliation after the dispensing of medications.
3. **Unsustainable administrative burden.** We anticipate each manufacturer's rebate model having a different system, set of requirements, and waiting period, creating additional administrative burden and cost to covered entities who can least afford it.
4. **Unauthorized audit practices and access to data.** In many of the rebate models that have been proposed, pharmaceutical manufacturers are requesting a significant amount of claims data which they do not have the right to access under any relevant statute. As part of their responsibilities as covered entities, health centers review and determine patient eligibility for the 340B program, and these policies, procedures and practices are regularly reviewed through audit by HRSA. Under the 340B statute, pharmaceutical manufacturers have no right to audit health centers' 340B programs unless specifically approved by HRSA.

We also draw your attention to the strong bipartisan opposition to the transition of the 340B program into a rebate-based program. Last year, nearly 200 bipartisan members of Congress [wrote to the US Department of Health and Human Services](#) to urge them to reject a rebate model proposal.

Thank you to you and your staff for your efforts to preserve the discount model for health centers and other safety net entities. We would welcome the opportunity to meet with you to discuss this important issue. Please contact me at apearskelly@advocatesforcommunityhealth.org and/or Stephanie Krenrich, our Senior Vice President of Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org to discuss this further.

Thank you for your consideration.

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