Advancing High Performance Health

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

Re: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025- 14998)

Dear Administrator Engels,

On behalf of AMGA, we appreciate the opportunity to comment on the 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program. The 340B Drug Pricing Program is critically important to AMGA members, as it allows them to purchase outpatient drugs at significantly reduced prices, helping stretch scarce resources and expand access to care for vulnerable patient populations. By lowering drug costs, AMGA members can reinvest savings into other vital services. While we recognize Department of Health and Human Services' (HHS') stated goal of gathering real-world data, the proposed shift from an upfront discount to a post-sale rebate model poses serious financial, operational, and other mission-threatening challenges for safety-net providers and the vulnerable patients AMGA members serve.

Founded in 1950, AMGA is a trade association leading the transformation of healthcare in America. Representing multispecialty medical groups and integrated systems of care, we advocate, educate, innovate, and empower our members to deliver the next level of high-performance health. AMGA is the national voice promoting awareness of our members' recognized excellence in the delivery of coordinated, high-quality, high-value care. More than 177,000 physicians practice in our member organizations, delivering care to more than one in three Americans. Our members are also leaders in high-value care delivery, focusing on improving patient outcomes while driving down overall healthcare costs.

AMGA offers the following comments in strong opposition to the proposed 340B Rebate Model Pilot Program announced on July 31, 2025.

Key Concerns

- **Severe financial strain and cash flow disruptions:** Forcing safety-net providers to purchase drugs at wholesale acquisition cost (WAC) before receiving rebates will drain limited operating funds, delay care, and threaten the viability of hospitals and clinics.

- **Increased complexity and administrative burden:** The proposed rebate model imposes new reporting, tracking, and claims processes under unrealistic timelines and will divert staff time and resources away from direct patient care.
- **Risk of greater manufacturer control over the 340B Program:** Allowing manufacturers to dictate payment terms and data requirements erodes statutory protections and shifts program governance.
- **Insufficient safeguards for providers:** Vague enforcement guidelines and rebate requirements only increase the financial and operational risks for providers.
- **Threat to the safety net:** Delayed savings from rebates undermine the 340B Program's stated intent and ability to support uncompensated care, particularly in low-income, rural, and underserved communities.

AMGA's full comments on the rebate model are below.

Severe Financial Burdens and Cash Flow Disruptions
The cornerstone of the 340B Program's success has been its upfront discount mechanism, which provides covered entities with immediate cost savings at the point of purchase. Replacing this proven mechanism with a delayed rebate system would require covered entities to purchase drugs at WAC—often several times higher than the 340B price—while waiting for reimbursement. This change would cause significant cash flow disruptions, forcing safety-net hospitals and clinics to divert limited operating funds toward drug costs instead of patient care, with a minimum of 60 calendar days' notice.

For many providers already operating on razor-thin margins, the requirement to advance funds at WAC, combined with delays in reimbursement, could lead to deferred care, cutbacks in essential services, or even program closures. This model would further exacerbate additional regulatory pressures. For instance, in the Calendar Year (CY) 2026 Medicare Hospital Outpatient Prospective Payment System Proposed Rule—if finalized—accelerated 340B remedy payments would place an even greater burden on covered entities. This rebate pilot fails to adequately address the financial strain or the risk of insolvency for smaller covered entities. By forcing covered entities to absorb significant upfront costs, the pilot would destabilize the very institutions patients in underserved communities depend on most.

Increased Complexity and Administrative Burden
The rebate pilot significantly increases the administrative and operational challenges facing covered entities. New reporting and claims submission requirements introduce layers of complexity to already overextended pharmacy, billing, and compliance systems. Even with manufacturers covering IT platform costs, labor and workflow changes will be substantial, especially if providers must navigate multiple new IT interfaces. In addition, staff must track, validate, and submit rebate claims within 45 days, monitor payment timelines, and resolve disputes—all of which require time, training, and resources that could otherwise be devoted to patient care.

In addition, the Health Resources and Services Administration's (HRSA's) accelerated implementation timeline for the model will force already overextended providers to implement drastic changes with limited notice. With manufacturers only required to provide 60 calendar days' notice to providers before instituting a rebate program, providers must make financial and operational decisions on unreasonable timelines. Smaller rural hospitals and clinics, many of

which lack a robust administrative infrastructure, would be disproportionately affected. Rapid changes to systems and staffing cannot be made without disrupting patient services, and the risk of administrative errors increases when compliance requirements are rushed. The pilot would shift administrative costs and risks from manufacturers onto providers, further straining the very institutions intended to benefit from the 340B Program.

Risk of Greater Manufacturer Control Over the 340B Program
Allowing manufacturers to dictate payment terms and data requirements represents a troubling shift in program governance. The current structure—grounded in statutory discounts—places clear obligations on manufacturers. By contrast, the proposed rebate model increases manufacturer control over both the financial flow and the operational rules of the program. This could erode the 340B Program's protections and intent, moving the program further away from its original mission of supporting safety-net providers.

Insufficient Safeguards for Providers
While the notice outlines certain safeguards (e.g., timeliness of rebate payments, limits on data collection), the lack of clear enforcement penalties and dispute resolution processes makes providers potentially liable for errors caused by manufacturers. This leaves providers vulnerable to financial and operational risks, on top of the burden of paying full WAC prices up front. Even short delays in rebate processing can have compounding effects on provider budgets, and shifting program administration away from direct HRSA control will cause unnecessary confusion and damage.

The pilot's focus on drugs selected under the Medicare Drug Price Negotiation Program is particularly concerning, as it targets some of the highest-cost, often-essential medications. Subjecting these critical therapies to a delayed rebate structure could disrupt access for patients who depend on them, forcing safety-net providers to make difficult trade-offs between maintaining care, covering operational costs, and fulfilling program requirements.

Threats to the Safety Net
The 340B Program is a critical lifeline for hospitals and clinics serving low-income, rural, and underserved communities. The proposed rebate model fundamentally alters the program's financial dynamics in a way that disproportionately harms those least able to absorb payment delays. A weakened 340B Program directly undermines safety net providers' capacity to provide uncompensated and undercompensated care, jeopardizing access to affordable medications for patients who need them most.

Conclusion
The proposed rebate model jeopardizes the financial stability, operational efficiency, and patient-serving capacity of safety-net providers. It introduces unnecessary complexity and the risk of ceding undue control of the 340B Program to drug manufacturers.

We urge HHS to withdraw the pilot program in its current form and instead focus on strengthening the existing upfront discount model, which has proven effective in sustaining safety-net providers and improving access to affordable medications.

We thank you for your consideration of our comments. Should you have questions, please do not hesitate to contact AMGA's Darryl M. Drevna, senior director of regulatory affairs, at

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Sincerely,

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President and Chief Executive Officer, AMGA