



April 20, 2026

Thomas J. Engels
Administrators
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RE: Request for Information: 340B Rebate Model Pilot Program (Docket No. HRSA-2026-03042)

Submitted electronically to [regulations.gov](https://www.regulations.gov)

Dear Administrator Engels,

Thank you for the opportunity to provide comments on the notice for the voluntary 340B Rebate Model Pilot Program for drugs. The Council for Affordable Health Coverage (CAHC, www.cahc.net) is a broad-based alliance with a singular focus: ensuring all Americans have access to affordable coverage. CAHC promotes policies that lower health costs through competition, transparency, empowered consumers, and expanded choice.

CAHC has long supported reduced drug costs, greater access to drug therapies, and fostering innovation to help treat and cure disease.

We applaud HRSA for exploring steps to improve the 340B program, including through a rebate model, and encourage HRSA to move away from a discount approach to facilitate lower cost drugs for patients and to better stretch resources for entities that serve low-income populations.

In our September 2025 [comment letter](#) regarding the pilot, we highlighted concerns regarding the unchecked expansion of the 340B program, persistent rebate duplication, and the growing complexity caused by the Inflation Reduction Act (IRA). We build on those comments here and emphasize how a rebate-based model can address program inefficiencies, including misallocated resources, which are key drivers of higher costs for patients.

The Unchecked Expansion of the 340B Program

The 340B Drug Pricing Program has strayed far from its original purpose and is now a significant driver of market consolidation and higher health care costs. Since 2010, 340B drug purchases have grown more than sixfold, rising from roughly \$7 billion to more than \$81 billion annually.

While intended to support safety-net providers, the program allows participating hospitals to purchase deeply discounted drugs and bill insurers and Medicare at full market rates, retaining the spread. These incentives have encouraged large nonprofit hospital systems to acquire physician practices and expand outpatient facilities to capture 340B margins, shifting care into higher-cost settings without demonstrable improvements in access for vulnerable patients.

The Congressional Budget Office found that between 2013 and 2021, the number of off-site outpatient clinics participating in the 340B program increased from about 6,100 to 27,700, and the share of hospitals with at least one off-site outpatient clinic increased from 50 percent to 76 percent.¹ CBO also found that this has resulted in disproportionate spending by 340B facilities on drugs in classes with higher spending growth and more revenue potential. CBO found that if 340B cancer drug spending had followed overall market growth, 2021 spending would have been 3.1 times 2010 levels. Instead, it rose to 8.6 times - from \$2.1 billion to \$18.1 billion.² High-cost drugs represent about one-third of total 340B program spending.

Even as coverage for the low-income population has greatly expanded, per capita charitable care has declined. In fact, data shows that as 340B hospitals buy more drugs at deep discounts, many are spending less on charity care, often prioritizing revenue for other purposes.³ In fact, in 47 states and D.C., more than half of the DSH hospitals in the 340B program earned more in 340B profit than they spent on charity care. In FY 2021, one-third of 340B DSH hospitals spent less than 1 percent of their operating expenses on charity care.⁴

Additionally, higher spending is not passed along in better benefits or lower costs to patients. In fact, 340B entities buy products at steeply discounted prices and mark them up significantly, causing patients to pay excessive cost-sharing that is sometimes more than an entity's acquisition cost. Because there is little accountability and data, very little is known about how entities use 340B discounts to benefit specific patients. What is known is that according to HRSA's audits, 49 percent of entities received adverse findings.

This is a program in need of reform and greater oversight. A rebate-based model introduces a necessary structural correction. Basic transparency and program integrity require claims-level verification before a 340B discount is realized. A revised program that moves to a rebate approach would help achieve this goal by ensuring discounts are only applied to eligible claims. This shift would bring the program closer to standard practices across the healthcare system, where payment follows verification.

Addressing Waste and Abuse to Improve Affordability

A central advantage of a rebate-based 340B model is its ability to meaningfully address long-standing waste and abuse that drive higher costs throughout the health care system.

Under the current upfront discount framework, manufacturers provide reduced prices before eligibility is confirmed. This lack of real-time verification has enabled documented problems, including diversion to ineligible patients, manipulation of claims to maximize revenue, and, most

¹ [Growth in the 340B Drug Pricing Program | Congressional Budget Office](#)

² Ibid

³ [2023-Charity-Care-Report-Final-1.pdf](#)

⁴ Ibid

significantly, duplicate discounts across federal programs. Once an improper discount is applied, it is difficult to identify and even harder to recover, creating systemic inefficiencies that ultimately raise costs for patients, employers, and taxpayers.

Requiring basic claims-level data before rebate payment offers a practical solution. A rebate-based verification model would:

- Confirm eligibility before a 340B benefit is realized
- Prevent duplicate discounts across overlapping programs
- Create a clear audit trail for oversight and enforcement
- Aligns the program with standard payment practices used in Medicare, Medicaid, and commercial insurance

By addressing these sources of waste and abuse, the model can help reduce excess costs that are ultimately felt by patients through higher premiums, cost-sharing, and taxes.

Preventing Duplicate Discounts in a Post-IRA Environment

Duplicate discounts remain the most significant operational and compliance risk within the 340B program and are an issue that has been compounded by the Inflation Reduction Act's (IRA) drug pricing provisions. Without effective coordination, manufacturers may be required to provide multiple discounts on the same drug.

The suggested pilot approach should include documentation, verification, and reporting requirements that can ensure a single prescription receives only one applicable discount. Leveraging standardized, claims-level data will not only reduce legal and financial risk for stakeholders but also create a scalable framework for long-term program integrity as additional IRA-selected drugs come into scope.

Absent these guardrails, unauthorized duplicate discounts could reach billions of dollars annually, undermining both affordability and confidence in federal drug pricing programs.

Maintaining Access While Improving Affordability

It is essential to emphasize that a rebate model can strengthen program integrity without compromising patient access or imposing undue burden on legitimate safety-net providers.

Patients would continue to receive medications without delays, and eligibility determinations would occur post-dispensing, consistent with existing billing and compliance workflows. Providers already collect the data required for verification as part of routine operations, minimizing administrative impact. In many cases, rebate reconciliation timelines can align with existing payment cycles, mitigating cash-flow concerns while improving accuracy.

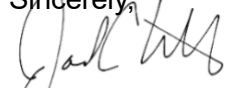
Conclusion

CAHC supports HRSA's efforts to modernize the 340B program through a rebate-based approach. By improving transparency, strengthening oversight, and preventing duplicate and improper discounts, the pilot represents a meaningful step toward restoring program integrity.

Most importantly, these reforms are essential to advancing affordability. When the 340B program operates without adequate safeguards, excess costs are passed on to patients, employers, and taxpayers. A rebate-based verification model helps ensure that program savings are appropriately targeted and that 340B functions as intended: to support vulnerable patients rather than fuel unnecessary spending.

CAHC appreciates the opportunity to provide these comments and looks forward to continued engagement on policies that promote access, accountability, and affordability.

Sincerely,

A handwritten signature in black ink, appearing to read "Joel White", written over the word "Sincerely,".

Joel White
President