



September 8, 2025

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

RE: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (Docket No. HRSA-2025-14619)

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 on the CMS Medicare Drug Price Negotiation Selected Drug list for 2026, subject to a maximum fair price (MFP). 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. Our member organizations are pro-patient, pro-competition, and pro-innovation, and include employers, medical providers, patient groups, insurers, agents and brokers, technology companies, and pharmaceutical manufacturers.

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 taking steps to improve the 340B program through the pilot program and encourage the final version to be more robust to address longstanding concerns around transparency, compliance, and duplication. We offer the following comments focused on three key areas in this letter:

1. The unchecked expansion of the 340B program,
2. The persistent issue of rebate duplication, and
3. The potential for this pilot to mitigate complications caused by the Inflation Reduction Act (IRA).

The Growth of the 340B Program

The original purpose of the 340B Drug Pricing Program was to provide greater access to care for patients who were uninsured and low-income; however, the program has not resulted in its original goal and instead has led to unintended consequences as its scale and complexity have outpaced the necessary oversight.

340B purchases at list price reached \$147.8 billion in 2024, representing a 174.6% increase between 2018 and 2024, compared to a 53.3% increase for non-340B purchases.¹ While the program has grown exponentially, the number of disproportionate share hospitals (DSH) providing charity care has decreased, as less than 1% of DSH hospitals' total operating costs were spent on charity care in 2021.² Currently, HRSA audits only 0.33% of covered entities annually, but returns adverse findings in 70% of these audits.³ These factors have aided and abetted misuse and diversion to become a systemic issue.

This is unsurprising as 340B entities buy low and mark up drugs to sell high to taxpayers and patients, earning hefty profits on the backs of consumers and the public. These profits largely benefit health systems and contract pharmacies, and discounts rarely reach patients. A 2022 study from IQVIA found that only 1.4% of 340B-eligible prescriptions at contract pharmacies shared any direct savings with patients.⁴

The proposed rebate model offers a promising framework for accountability by requiring manufacturers to submit detailed plans and obtain HRSA approval before implementation. Additionally, under the pilot program, rebates could alleviate some of the issues manufacturers face under the current model of providing upfront discounts.

Rebate Duplication

Rebate duplication, particularly between 340B discounts and Medicare or IRA-related rebates, poses significant compliance and liability risks. The pilot's requirement that manufacturers document reasons for rebate denials and ensure adherence to 340B(a)(5)(A) and (B) is a critical safeguard against these risks. The model should help limit or eliminate duplicate discounts for covered entities for the same drug. By enforcing transparency and accountability, the pilot helps mitigate legal exposure and supports the integrity of rebate systems.

The structured data collected through this pilot can serve as a tool to prevent manufacturers from accidentally providing rebates to multiple covered entities for the same claim. This issue is historically very difficult to detect and prevent because of the lack of transparency into claims-level data across programs. By improving documentation and data-sharing protocols, the pilot lays the groundwork for a more transparent and efficient rebate system. This will reduce financial waste and enhance program compliance.

Inflation Reduction Act Complexities

The IRA's drug pricing provisions have introduced new complexities for manufacturers, payers, and providers. The intersection of IRA price setting and 340B compliance creates a high risk of operational conflicts. We believe this pilot can serve as a model for reconciling IRA mandates with 340B requirements, and we strongly encourage HRSA to consider expanding the program to 2027 IRA-selected products and beyond, once initial results are assessed.

¹ Martin, R., and Karne. H. (May 2025). *The Size and Growth of the 340B Program in 2024*. IQVIA. <https://www.iqvia.com/locations/united-states/library/white-papers/the-size-and-growth-of-the-340b-program-in-2024>

² Sullivan, M., et al. (2024). *Can Comprehensive 340B Reform Generate Federal Savings*. Avalere Health. <https://advisory.avalerehealth.com/insights/can-comprehensive-340b-reform-generate-federal-savings>

³ ADVI. (March 2025). *HRSA 340B Covered Entity Audits*. <https://advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits/>

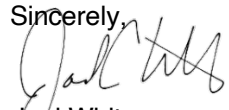
⁴ Martin R. and Illich, K. (2022). *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies*. IQVIA. <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf>

Conclusion

CAHC continues to support the administration's overarching goal of lowering prescription drug costs and improving affordability for patients.

We appreciate the opportunity to submit these comments and welcome further dialogue on how to ensure the 340B program is implemented in a manner that supports long-term value, equity, and trust. If you have questions about these comments, please do not hesitate to contact me.

Sincerely,



Joel White
President