

Department of Health and Human Services
Health Resources and Services Administration
Rockville, MD 20852

In The Matter of Request for Information: 340B Rebate Model Pilot Program Extension

The American Consumer Institute is an independent 501(c)(3) education and research organization. Its mission is to identify, analyze, and protect the interests of consumers in selected legislative and rulemaking proceedings in information technology, health care, insurance, and other matters.

We write regarding the 340B Rebate Model Pilot Program Extension. While rebates are a potentially helpful way to mitigate flaws in the 340B Drug Pricing Program, a stronger and more permanent approach would be to address these flaws head on.

The 340B Drug Pricing Program was created in 1992 under the Veterans Health Care Act to serve a narrow, targeted purpose: allow safety-net providers—primarily those serving a disproportionate share of low-income and uninsured patients—to purchase outpatient drugs at steep discounts so they could stretch scarce federal resources and expand access to care.¹ At the time, the program was relatively small and limited to a defined set of “covered entities,” such as disproportionate share hospitals. The implicit bargain was straightforward: manufacturers would provide discounts in exchange for access to Medicaid and Medicare markets, and providers would use the savings to subsidize care for vulnerable populations.

Over time, however, statutory changes, administrative decisions, and especially the growth of contract pharmacy arrangements have fundamentally altered how the program operates in practice. Guidance from Health Resources and Services Administration (HRSA) in 2010² allowed covered entities to contract with multiple external pharmacies, rather than a single in-house pharmacy, dramatically expanding the size of the program.³ The number of contract pharmacies grew dramatically nationwide, with a disproportionate concentration in higher-income urban and suburban markets where prescription volume—and therefore profit potential—is highest and patients have the least need of assistance.⁴

¹ “Veterans Health Care Act of 1992, Public Law 102-585,” Health Resources and Services Administration, last reviewed April 2017, <https://www.hrsa.gov/opa/program-requirements/public-law-102-585>.

² Federal Register, vol. 75, no. 43, March 5, 2010, <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>.

³ “340B Drug Pricing Program,” National Pharmaceutical Council, accessed April 16, 2026, <https://www.npcnow.org/topics/health-spending/340b-drug-pricing-program>.

⁴ Mary Caffrey, “As Court Action Heats Up, Study Shows More Money Made on 340B in Wealthy Areas,” The American Journal of Managed Care, April 3, 2025, <https://www.ajmc.com/view/as-court-action-heats-up-study-shows-more-money-made-on-340b-in-wealthy-areas>.

This structural shift has weakened the connection between 340B discounts and the low-income and uninsured patients the program purports to help. Large, well-capitalized hospital systems have strong incentives to acquire physician practices and open outpatient clinics in affluent areas, then designate those sites as a 340B covered contract pharmacy. Prescriptions written in these settings—often for well-insured, higher-income patients—can be filled using 340B discounts, with all or part of the discount retained by the hospital and pharmacy. Because the statute does not require that 340B covered entities pass discounts directly to patients, nor does it have reporting requirements on how covered entities use the savings, these prescriptions become a revenue stream rather than a targeted subsidy. Empirical analyses have found that 340B-eligible hospitals are more likely to expand into wealthier communities and oncology markets where margins are highest.⁵

Hospitals maximize the volume of high-reimbursement drugs dispensed under 340B pricing, while manufacturers face a growing share of sales subject to mandatory discounts, incentivizing them to increase list prices to preserve revenue. The result is cross-subsidization in which privately insured patients bear higher costs, while the program loses its focus on low-income patients. A program designed as a targeted safety-net subsidy has morphed into a broad, opaque transfer of wealth toward hospitals in higher-income urban areas rather than underserved rural or low-income communities.

Refocusing the program on its original mission requires structural—not incremental—reform. The HRSA has authority to redefine eligibility and program parameters, and it should use that authority to better align the program with the needs of low-income patients. Hospitals and contract pharmacy arrangements located in high-income ZIP codes or serving well-insured populations should either not qualify, or be subject to stricter eligibility thresholds, and should demonstrate the patients' specific need for the program. This would limit the incentive to expand into affluent markets simply to capture 340B margins.

At the same time, HRSA should broaden eligibility for providers that clearly serve vulnerable populations but are currently excluded.⁶ Rural emergency hospitals often operate on thin margins and serve lower-income and less insured populations, yet do not automatically qualify for 340B status. Extending eligibility to these facilities would better align program benefits with the patients Congress created to help. Similarly, simplifying qualification criteria for hospitals in low-income urban and rural areas make it easier for smaller providers to meet the program's requirements without the infrastructure of large hospital systems.

Transparency is the other critical improvement. Without reporting requirements, covered entities can claim discounts without demonstrating patient benefit. Requiring hospitals to document patient eligibility criteria, quantify the discounts received, and disclose how much savings hospitals and pharmacies pass through to patients (either as reduced cost-sharing or uncompensated care) would introduce accountability and enable policymakers to distinguish between genuine safety-net healthcare delivery and maximizing revenue. Additional reforms could include narrowing the definition of eligible prescriptions to only those directly associated with low-income or uninsured patients.

⁵ Robert Nurdyke, James Motyka, and Julie Patterson, "The Association of 340B Program Drug Margins with Covered Entity Characteristics," *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, March 23, 2025, <https://journals.sagepub.com/doi/10.1177/00469580251324051?utm>.

⁶ "340B Exposed: New Study Shows Wealthy Hospitals Profit While Rural Patients Lose Out," *Patients Rising*, April 1, 2025, <https://www.patientsrising.org/advocacy-updates/340b-new-study-wealthy-hospitals-profit>.

Without changes, the program will continue to distort provider behavior, encourage expansion into wealthier markets, and contribute to upward pressure on drug prices, undermining both affordability and access for everybody, especially the very populations it was created to serve.

Respectfully,

Justin Leventhal
Senior Policy Analyst
The American Consumer Institute

4350 N. Fairfax Drive
Suite 725
Arlington, VA 22203

Justin@TheAmericanConsumer.Org
www.TheAmericanConsumer.org

