THE TRUTH ABOUT THE 340B DRUG PRICING PROGRAM

The congressionally created 340B Drug Pricing Program is one of the longest-standing tools to shield safety net hospitals and their patients from the impact of rising prescription drug costs. The program's reach and importance has expanded over time in accord with policymakers' intentional changes and with manufacturers' increasingly pricey drugs. Concerningly, some drug manufacturers have turned to unilateral actions to weaken the program and dramatically restrict its scope. These manufacturers are walking away from their commitment to the Medicaid and Medicare programs, often in flagrant violation of federal statute and federal agency direction. Congress must maintain this lifeline that preserves access to care for low-income patients and essential hospitals.

PROHIBIT RESTRICTIONS ON DISCOUNTS TO PATIENT-ACCESSIBLE PHARMACIES

In recent years, drug manufacturers have unilaterally restricted access to 340B drugs dispensed by pharmacies with which hospitals contract to extend the program's reach. These pharmacies serve more low-income patients where they live and safely handle certain specialty drugs. Contrary to explicit federal agency directive, these drug manufacturers have imposed onerous reporting requirements as a condition for 340B discounts or have refused to offer discounts to one or more of an entity's contract pharmacies entirely.

Contract pharmacy restrictions undermine 340B benefits for patients and financially strained essential hospitals only to pad manufacturers' bottom line. They jeopardize the health of disadvantaged patients who depend on their local pharmacies for access to lifesaving drugs.

To stem the damage of these shameful actions, 21 states have passed laws as of February 2026—a marked increase over the previous year—to ensure patients have access to lifesaving drugs through contract pharmacies.[1] These state laws serve as a successful model for Congress.

PRESERVE UP-FRONT ACCESS TO DISCOUNTED DRUGS

To expand restrictions beyond contract pharmacies to all 340B drugs, manufacturers announced plans to unilaterally replace up-front discounts with rebates provided only after manufacturer review and approval. Despite the Health Resources and Services Administration's (HRSA) statement that federal law requires agency approval to implement a rebate model, at least one manufacturer continued its efforts until faced with enforcement action. When HRSA declined to approve the proposed rebate programs, multiple manufacturers sued.

In July 2025, HRSA announced a voluntary 340B Rebate Model Pilot Program to begin Jan. 1, 2026, that was open to drugs on the Centers for Medicare & Medicaid Services Medicare Drug Price Negotiation Selected Drug List for 2026. The pilot was hastily designed and failed to provide important protections for 340B covered entities. One stakeholder study found compliance with the rebate model would cost covered entities approximately $400 million. Further, the pilot failed to consider fallbacks in case of cyberattacks or how to penalize misuse of the model by manufacturers.[2]

The association urged the agency to rescind its pilot and continually advocates for additional protections for essential hospitals. After a court order found HRSA likely violated the Administrative Procedure Act when it failed to consider how rebates would affect 340B covered entities, HRSA withdrew the rebate pilot and paused implementation.

These rebate models run afoul of Congress' intent to help safety net providers stretch scarce federal resources, as

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expressed by bipartisan groups in Congress. Rebate models force hospitals to purchase 340B drugs at their wholesale acquisition cost, which can be exponentially higher than the current 340B discounted rate, effectively requiring 340B hospitals to float millions of dollars to pharmaceutical companies. They will add unnecessary barriers to care, delay critical payments to health systems, and burden hospitals already operating on thin margins with new administrative costs. A rebate model is not necessary for participation in the Medicaid drug price negotiation program, as the Department of Health and Human Services (HHS) argued during the rebate litigation.

We appreciate Congress' bipartisan opposition to 340B rebate proposals. In September 2025, Reps. Dusty Johnson (R-S.D.) and Doris Matsui (D-Calif.), with Reps. Tracey Mann (R-Kan.) and Debbie Dingell (D-Mich.) as co-leads, led a bipartisan group of 166 House colleagues that sent a letter to HHS Secretary Robert Kennedy Jr. expressing concerns with HRSA's pilot program. In September 2024, Reps. Doris Matsui (D-Calif.), Abigail Spanberger (D-Va.), Dusty Johnson (R-S.D.), Rob Wittman (R-Va.), Debbie Dingell (D-Mich.), and Tracey Mann (R-Kan.) led a bipartisan group of 188 House colleagues in sending a letter to HHS expressing concerns with manufacturer proposals. **We urge lawmakers to continue working to ensure essential hospitals maintain access to up-front 340B discounts.**

KEY PROGRAMMATIC TRUTHS

1. Despite disinformation from manufacturers, 340B is working as Congress intended.

- Congress created 340B to help safety net providers "stretch scarce federal resources" to reach more patients and offer more comprehensive services.
- The program costs taxpayers next to nothing but provides enormous community benefit.
- These real-world impacts show 340B's value in enabling hospitals to meet community needs beyond their walls.

2. Program growth reflects drug price growth and compliant utilization—not abuse.

- Claims that 340B has "grown dramatically" ignore context. A primary driver of dollar growth is the increase of drug prices, regularly above inflation, by manufacturers.
- Hospitals that participate in 340B are more likely to offer specialty services like oncology than non-340B facilities. Enabling access to complex care is the exact intent of the 340B program.
- Growth also reflects patient access to care—a sign the program is functioning exactly as Congress intended. The 340B program is a policy success, not a flaw—no matter how much manufacturers might message otherwise.

3. Manufacturers are undermining the law at the expense of patients.

- Courts have repeatedly found that drug manufacturers have restricted access to 340B pricing at contract pharmacies, imposing burdensome data demands or cutting off discounts entirely.
- These actions seek to pad manufacturers' bottom lines and shift authority from HRSA to drug manufacturers.
- The 340B program establishes a clear requirement for pharmaceutical manufacturers to contribute to the care of Americans served by federal programs as a condition of having their drugs covered by Medicare and Medicaid.
- Altering the program would undermine the fundamental spirit of the agreement.

Endnotes

1. Young S. HRSA Releases Request for Information Seeking Comments on Whether to Move Forward with 340B Rebate Pilot. *340B Report*. Feb. 13, 2026. https://340breport.com/hrsa-releases-request-for-information-seeking-comments-on-whether-to-move-forward-with-340b-rebate-pilot/. Accessed Feb. 17, 2026.

2. American Hospital Association. AHA says HRSA vastly underestimates costs 340B Rebate Pilot Program will inflict on hospitals, urges agency to delay implementation. Sept. 30, 2025. https://www.aha.org/news/headline/2025-09-30-aha-says-hrsa-vastly-underestimates-costs-340b-rebate-pilot-program-will-inflict-hospitals-urges. Accessed Feb. 9, 2026.

3. H.R. REP. 102-384(II), p. 12.