



340B Program Update

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TO: Selected Clients

FROM: Devon Seibert-Bailey, Sr. VP

Overview

The 340B Drug Discount Program remains under intense scrutiny, with new proposals, legal developments, and industry actions creating uncertainty for covered entities. Below is a summary of the most significant federal updates.

HRSA's Rebate Pilot Program

HRSA has issued guidance for a voluntary rebate model under the 340B program, applicable only to drugs listed in the Inflation Reduction Act's Medicare Drug Price Negotiation list. Manufacturers must submit participation plans by **September 15**, with approvals by **October 15**, and a launch date of **January 1, 2026**. For a two-page memo on the guidance with the qualifications and requirements, click [here](#). Click [here](#) for the guidance document and [here](#) for the press release from HRSA.

- Covered entities have expressed serious concerns about the model's limitations and financial risks.
- Pharmaceutical manufacturers argue the pilot is too narrow in scope.
- A bipartisan group of over 150 House members has urged HHS to cancel the pilot, and there are rumors of a possible one-year delay. Click [here](#) for the letter

CMS's \$7.8 Billion Clawback Plan

CMS is accelerating its plan to recover \$7.8 billion in Medicare payments related to unlawful 340B reimbursement cuts from 2018–2022. Originally proposed as a 0.5% annual reduction over two decades, the updated plan increases the cut to 2% annually, aiming for full recovery by **2031**. Click [here](#) for the CMS fact sheet.

Legal Developments Supporting Covered Entities

Recent court rulings have upheld state laws protecting 340B discounts at contract pharmacies:

- A federal judge in Maine denied injunctions from AbbVie and Novartis challenging a new state law. For more on the case from the AHA, click [here](#).

- Appellate courts in Arkansas and Mississippi have similarly rejected drug manufacturers' challenges. Legislators in Colorado, Nebraska, Utah, and other states are introducing bills to protect contract pharmacy arrangements. For more on these developments, click [here](#).
- Additionally, a federal judge upheld HHS's authority to preapprove rebate models, dismissing Johnson & Johnson's lawsuit. Click [here](#) to read the ruling.
- The AHA has accused five major drugmakers of potential collusion by all pursuing a similar rebate-based model for 340B. In September 2025, the AHA called on the FTC and DOJ to investigate this coordinated activity, which they view as harmful to hospitals and patients. To read the letter to the Administration, click [here](#).

Congressional Activity and CBO Report

A CBO report estimates the 340B program's cost at **\$66 billion**, with over **500% growth** in the past 11 years. Requested by Rep. Buddy Carter (R-GA), the report has fueled debate over program reform. Click [here](#) for the report, and [here](#) for the Energy and Commerce Committee's press release.

- Rep. Carter and Rep. Harshbarger introduced the **340B ACCESS Act**, proposing transparency and structural changes. Notably, the National Association of Community Health Centers withdrew its support. Click [here](#) for the press release, and [here](#) for the legislation.
- Rep. Matsui and Sen. Welch reintroduced the **340B PATIENTS Act**, which would codify contract pharmacy use and penalize manufacturers that violate discount rules. Click [here](#) for Matsui's press release, and [here](#) for the legislation.
- The Senate "Gang of Six" continue to meet and develop comprehensive 340B reform legislation. In May, they announced that original members Sens. Jerry Moran (R-KS), Tammy Baldwin (D-WI) and Shelley Moore Capito (R-WV) welcomed Sens. Tim Kaine (D-VA), Markwayne Mullin (R-OK) and John Hickenlooper (D-CO) as new members of the Senate 340B bipartisan working group. In February 2024, the 340B working group released a legislative discussion draft and supplemental request for information which included solutions to improve the 340B program, click [here](#) for the draft.

PhRMA's Campaign and Media Narrative

PhRMA has launched its largest anti-340B ad campaign to date, aiming to influence year-end Congressional decisions. Click [here](#) for the ad. A recent *Wall Street Journal* editorial echoed industry criticisms, accusing hospitals of misusing 340B savings and fueling consolidation. Click [here](#) to read the full editorial.

- A report from PhRMA, conducted by the Berkeley Research Group, looks at states' use of private managed care organizations to operate their Medicaid programs. It found that the 340B program reduced the amount rebated to beneficiaries by \$6.5 billion in 2024, click [here](#).
- The Pioneer Institute is aggregating anti-340B initiatives at the state and employer level, click [here](#).

“Most Favored Nation” Drug Pricing Deal and Trump Rx

The Trump Administration announced a deal with Pfizer to offer drugs at discounted prices to the United States under the ‘most favored nation’ model, in which the U.S. pays no more than the lowest price charged in other developed countries, effective immediately. Click [here](#) for the announcement from Pfizer, [here](#) for the White House fact sheet, and for additional analysis from *CBS News*, click [here](#).

- Administration officials at a news conference also teased a new website - TrumpRx - which they said would allow direct-to-consumer sales of medications at discounted rates. Many in the 340B community worry that this could undermine the discount drug program and eliminate savings.
- It is important to note that based on recent events, pharmaceutical companies may be using the 340B program as leverage in negotiations with the White House over broader drug pricing policies. In exchange for concessions on programs like Medicare drug price negotiation and new tariffs, some drugmakers have voluntarily agreed to reduce prices on specific drugs for U.S. patients.

Conclusion

The 340B program is at a pivotal moment. While legislative reform appears unlikely in 2025, ongoing regulatory changes, legal victories, and industry pressure are shaping its future. Stakeholders should remain engaged, monitor developments closely, and prepare for potential shifts in program structure and reimbursement.

We will continue to keep you posted on important developments.