H.R.10770 - 340B Rebate Model Delay Act

Bill Text: H.R.10770

Cosponsors: Rep. Rob Bresnahan (R-PA), Rep. Debbie Dingell (D-MI), Rep. Tracey Mann (R-KS), Rep. Lois Frankel (D-FL)

Overview

The discussion draft of the 340B Rebate Model Delay Act, introduced by Rep. Rob Bresnahan (R-PA), would temporarily prohibit the implementation of manufacturer rebate-based purchasing arrangements under the 340B drug pricing program and delay the 340B Rebate Model Pilot Program announced by the Department of Health and Human Services (HHS). The legislation would apply from either January 1, 2027, or the date of enactment (depending on final legislative language), through December 31, 2028.

The bill responds directly to HHS's proposed rebate pilot program, which would allow drug manufacturers to require certain covered entities to purchase drugs at market prices and subsequently receive rebates to obtain the statutory 340B discount. The legislation would preserve the traditional point-of-sale discount model for most covered entities during the temporary moratorium period.

Key Provisions

Temporary Restriction on Rebate-Based Drug Purchasing

The bill amends Section 340B(a) of the Public Health Service Act by adding a new paragraph that would prohibit the Secretary of HHS from entering into 340B participation agreements with manufacturers that require covered entities to pay more than the applicable 340B ceiling price at the time a covered outpatient drug is purchased. This restriction would remain in effect through December 31, 2028. Notably, the provision excludes children's hospitals described in Section 340B(a)(4)(E) of the Public Health Service Act from the restriction. (Sec. 2(a), p. 2)

Impact

The provision would effectively prevent manufacturers participating in the 340B program from shifting covered entities to a rebate-based purchasing model during the moratorium period. Covered entities would continue obtaining drugs at the discounted 340B ceiling price at the point of sale rather than paying a higher upfront cost and subsequently seeking reimbursement through manufacturer rebates.

For hospitals and other covered entities, maintaining point-of-sale discounts could reduce cash-flow pressures and administrative burdens associated with tracking purchases, submitting rebate claims, and reconciling manufacturer payments. The provision may be particularly significant for

safety-net providers that rely on immediate access to discounted drug pricing to support uncompensated care and other patient services.

Manufacturers that have advocated for rebate-based models as a mechanism to address concerns about duplicate discounts, diversion, and oversight would be unable to implement those arrangements through HHS-approved 340B agreements during the covered period.

Delay of the 340B Rebate Model Pilot Program

The bill would prohibit HHS from implementing the 340B Rebate Model Pilot Program described in the agency's August 3, 2026 notice (91 Fed. Reg. 48883) or any substantially similar program between the effective date and December 31, 2028. (Sec. 2(b), p. 2)

Impact

This provision would place a statutory hold on HHS efforts to test a rebate-based approach within the 340B program. By barring implementation of the pilot and similar initiatives, Congress would effectively preserve the current operational structure of the 340B program while broader debates continue regarding program oversight, manufacturer restrictions, and contract pharmacy policies.

The delay could provide hospitals, federally qualified health centers, Ryan White clinics, and other covered entities with additional certainty regarding drug purchasing arrangements through the end of 2028. It would also postpone the collection of operational and program integrity data that HHS may have sought to obtain through the pilot program.

For manufacturers, the legislation would temporarily foreclose a potentially significant alternative framework that some companies have argued would improve transparency and accountability in the 340B program.

Key Takeaway

The 340B Rebate Model Delay Act would temporarily block HHS and participating manufacturers from moving most 340B covered entities to a rebate-based purchasing model and would suspend implementation of the agency's proposed 340B Rebate Model Pilot Program through December 31, 2028. If enacted, the bill would preserve traditional upfront 340B discounts for covered entities while delaying a major potential restructuring of how 340B drug discounts are administered. (Sec. 2(a)-(b), p. 2)