CAPITOL STREET

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New Bipartisan House 340B Bill Provides Program Requirements

Legislation Faces a Long Road to Passage But Aligns with CMS & Admin Efforts to Rein in 340B

Relevant Companies: HOSPITALS & BIOPHARMA

Our Take & Next Up

While legislators continue to hash out different 340B reform priorities, major program reforms are unlikely to come to fruition in 2026. Today, a bipartisan group of House members released legislation that is more definitional in nature and intended to set up a legislative framework for 2027+ as sponsors continue to seek consensus and broader Congressional buy-in. The 340B reform bill includes eligibility requirements for patients who receive 340B discounted drugs, as well as new standards for non-hospital covered entities and contract pharmacies. See legislative text here.

We note that the proposed legislation aligns with the increased scrutiny on the 340B program by the White House. Last week, CMS proposed a significant cut in 340B drug payments to 340B hospitals starting in 2027. See our analysis of the 340B proposal from CMS here.

Key Points

The newly released House 340B bill includes establishing a patient definition, eligibility requirements for contract pharmacies and child sites, and program integrity & data reporting. The bill is sponsored by multiple members of the House E&C Cmte (Chair Guthrie, R-KY), and led by Reps. Scott Peters (D-CA) and John Joyce (R-PA). Reforms include:

- Establishing a clear patient and provider definition
- Restrictions and HHS oversight requirements for contract pharmacies participating in 340B
- Eligibility requirements for child sites
- Requirements for patient financial assistance
- Data reporting for 340B covered entities (total prescriptions, number of individuals who received 340B drugs, descriptions of use of savings, financial demographics of patients, third party administrators)
- Auditing requirements including audits of 340B vendor info and contract pharmacies
- Creating a 340B clearinghouse for data collection and exchange
- Creating a user fee program (0.1% of dollar amount paid for covered drugs in the previous year) for HRSA to fund program oversight.

On the Senate side, outgoing Senate HELP Chair Cassidy (R-LA) recently proposed a comprehensive package of 340B program changes. A discussion draft released in June builds on Sen. Cassidy's RFI on the 340B Program, including a report in 2025 detailing the results from an investigation into how covered entities use and generate revenue from 340B.

Shared bipartisan reforms – patient definition, 340B reporting requirements, claims clearinghouse, contract pharmacy requirements – could pass muster and gain momentum (2027+). Both the Senate and House bills include definition of key terms (patient 340B eligible entities, child sites), 340B-covered entities reporting requirements and requirements on a 340B claims clearinghouse. However, Senate reforms include codification of discount requirements (including option for retroactive rebates by manufacturers) and location restriction as well as caps on number contract pharmacies that hospitals can contract with.

Overall, we think 340B legislation is unlikely to pass in the near-term. However, we note that biopharma would be a potential beneficiary of 340B changes (some orphan drugs could be impacted negatively), while PBMs and hospitals are expected to be impacted by 340B reporting requirements & contract pharmacy restrictions.

340B pressure is also coming from HHS, after a failed attempt under the first Trump CMS. CMS is looking to rein in the 340B program by recycling a proposal from 2018 but making it more impactful for 2027 hospital outpatient departments. Last week, CMS proposed payment cuts for 340B drugs to ASP-33% in the proposed 2027 Hospital Outpatient Prospective Payment System (OPPS) rule. See our analysis here.

Recall, CMS is also set to reintroduce a new 340B rebate model pilot shortly. We believe the pilot will mirror the previous 340B alternative rebate model (struck by courts) and will impact 2026 & 2027 IRA Medicare negotiated drugs. The prior 340B model attempted to implement alternative backend rebates for 2026 selected negotiation drugs, but was subsequently withdrawn due to litigation from the hospital industry (*American Hospital Association et al. v. Kennedy et al.*). Our take is here.

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