impact
health policy partners
1301 K Street NW, Suite 300W
Washington, D.C. 20005
(202) 309-0796

Insights for Impact: The 340B Drug Pricing Program

The 340B Drug Pricing Program is intended to help safety-net providers "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" by requiring drug manufacturers that participate in the Medicaid Drug Rebate Program to provide discounts on outpatient drugs purchased by eligible health care organizations. These covered entities (CEs) include federally qualified health centers, critical access hospitals, and other safety-net providers. However, the program has come under increasing scrutiny due to significant growth in both the number of CEs and the volume of drugs purchased, CE use of contract pharmacies, pharmaceutical manufacturers imposing limitations on 340B discounts, and ensuing litigation. States have taken the lead on enacting legislation to address some of these concerns, particularly the use of contract pharmacies, but these trends have also led Congress and the Administration, through the Health Resources and Services Administration (HRSA), to increase their scrutiny of the program to ensure it is operating as intended.

In this *Insights for Impact*, we present a high-level overview of the perspectives of the stakeholders involved, major recent legislative and regulatory updates, and what the potential next steps may be.

Perspectives

While CEs and manufacturers both believe that the 340B program is critical in assisting low-income individuals access prescription drugs and needed care, they each have concerns about the way the program operates. Below we highlight current policy positioning from the stakeholders:

i. Manufacturers

The Pharmaceutical Research and Manufacturers of America (PhRMA) asserts that the 340B program has strayed from its original intent to support safety-net providers, and is instead being leveraged to derive profit off the deeply discount drugs. PhRMA has also expressed concern that the 340B program has created financial incentives for hospitals to acquire community-based physician practices, resulting in increased consolidation and movement away from medically underserved areas. PhRMA has advocated for reforms that ensure benefits reach low-income patients by defining "eligible patient" in statute, confirming that only true safety-net entities are participating in 340B, and requiring strong accountability and oversight of the program through public reporting requirements for CEs and a clearinghouse for 340B claims. Additionally, manufacturers argue the limitations they have placed on CE use of contract pharmacies beginning in 2020 are necessary to prevent duplicate discounts and unlawful distribution of 340B drugs to nonpatients.

ii. Providers

CEs are primarily concerned about the conditions and restrictions drug manufacturers are imposing on 340B drug purchases, especially those limiting the use of contract pharmacies, arguing that these limitations reduce 340B savings which impair their ability to furnish quality services to low-income, uninsured, and underinsured individuals. 340B Health, the advocacy organization representing

participating hospitals and health systems, has pushed for reforms that clearly establish the 340B benefit for drugs dispensed through contract pharmacies, prohibit drug companies from implementing conditions that restrict the ability to purchase drugs at the 340B price, and allow CEs to directly challenge manufacturers that unlawfully limit access to the 340B benefit. The group has also sought greater authority for HRSA.

CEs have also expressed concern with payer and pharmacy benefit manager (PBM) policies that discriminate against CEs, the orphan drug exclusion and group purchasing order prohibition on certain types of hospitals, and Medicaid mandates that change program dynamics.

Regulatory Update

The Office of Pharmacy Affairs within HRSA has administered the 340B program since its creation in 1992, however, the agency's authority is limited to regulating the administrative dispute resolution (ADR) process, calculating the 340B ceiling price, and imposing civil monetary penalties for program noncompliance. HRSA finalized a rule revising requirements and procedures for the program's ADR process to improve accessibility, administrative feasibility, and timeliness earlier this year. The agency also provides oversight, conducting audits of both CEs and manufacturers. Given statutory limitations, the agency lacks the regulatory authority to address core issues of the program such as clarifying the definition of "eligible patient" or enforcing its guidance that allows CEs to use unlimited contract pharmacies.

In 2021, HRSA began issuing violation letters to drug manufacturers restricting access to 340B pricing for CEs that used contract pharmacies. The letters informed manufacturers that their policies violated the 340B statute and threatened civil money penalties if they continued. Several manufacturers then sued the agency, claiming it lacked the authority to issue the letters because the statute permitted such restrictions. Both the Third and D.C. Circuits have subsequently determined manufacturer policies restricting the use of contract pharmacies are lawful due to the statute's silence on the issue.

Most recently, HRSA warned drug manufacturer Johnson & Johnson (J&J) that it would be removed from the 340B program and could face enforcement action unless it ended a plan to replace upfront drug discounts with a new rebate approach for disproportionate share hospital participants. Signing on to a letter to Secretary Becerra, 190 members of Congress also expressed their concern with the drugmaker's rebate model. J&J ultimately dropped the policy.

Legislative Update

In response to ongoing litigation, lawmakers have sought information from stakeholders and introduced legislation to address shortcomings of the 340B program. In September 2023, Sen. Bill Cassidy (R-LA), Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member, launched an investigation into the 340B program, and has since requested information from hospitals, community health centers, contract pharmacies, and manufacturers. Six senators also formed a Bipartisan 340B Working Group and solicited input on policies to increase stability and oversight of the program.

The primary bills introduced in the 118th Congress to improve the 340B program are:

- **The Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B (SUSTAIN 340B) Act** discussion draft is the product of the Bipartisan 340B Working Group and aims to address concerns raised by stakeholders, including HRSA's limited authorities and resources, contract pharmacy arrangements, the role of PBMs, duplicate discounts, and the need for transparency. The formal introduction of the bill was anticipated in September but has been delayed.
- **The 340B Pharmaceutical Access To Invest in Essential, Needed Treatments & Support (PATIENTS) Act of 2024** has been introduced by Democrats in both the House and Senate, and it: 1) clarifies that manufacturers are required to provide 340B proves to CEs, regardless of the manner or location in which the drug is dispensed; 2) prohibits manufacturers from placing conditions on CEs; and 3) and establishes penalties on manufacturers that violate such requirements. The bill is endorsed by the American Hospital Association, America's Essential Hospitals, Children's Hospital Association, National Rural Health Association, and other provider groups.
- **The 340B Affording Care for Communities and Ensuring a Strong Safety-Net (ACCESS) Act** (H.R. 8574) was introduced by three House Republicans and aims to increase oversight and transparency of the 340B program. The bill includes provisions to define contract pharmacies and patients and addresses hospital and child site eligibility. This bill is endorsed by the National Association of Community Health Centers and the Alliance to Save America's 340B Program, a coalition including PhRMA and provider and patient groups, among other stakeholders.
- **The Preserving Rules Ordered for the Entities Covered Through (PROTECT) 340B Act** (H.R. 2534) was introduced by Reps. Abigail Spanberger (D-VA) and Dusty Johnson (R-SD) and would prohibit PBMs and health plans from discriminating against 340B CEs and their contract pharmacies by imposing requirements that differ from non-340B CEs. The bill is endorsed by America's Essential Hospitals, the National Association of Community Health Centers, National Rural Health Association, and 340B Health, a coalition of public and private nonprofit hospitals and health systems, among other stakeholders.

Get Involved

The 340B program is primed for federal policymaking in 2025 and beyond. The uncertainty looming over the program due to ongoing litigation and new tactics by manufacturers, as well as financial challenges faced by safety-net providers, is likely to spur Congress to act. Other activity may also influence these deliberations. The Medicaid Payment Advisory Commission (MACPAC) plans to update and reissue its state-level hospital payment index with new data this cycle, which may include an examination of 340B hospitals. Additionally, we expect the next administration will manage and oversee the program in much the same way, regardless of the outcome of the Presidential election, as both former President Trump's administration and the Biden-Harris administration have responded similarly to disagreements between CEs and manufacturers in the past.

If 340B policy is important to you, be sure to include a position in your advocacy plan for 2025. Impact Health can help you develop policies and positions, think through strategy, and craft arguments to influence policymakers. Please reach out to us with any questions.