

Issue Brief

Congress Releases 340B Report; Potential Legislative Options

Background

On January 10, 2018, the Energy and Commerce Committee of the United States House of Representatives released their report, [Review of the 340B Drug Pricing Program](#). The Committee spent the last 2 years examining the structure, operation, and oversight of the 340B program through stakeholder meetings, Committee hearings, and document collection. Chairman Greg Walden (R-OR) stated that there would be legislative efforts to change the 340B program this year to focus on definition, transparency, and oversight.

Congress enacted the 340B program 25 years ago with bipartisan support of the statute. Entities covered under the 340B program include hospitals that serve low-income patients such as disproportionate share hospitals (DSH), rural referral centers, critical access hospitals, children's hospitals, and cancer hospitals. Other types of safety net providers include federally qualified health centers, state and local health departments, HIV clinics, and hemophilia treatment centers. Together, these providers serve tens of millions of uninsured and underinsured people every year.

The 340B program requires pharmaceutical manufacturers participating in the Medicaid or Medicare Part B programs to enter into a pharmaceutical pricing agreement (PPA) with the federal government. The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified safety net providers, known as "covered entities," that serve the nation's most vulnerable patient populations

Findings

The following is a summary of what the Committee believes to be the current status of the 340B program:

- The Health Resources and Services Administration (HRSA) has neither issued nor implemented regulations on the Administrative Dispute Resolution Process, calculation of ceiling prices, and manufacturer civil monetary penalties in a timely manner.
- HRSA needs more regulatory authority to promote compliance and ensure program integrity.
- Given HRSA's limited regulatory authority over the 340B program, HRSA has limited insight of a covered entity's use of the program during the audit process.



- HRSA’s annual audits uncovered a high level of non-compliance by covered entities.
- Without access to ceiling prices, covered entities may not know that they are not getting an accurate price and that they should report the violation to HRSA.
- Program participation has more than quadrupled over the past decade, but HRSA’s oversight authority has remained limited.
- Congress did not clearly identify its intent for the program and did not clearly identify the program’s parameters, leaving the statute silent on many important program requirements.
- Congress did not establish any mechanisms to monitor or calculate program savings or specify how they are used.
- The 340B statute does not require covered entities to report the level of charity care provided. There is no universal definition of charity care so comparison across covered entities may not be possible.
- There is a financial incentive for 340B hospitals to prescribe more, and/or more expensive drugs to Medicare Part B beneficiaries.
- There has been a marked increase in consolidation of private oncology practices, which, in some instances, negatively impacts the quality of patient care and can result in increased patient cost.
- The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the outpatient population for the hospital.

Potential Legislative Action

The report also makes a number of recommendations, most of which require Congressional action. Based on these recommendations, ASHP believes that the Committee will focus their legislative efforts on the following:

- Give HRSA sufficient regulatory authority to adequately administer and oversee the 340B program.
- Require independent audits of program compliance based on a uniform set of measures.
- Provide HRSA with more resources and staff to conduct oversight and management of the 340B program.
- Identify and reduce duplicate discounts for drugs paid for under Medicaid managed care.
- Expand HRSA’s audits to cover other features of the 340B program beyond compliance, such as how covered entities use their savings.
- Clarify the intent of the 340B program to ensure that HRSA administers and oversees the 340B program in a way that is consistent with that intent.
- Promote transparency in the 340B program, including ensuring that covered entities and other relevant stakeholders have access to ceiling prices and requiring covered entities to disclose information about annual 340B program savings and/or revenue.

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- Define charity care and establish a mechanism to monitor the level of charity care provided by covered entities.
- Reassess whether DSH is an appropriate measure for program eligibility, or whether a metric based on outpatient population would be more appropriate.

ASHP remains supportive of the 340B program. We will continue to work with external stakeholders, including the Energy and Commerce Committee, to ensure that any legislative changes to the 340B program are consistent with [ASHP's Principles on Healthcare Reform](#) and do not jeopardize patient access or care.