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Drug Discount Plan Remains Target for Possible Legislation

By Nisha Shetty

- Attorneys see Congress scrutinizing hospitals
- Agency seeks extra regulatory authority to enforce rules

Some members of Congress might push for more transparency about how hospitals use their federal drug discount program savings after a study by a government watchdog, attorneys say.

The 340B program requires drugmakers to discount drugs for covered entities—qualifying hospitals, clinics, and providers—that treat low-income Medicare and Medicaid patients, as measured by each hospital's disproportionate share hospital (DSH) adjustment percentage.

Under the program, drugmakers participating in Medicaid agree to provide outpatient drugs to those qualifying providers at significantly reduced prices.

The House Energy and Commerce Committee asked the General Accountability Office to review the process used by the Health Resources and Services Administration for offering eligibility exception to hospitals due to Covid-19. The study found that 53 hospitals were granted an exception.

The study also indicated that HRSA's oversight of the 340B program could be better. The GAO made 20 recommendations to improve oversight since 2011. HRSA has only implemented five of the suggestions, in part because it said it has limited regulatory authority.

"It is clear that there is interest in Congress in overseeing certain aspects of hospitals" including the 340B program, said Emily Cook, a partner at McDermott Will & Emery LLP who represents providers. "I wouldn't be surprised to see a bill being introduced that imposes more explicit oversight requirements."

GAO Casts Wide Net

The Consolidated Appropriations Act, enacted in March 2022, allowed certain 340B hospitals to request temporary exceptions to the DSH percentage eligibility requirement if they were unable to meet the requirement because of factors related to Covid-19. For example, if a hospital treated fewer Medicaid patients and more non-Medicaid Covid patients, it could request an exception, the report said.

The exception applied to DSH percentages from hospital cost-reporting periods that began during fiscal year 2020 (or a subsequent fiscal year) and that ended no later than Dec. 31, 2022, which would allow some hospitals to request exceptions in 2023.

Of the 61 hospitals that requested exceptions as of May 31, 2022, 53 were approved—33 were disproportionate share hospitals, 14 were community hospitals, and six were rural referral centers.

The study answered the questions Congress asked but also included trends in amounts of charity care, uncompensated care, and total unreimbursed and uncompensated care—that weren't requested by the committee.

Maureen Testoni, the president and CEO of 340B Health that represents covered entities, was "very concerned" about questions that linked the 340B program to charity care. "It ignores the fact that there are a lot of things that hospitals have to do in order to be a strong provider in their community," she said.

HRSA Hamstrung

The GAO flagged issues with HRSA's audits as well. The agency audited 25 hospitals and issued 19 findings related to noncompliance for 14 hospitals. There were nine cases related to the potential for duplicate discounts.

Duplicate discounts occur when a hospital obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication. One of the requirements in the 340B program is that hospitals must avoid duplicate discounts.

"In my experience, there are rarely actual duplicate discounts," said Cook. "Neither HRSA nor the covered entity have any way of knowing whether an actual duplicate discount occurred because the state won't provide the necessary information to determine if a rebate was requested."

HRSA's audits also showed there were five cases of diversion of 340B drugs to ineligible patients. HRSA requires covered entities to submit corrective action plans to address the findings but doesn't require them to show that the plans were implemented prior to closing audits.

Instead, the agency relies on covered entities to self-attest that the findings have been addressed.

Michelle Rosenberg, the GAO director, said that was a red flag. "That's why it's important for HRSA to ensure that if they find areas of noncompliance, those entities take action, implement their corrective action plans and address those areas of noncompliance to hopefully prevent them in the future," she said.

However, HRSA can re-audit covered entities, said Testoni. "They absolutely do conduct re-audits to make sure that the issues have been effectively addressed," she said.

Another item that was highlighted in the study was that HRSA issued 39 areas for improvement for 22 of the audited hospitals but don't require them to take any action.

Some covered entities implement the guidelines but Cook said, “It is kind of pointless. They can’t require you to do it. They would like for you to do it, but you don’t have to do it.”

“What HRSA is and has been asking for a while is formal legislation that provides more solid oversight and enforcement authority over their own rules which, as of now, they don’t necessarily have,” said Michael French, an attorney at Quarles & Brady LLP who represents providers.

Bipartisan members of Congress wrote a letter to HRSA in 2018 responding to their request for more rulemaking authority by telling it to first use their existing authority to better monitor the 340B program.

There was also bipartisan support for 340B reform legislation to be included in the 21st Century Cures bill the House passed in 2015, but legislators later dropped it.

Currently, there is a discussion draft introduced by Rep. Larry Bucshon (R-Ind.), a member of the Energy and Commerce Committee, that would require covered entities to have a new level of transparency in the 340B program.

Still, Peggy Tische, counsel at Powers Pyles Sutter & Verville PC in the public policy and government relations group, was skeptical. “It is not likely this year that anything big could get past Congress,” she said.

Rosenberg said the GAO will continue to monitor the open recommendations until they are implemented by HRSA.

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Documents

GAO study