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Highlights

Highlights of GAO-11-836, a report to congressional committees

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within in the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View GAO-11-836. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.