

GAO Highlights

Highlights of [GAO-15-455T](#), a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The 340B Drug Pricing Program requires drug manufacturers to sell outpatient drugs at discounted prices to eligible hospitals, clinics, and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid. HRSA, an agency within the Department of Health and Human Services, is responsible for administering and overseeing the 340B Program. In recent years, questions have been raised regarding HRSA's oversight of the program, particularly given growth in the program since its inception in 1992. According to HRSA officials, as of 2015, more than 11,000 covered entities were participating in the 340B Program—an increase of approximately 30 percent since 2008.

In September 2011, GAO identified inadequacies in HRSA's oversight of the 340B Program and made recommendations to improve program oversight and ensure appropriate use of the program. This testimony describes (1) inadequacies in 340B Program oversight that GAO previously identified, and (2) progress HRSA has made implementing GAO's recommendations to improve program oversight.

This testimony is based largely on GAO's September 2011 report. For this testimony, GAO also obtained information and documentation from HRSA officials about any significant program updates and steps they have taken to implement GAO's 2011 recommendations.

View [GAO-15-455T](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

March 5, 2015

DRUG DISCOUNT PROGRAM

Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight

What GAO Found

In its September 2011 report, GAO found that the Health Resources and Services Administration's (HRSA) oversight of the 340B Program was inadequate to provide reasonable assurance that program participants—covered entities and drug manufacturers—were in compliance with program requirements. Specifically, GAO found the program

- primarily relied on covered entities and manufacturers to police themselves and ensure their own compliance with 340B Program requirements, and engaged in few other activities to oversee the program and ensure its integrity. For example, although HRSA had the authority to conduct audits to determine whether program violations had occurred, at the time of GAO's report, the agency had not conducted any.
- lacked guidance on key requirements with the level of specificity necessary to provide clear direction, making self-policing difficult, and raising concerns that the guidance could be interpreted in ways that were inconsistent with its intent. In particular, GAO found HRSA's guidance lacked needed specificity on the definition of a patient eligible for drugs discounted under the program, criteria hospitals not publicly owned or operated needed to meet to qualify for the program, and nondiscrimination guidance manufacturers needed to follow to ensure drugs were distributed equitably to both covered entities and non-340B providers.
- had increasingly been used in settings, such as hospitals, where the risk of diverting 340B drugs to ineligible patients was greater, because these settings were more likely to serve such patients.

To address these oversight inadequacies and to ensure appropriate use of the program, GAO recommended HRSA (1) conduct selective audits of covered entities to deter potential diversion; (2) further specify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; (3) finalize new, more specific guidance on the definition of a patient eligible to receive discounted drugs; and (4) issue guidance to further specify the criteria that hospitals not publicly owned or operated must meet to be eligible for the 340B Program.

In fiscal year 2012, HRSA implemented two of GAO's four 2011 recommendations. Specifically, the agency implemented a systematic approach to conducting audits of covered entities and issued updated nondiscrimination guidance. With regard to the other two recommendations, HRSA planned to address the definition of a patient and hospital eligibility criteria in a comprehensive 340B Program regulation it submitted to the Office of Management and Budget in April 2014. However, HRSA withdrew this proposal following a May 2014 federal district court ruling addressing HRSA's statutory authority to issue a separate 340B regulation, which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA reported that after assessing this ruling, it plans to issue proposed guidelines later this year to address 340B Program areas where it does not have explicit rulemaking authority, including the definition of a patient and hospital eligibility.