

GAO Highlights

Highlights of [GAO-21-107](#), a report to congressional requesters

Why GAO Did This Study

Covered entities can realize substantial savings through 340B Program price discounts, enabling them to stretch federal resources to reach more eligible patients and provide more comprehensive services.

GAO was asked to provide information on HRSA's efforts to oversee covered entities' compliance with 340B Program requirements. This report describes (1) the audit findings that HRSA issued to address covered entity noncompliance with 340B Program requirements; and (2) other efforts HRSA uses to help ensure that covered entities comply with 340B Program requirements.

GAO reviewed documentation, including relevant federal laws and regulations and HRSA's policies, procedures, and guidance, related to 340B Program oversight. GAO also reviewed HRSA data on the number and type of audit findings made from audits finalized during fiscal years 2012 through 2019 as of September 2020—the latest data available at the time of the audit. GAO also interviewed officials from HRSA, agency contractors, and 340B Program stakeholders.

GAO provided a draft of this report to HHS for review. The agency provided written and technical comments on the draft, both of which were incorporated as appropriate.

View [GAO-21-107](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

December 2020

DRUG PRICING PROGRAM

HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements

What GAO Found

The 340B Drug Pricing Program (340B Program) requires drug manufacturers to sell outpatient drugs at a discount to covered entities—eligible hospitals and other entities participating in the program—in order for their drugs to be covered by Medicaid. Participation in the 340B Program has grown from nearly 9,700 covered entities in 2010 to 12,700 in 2020. The Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) administers the program and oversees covered entities' compliance with 340B Program requirements through annual audits, among other efforts. If audits identify noncompliance with program requirements, HRSA issues findings to covered entities and requires them to take corrective action to continue participating in the 340B Program (see table).

Audit Findings Issued to Covered Entities by the Health Resources and Services Administration (HRSA) for Fiscal Years 2012-2019, as of September 2020

340B Program findings of noncompliance	Number
Eligibility of covered entities. Failure to maintain eligibility-related requirements (e.g., covered entities' oversight of their contract pharmacies).	561
Diversion of 340B drugs to ineligible patients. 340B drugs distributed to individuals who are not eligible patients of a covered entity (e.g., patients' health records are not maintained by the covered entity).	546
Duplicate discounts. Prescribed drugs that may have been subject to both the 340B price and a Medicaid rebate.	429
Total	1,536

Source: GAO analysis of information received from HRSA. | GAO-21-107

HRSA officials told GAO that, beginning in fall 2019, the agency started issuing findings only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that guidance, which is used to interpret provisions of the 340B statute for the purposes of promoting program compliance among covered entities, does not provide the agency with appropriate enforcement capability. For example, HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency did not issue findings for a failure to comply with guidance related to contract pharmacies in part because the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation.

In addition to audits, HRSA provides education to covered entities about 340B Program requirements and has implemented other efforts to identify noncompliance. For example, HRSA

- requires all covered entities to recertify their eligibility to participate in the 340B Program annually (e.g., self-attesting to compliance); and
- uses a self-disclosure process through which covered entities can disclose and correct self-identified instances of noncompliance.