

GAO Highlights

Highlights of [GAO-20-108](#), a report to congressional requesters

Why GAO Did This Study

The number of nongovernmental hospitals participating in the 340B Program has grown over time. HRSA requires participating hospitals to register and annually recertify their eligibility. HRSA also reviews hospitals' eligibility through audits of a small sample each year.

GAO was asked to provide information on 340B-participating hospitals' contracts with state and local governments. This report (1) describes any obligations in selected nongovernmental hospitals' contracts to serve low-income individuals, and (2) examines HRSA's processes to assess nongovernmental hospitals' eligibility. GAO examined contract documentation from all 258 nongovernmental hospitals HRSA reviewed in 2017 and 2018; and HRSA's policies, procedures, and guidance related to 340B hospital eligibility. GAO also interviewed HRSA officials.

What GAO Recommends

GAO is making six recommendations, including that HRSA implement a process to verify that all nongovernmental hospitals have contracts in place, including throughout hospitals' audit periods; amend its contract reviews to include an assessment of whether contracts meet statutory requirements; and provide better guidance on contract reviews. HHS concurred with all of the recommendations except the one to implement a process to verify that all nongovernmental hospitals have contracts. GAO continues to believe this action is needed to ensure that only eligible hospitals are allowed to participate in the 340B Program.

View [GAO-20-108](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

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340B DRUG DISCOUNT PROGRAM

Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements

What GAO Found

Under the 340B Drug Pricing Program (340B Program), administered by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), drug manufacturers provide discounted prices on outpatient drugs to certain hospitals and other entities. About two-thirds of hospitals participating in the 340B Program (approximately 1,700) are nongovernmental hospitals (private, nonprofit hospitals), which qualify for the program, in part, based on having contracts with state or local governments to provide health care services to the 340B-specified low-income population—low-income individuals not eligible for Medicaid or Medicare. GAO's review of contract documentation for 258 nongovernmental hospitals found that most contracts obligated these hospitals to provide health care services to low-income individuals. However, few of the contracts reviewed included details about those obligations, such as the amount or type of care hospitals were required to provide. The statute does not require the contracts to contain such details.

GAO found that HRSA's processes do not provide reasonable assurance that participating nongovernmental hospitals meet eligibility requirements. For example, HRSA primarily relies on hospitals' self-attestations to verify the existence of contracts with state and local governments. The agency reviewed contract documentation for less than 10 percent of nongovernmental hospitals per year in 2017 and 2018. GAO also identified several weaknesses in HRSA's review of the nongovernmental hospital contracts:

- HRSA does not conduct reviews to determine whether the documents submitted by nongovernmental hospitals are actual contracts, namely that they are mutually binding agreements to provide services or supplies in exchange for something of value. GAO found that 18 of the 258 hospitals reviewed submitted documents that did not appear to be contracts, such as descriptions of community programs, yet all of these hospitals were permitted to participate in the program.
- When audits have identified hospitals that did not have contracts in place throughout the audits' periods of review, HRSA has allowed hospitals to avoid audit findings by, for example, entering into new contracts with retroactive start dates. This practice undermines the integrity of HRSA's audits.
- HRSA's contract reviews do not always include assessments of whether contracts are consistent with the statutory requirement to provide health care services to the 340B-specified low-income population and HRSA's guidance for conducting such assessments, when required, lacks detailed instructions. As a result, GAO found that contracts for 13 hospitals reviewed did not appear to require hospitals to serve the 340B-specified low-income population. Despite this, these 13 hospitals were permitted to participate in the program.

Given these weaknesses, some nongovernmental hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible.